FDA's Final Rule on Requirements for Additional Traceability Records for Certain Foods (Written Comments)

Comments were accepted at FinalRule@reaganudall.org during the open comment period

AMERICAN FROZEN FOOD INSTITUTE

October 24, 2024

Submitted via email to FinalRule@ReaganUdall.org

The Reagan-Udall Foundation
1333 New Hampshire Ave NW
Suite 420
Washington, DC 20036
finalrule@reaganudall.org

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:

The American Frozen Food Institute (AFFI) appreciates to opportunity to comment 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. From manufacturers to distributors to suppliers to packagers, AFFI is proud to represent publicly traded and family-owned companies who help produce frozen foods and beverages for today's food service and retail marketplace and serve as economic pillars within their communities throughout the U.S. The frozen food industry contributes approximately $65 billion to the U.S. GDP and accounts or 670,000 U.S. jobs. In addition, our members' strong role in economic growth, AFFI members share a commitment to food safety and supply chain transparency.

AFFI appreciates the Reagan-Udall Foundation's efforts to collaborate with FDA and the food industry to facilitate the effective implementation of the Traceability Rule. Our members have a deep commitment to food safety and fully support the FDA's efforts to develop a system that allows for fast and efficient traceback investigations and is protective of public health. Although the Traceability Rule largely excludes frozen foods, our members handle a number of foods on the Food Traceability List (FTL) in the manufacturing of their products and as a result have been directly impacted by the rule. Our members have been working diligently to implement the rule's requirements but based on the current timeline of industry data standardization efforts and retailers recently announcing they intend to require all suppliers to provide traceability records for all foods, meeting the January 20, 2026, compliance date will be challenging. While technical compliance by this date may be achievable, AFFI and our members are concerned that rushing the implementation process in order to achieve technical compliance will result in an inefficient and ineffective system that does not meet FDA's public health objectives. For these reasons, AFFI respectfully requests the compliance deadline be extended.

Timeline of Industry Efforts to Develop Data Standards and Technological Solutions

As our members and their supply chain partners have been collaborating to implement the Traceability Rule, it has become increasingly clear that effective compliance with the rule will require each supply chain participant to implement a system that allows for the easy transformation of key data elements through different recordkeeping systems. This means that industry needs to align on and implement uniform data standards. Because the FDA has consistently taken the position it will not provide guidance on how companies will comply with the Traceability Rule, industry is working to develop a system of data standards on its own. This process is in its infancy and in order to ensure industry resources are used most efficiently, companies need to be able to postpone implementing new technology systems until after the data standardization process has been completed. In addition, industry is working to evaluate potential technology systems to facilitate compliance with the rule and customer requests, but the work to evaluate the functionality, storage capacity, connectivity, and costs associated with various offerings takes time. Because of this, AFFI urges FDA to extend the compliance deadline to allow industry to complete these two parallel work streams. This will help ensure that companies are not only compliant with the Traceability Rule, but that the implemented system can be easily navigated and is responsive to FDA's needs.

Impact of Retailers Requesting Traceability Records for All Foods

At least two major retailers have announced they will require all suppliers to provide records consistent with the Traceability Rule for all foods. Although this action does not create a regulatory compliance requirement, this action functionally requires all members of the food industry to implement the Traceability Rule for all foods. With this announcement, many companies who had not previously been engaged in discussions regarding the implementation of the rule are now working to understand the rule, understand how it will apply to their operations, and identify any roadblocks to meeting the rule's requirements. As discussed above, in order for the implementation of the Traceability Rule to be effective, industry must develop a single cohesive and collaborative system for transferring key data elements among the various critical tracking events and evaluate, purchase, and implement technological enhancements to their recordkeeping systems. The companies that are not covered by the Traceability Rule but are implementing its requirements due to retailer demands need to be part of the development of these systems if they will truly be effective.

Additionally, before the retailers announced they would expect uniform records for all foods, many companies were choosing to only make investments to upgrade

recordkeeping systems in the facilities that handle foods on the FTL. If these companies now choose to apply the rule's requirements to all of their operations to meet retailer demands, many will need to exponentially increase their investments in technology and add additional resources, which will take additional time. The undertaking of these efforts will benefit the public interest by ensuring the Traceability Rule's framework is applied to more foods. As such, FDA should help facilitate this expansion of the Traceability Rule by extending the compliance date to allow industry more time to consider solutions that address their entire operations.

* * *

AFFI appreciates the opportunity to provide comments on the Traceability Rule and thanks the Reagan-Udall Foundation for facilitating engagement on this important issue. Please do not hesitate to contact me with any questions regarding these comments.

Respectfully submitted,

Donna Garren, Ph.D.
Executive Vice President, Science and Policy

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October 24, 2024

The Reagan-Udall Foundation
1333 New Hampshire Ave NW
Suite 420
Washington, DC 20036
finalrule@reaganudall.org

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:

Big Y Foods, Inc. appreciates the opportunity to provide comments on The Reagan-Udall Foundation's (RUF) Virtual Public Meeting on the Food and Drug Administration's (FDA) Final Rule on Requirements for Additional Traceability Records for Certain Foods (the Traceability Rule). As a Grocery Retailer and Grocery Distributor, Big Y Foods is directly impacted by the Traceability Rule's requirements and we have been working diligently to meet the compliance deadline. Through our collaboration with our supply chain partners to bring our operations into compliance, we have identified a number of hurdles and challenges impacting industry. Big Y Foods supports the comments provided by FMI, The Food Industry Association. In these comments we will discuss these challenges and our requests of FDA.

Since the final rule was published in November 2022, we have been working diligently to educate our supply chain partners and to identify and implement our compliance strategy. The food industry is committed to enhancing traceability throughout the supply chain as demonstrated by the hundreds of millions of dollars that have already been invested in Traceability Rule compliance efforts.

Big Y Foods has to date:

held over 150 meetings with internal personnel, existing and potential new vendors;
utilized over 500 labor hours; and
tested the feasibility and compatibility of various existing and potential software programs;

without coming close to being complete and compliant for the Traceability Rule. Notwithstanding these efforts, much more work and more financial investment is needed before compliance can be achieved.

At this time, the biggest challenge facing industry is the overwhelming complexity involved in implementing the Traceability Rule. The implementation complexity stems from both the number of products the rule implicates, the reliance on other entities' compliance to ensure your own obligations are met, and the need to evaluate new technologies and systems, and the desire to ensure interoperability. As explained below, these challenges highlight the need for greater flexibility in the Traceability Rule, specifically related to the use of traceability lot codes, and more time to perform pilot projects and implement the Traceability Rule's requirements.

The Need for Greater Flexibility

First, industry and consumers would benefit from being able to provide a range of lot codes rather than a single lot code for products. Most of the products on retail stores must travel through a distribution center before reaching the store shelves and distribution centers are struggling to find feasible ways to trace single lot codes through their operations without implementing case-level tracking. Because distribution centers already have strong visibility into their product's path through the supply chain, allowing a range of traceability lot codes would ease the complexity without hindering FDA's ability to complete an efficient traceback investigation.

The Need for Pilot Projects

In order for industry to successfully implement the Traceability Rule, pilot projects must be completed to evaluate whether different entities in the supply chain can coordinate with each other to ensure compliance and whether the goals of the Traceability Rule – more efficient and effective traceback investigations - can be met. Quite simply, pilot projects can explore what gaps in implementation need to be addressed *before* significant investments in technology, recordkeeping systems, training and more have been made. Pilot projects also would enable industry and the agency to explore alternative solutions that reduce the burden on industry while protecting public health. In order for the learnings from these pilot programs to be effectively implemented, the compliance date should be two years after their completion.

The Need for An Extension to the Compliance Date

Given the complexity of the Traceability Rule, the need to educate the supply chain, the need to identify and evaluate new technologies and new recordkeeping systems, and the desire to ensure our systems are interoperable, more time is needed to comply with the rule. In light of the investments we have made thus far and the planned investments that are needed for compliance, we need to ensure we get it right. Additional time for compliance will help us do so.

* * *

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,
Big Y Foods, Inc.

Michael P. D'Amour
President & CEO

C&S Wholesale Grocers

October 22, 2024

The Reagan-Udall Foundation
1333 New Hampshire Ave NW
Suite 420
Washington, DC 20036
finalrule@reaganudall.org

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:

C&S Wholesale Grocers, LLC ("C&S") appreciates the opportunity to provide comments on The Reagan-Udall Foundation's (RUF) Virtual Public Meeting on the Food and Drug Administration's (FDA) Final Rule on Requirements for Additional Traceability Records for Certain Foods (the Traceability Rule). As an industry leader in supply chain solutions and wholesale grocer supply in the United States, C&S is directly impacted by the Traceability Rule's requirements and we have been working diligently to meet the compliance deadline. Through our collaboration with our supply chain partners to bring our operations into compliance, we have identified a number of hurdles and challenges impacting industry. C&S supports the comments provided by FMI, The Food Industry Association. In these comments we will discuss these challenges and our requests of FDA.

Since the final rule was published in November 2022, we have been working diligently to educate our supply chain partners and to identify and implement our compliance strategy. The food industry is committed to enhancing traceability throughout the supply chain as demonstrated by the hundreds of millions of dollars that have already been invested in Traceability Rule compliance efforts. Notwithstanding these efforts, more work and more financial investment is needed before compliance can be achieved.

At this time, the biggest challenge facing industry is the overwhelming complexity involved in implementing the Traceability Rule. The implementation complexity stems from both the number of products the rule implicates, the reliance on other entities' compliance to ensure your own obligations are met, and the need to evaluate new technologies and systems, and the desire to ensure interoperability. As explained below, these challenges highlight the need for greater flexibility in the Traceability Rule, specifically related to the use of traceability lot codes, and more time to perform pilot projects and implement the Traceability Rule's requirements.

The Need for Greater Flexibility

First, industry and consumers would benefit from being able to provide a range of lot codes rather than a single lot code for products. Most of the products on retail stores must travel through a distribution center before reaching the store shelves and distribution centers are struggling to find feasible ways to trace single lot codes through their operations without implementing case-level tracking. Because distribution centers already have strong visibility into their product's path through the supply chain, allowing a range of traceability lot codes would ease the complexity without hindering FDA's ability to complete an efficient traceback investigation.

The Need for Pilot Projects

In order for industry to successfully implement the Traceability Rule, pilot projects must be completed to evaluate whether different entities in the supply chain can coordinate with each other to ensure compliance and whether the goals of the Traceability Rule – more efficient and effective traceback investigations - can be met. Quite simply, pilot projects can explore what gaps in implementation need to be addressed *before* significant investments in technology, recordkeeping systems, training and more have been made. Pilot projects also would enable industry and the agency to explore alternative solutions that reduce the burden on industry while protecting public health. In order for the learnings from these pilot programs to be effectively implemented, the compliance date should be two years after their completion.

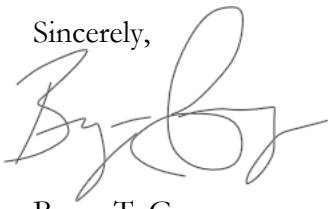
The Need for An Extension to the Compliance Date

Given the complexity of the Traceability Rule, the need to educate the supply chain, the need to identify and evaluate new technologies and new recordkeeping systems, and the desire to ensure our systems are interoperable, more time is needed to comply with the rule. In light of the investments we have made thus far and the planned investments that are needed for compliance, we need to ensure we get it right. Additional time for compliance will help us do so.

* * *

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,



Bryan T. Granger
Senior Vice President, Compliance and Administration
C&S Wholesale Grocers, LLC

CONSUMER
BRANDS
ASSOCIATION

October 25, 2024

Submitted Via Email at FinalRule@reaganudall.org

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

RE: FDA's Final Rule on Requirements for Additional Traceability Records for Certain Foods: Virtual Public Meeting, October 7, 2024.

Dear Reagan-Udall Foundation:

The Consumer Brands Association ("Consumer Brands" or "CBA") champions the industry whose products Americans depend on every day, representing nearly 2,000 iconic brands. From household and personal care products to food and beverage products, the consumer packaged goods (CPG) industry plays a vital role in powering the U.S. economy, contributing $2 trillion annually to the U.S. GDP, and supporting more than 20 million American jobs. Consumer Brands advocates for flexible and practical regulatory frameworks based on current science that promote product transparency, increase consumer choice, and build consumer trust across the sectors we represent. We appreciate the opportunity to provide comments to the Reagan Udall Foundation in follow up to its virtual public meeting on FDA's final rule on requirements for additional traceability records for certain foods (the "Traceability Rule" or "the Rule").

Consumer Brands members view their obligation to protect consumer health as their top priority, and they have extensive experience and capability to effectuate recalls rapidly and facilitate traceback investigations. Our members are diligently working to implement the Traceability Rule with the goal of meeting FDA's mission to make traceback investigations more efficient and actionable. Our members are investing heavily in recordkeeping solutions to ensure they are not simply implementing the Rule's requirements, but also are creating an effective traceability landscape that meets FDA's public health and traceability objectives.

Unlike past recordkeeping initiatives, such as the "one-up, one-back" requirements of the Bioterrorism Act, the Traceability Rule requires significant collaboration and harmonization across the industry and includes new supply chain partners. In addition, unlike other FSMA rules, Traceability Rule implementation requires the involvement of multiple cross-functional teams, not historically involved in food safety regulatory compliance, such as IT, procurement, sales, and others. In order to make sure implementation is effective, industry needs time to work together to identify solutions and common systems that will meet FDA's needs in a unified and efficient manner. There are currently a number of ongoing industry initiatives aimed at overcoming challenges to the Traceability Rule's implementation that need more time to reach fully developed strategies and solutions. These initiatives include (1) industry education efforts; (2) data standardization; and (3) implementing new data and technology systems. Consumer Brands encourages FDA to extend the Traceability Rule's January 20, 2026, compliance date to accommodate these important initiatives.

(1) Efforts to Educate Supply Chain Partners on the Traceability Rule's Requirements

Despite the forward-looking compliance date, certain segments within the food industry are requesting that manufacturers provide information related to the Traceability Rule well in advance. Some entities have gone as far as issuing "noncompliance" notices to their suppliers this calendar year, possibly under the erroneous impression that the Rule is already in effect. Our members are working to educate their suppliers, customers, and internal stakeholders about the Rule, but this process has been complicated by these accelerated timeframes.

This situation is further complicated by requests by some customers for traceability records for foods that are not on the FTL. Instead of focusing exclusively on high-risk foods, certain businesses are obligating manufacturers and suppliers to provide information for *all* foods supplied, whether or not they are on the FTL. Certain buyers are also ignoring situations where exemptions from the rule would apply or are being inconsistent regarding when a food qualifies for an exemption, such as when a kill step is applied to an FTL food that significantly minimizes pathogens. In other circumstances, certain buyers are seeking information for an entire product line, when only a limited segment of that line incorporates FTL ingredients (*e.g.*, snack bars with SKUs with and without nut butter).

Because of these expansive requests, the scope of businesses impacted by the wider application of Traceability Rule has exponentially grown, drawing in additional entities that are unfamiliar with the Rule and its provisions. There are now more entities that our members need to engage with before they can finalize their own internal strategies and systems. The collaboration required by the Rule and FDA's decision to implement a single compliance date rather than a phased approach means that all of industry needs to work through the implementation process in lockstep. As described in more detail below, data interoperability will be key to the success of the Traceability Rule so that data systems can communicate seamlessly, and that each component of the supply chain can easily provide key data elements to the other.

Companies that will be transferring key data elements due to customer requirements rather than regulatory requirements have only recently begun the process of understanding and implementing the Traceability Rule. If they are left behind as the companies that have been engaged in this effort for almost two years collaborate independently, two independent and incompatible data transfer systems may be developed. Because of this, it is important that businesses that may not be covered by the rule but are implementing traceability systems due to customer demands, engage in the rule's implementation process to ensure consistent practices across industry. As these supply chain participants are just beginning to implement the rule, more time is needed to engage interested entities in the implementation efforts. For those industry members with FTL foods, the expansion of customer requirements to all foods dramatically impacts their implementation efforts as well – as they will need to expand their efforts across multiple plants and systems – adding cost and complexity.

(2) Industry Efforts to Develop Interoperable Data Standards.

Ensuring that different data and technology systems used across the industry are interoperable or more simply, able to communicate with each other, is key to the success of the Traceability Rule and improving traceback investigations. The current recordkeeping and technology environment is highly fragmented, which is compounding challenges to implement the Rule. Buyers are frequently dictating the specific format for various data elements (e.g., the lot code). In addition, buyers are often requesting that their suppliers make use of preferred third-party

platforms or labeling technologies, which document traceability recordkeeping information inconsistently among the platforms and apply significant costs and fees on suppliers to integrate such services into their internal systems.

The industry is working to remedy these issues by developing interoperable data standards and best practices to facilitate efficient and effective recordkeeping across the food industry. This work however is still in early development, and more time is required to allow the industry to work through this process and create a consistent set of standards. Specifically, the Partnership for Food Traceability will be bringing together private industry and FDA to discuss challenges to implement the rule and act as a decision-making body aimed at driving alignment across industry. Through this initiative, industry is taking the lead in ensuring not only that companies come into compliance with the Traceability Rule, but that the rule is implemented in a manner that can achieve FDA's public health mission. Our members are committed to getting traceability right, not just complying with the rule, and the efforts to create interoperable data standards is integral to this commitment.

(3) Investments in New Technology Systems and Processes

The CPG industry is investing heavily in and implementing enhanced electronic recordkeeping systems, which are needed to enable companies to standardize and harmonize their recordkeeping practices with their supply chain partners. Retailers and manufacturers however are under considerable pressure from both consumers and policymakers to do everything possible to not increase the cost of goods, and ideally, to reduce them. The current regulation is anticipated to add significant costs to areas of food manufacturing and retail supply chains and impact the costs that consumers pay across departments in grocery stores. For example, one Consumer Brands member estimates it will cost approximately $50 million to implement the Rule solely for FTL items, but approximately $500 million to implement the same traceability standards for their entire product portfolio. These cost impacts associated with implementation of the Rule are being felt across the entire food industry supply chain.

Given the financial cost and the importance of interoperability, storage capacity, security, and functionality, industry needs time to ensure it is making the right investments that lead to an efficient and effective traceability system, which means these decisions should be made after the data alignment efforts are further developed. Further, implementation of new technology is a lengthy process and additional time is needed to ensure the implementation of these systems is successful. Our members want to ensure they adopt efficient and effective traceability systems, not just compliant ones, but in order to do this, more time is needed to allow the data standardization and technology implementation processes to develop.

Furthermore, most of the industry discussions to date have focused on the IT systems and capital investments to support FSMA 204 but have not focused sufficiently on the ongoing frontline labor impacts of case and item level tracking that will have a direct impact on the cost of products to consumers. There are significant costs associated with tracking through the warehouse and distribution system, especially when products are sold at the case level or individually. These ongoing and anticipated labor expenses may actually be greater than the upfront capital and IT systems investments. It would be beneficial for FDA to collaborate with industry experts on ways to minimize labor costs while improving digital traceability, which will be key to preventing further cost impacts to consumers. To provide the best chance at success for implementation, the FDA should consider exempting intra-company transfers from the rule.

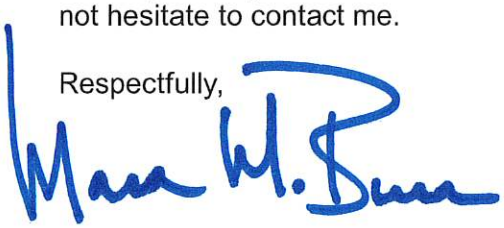
* * *

Consumer Brands and our members are committed to providing consumers safe and high-quality foods. Part of this commitment is protecting public health through efficient and actionable traceback investigations. It would be beneficial for FDA to undertake additional pilot programs, use the learnings from those pilots to implement appropriate exemptions to ease the burden of this Rule, and conduct further outreach and education to assist companies with their implementation efforts. FDA should also provide explicit guidance to public stakeholders that the Traceability Rule is primarily intended to aid the agency in more rapidly investigating and addressing public outbreak situations, and therefore, focus on the FTL and high-risk foods should be the first and most urgent priority for the food industry. Finally, and most critically, Consumer Brands urges FDA to provide additional time beyond the current compliance date for the food industry to develop the data standards, technologies, and best practices for successful implementation of the Rule, and to enable integration of these solutions broadly across the industry.

We value FDA's willingness to continue to engage with stakeholders on the Traceability Rule and encourage the agency to continue a transparent and collaborative approach to ensuring successful implementation. To make sure this ongoing work and collaboration is effective, the food industry supply chain needs time to work together and with FDA to develop solutions that will comply with the traceability requirements in a unified and effective manner.

Thank you for your time and attention to our comments. If you have any questions, please do not hesitate to contact me.

Respectfully,



Mara M. Burr, JD, LL.M
Vice President, Regulatory & Technical Affairs

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October 23, 2024

The Reagan-Udall Foundation
1333 New Hampshire Ave NW Suite 420
Washington, DC 20036
finalrule@reaganudall.org

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:

Fareway Stores Inc. appreciates the opportunity to provide comments on The Reagan-Udall Foundation's (RUF) Virtual Public Meeting on the Food and Drug Administration's (FDA) Final Rule on Requirements for Additional Traceability Records for Certain Foods (the Traceability Rule). As a grocery retailer, Fareway Stores Inc. is directly impacted by the Traceability Rule's requirements, and we have been working diligently to meet the compliance deadline. Through our collaboration with our supply chain partners to bring our operations into compliance, we have identified several hurdles and challenges impacting industry. Fareway Stores Inc. supports the comments provided by FMI, The Food Industry Association. In these comments we will discuss these challenges and our requests of FDA.

Since the final rule was published in November 2022, we have been working diligently to educate our supply chain partners and to identify and implement our compliance strategy. The food industry is committed to enhancing traceability throughout the supply chain as demonstrated by the hundreds of millions of dollars that have already been invested in Traceability Rule compliance efforts. At Fareway, we have invested countless hours specifically regarding the implementation of the traceability rules. Notwithstanding these efforts, more work, and more financial investment is needed before compliance can be achieved.

At this time, the biggest challenge facing industry is the overwhelming complexity involved in implementing the Traceability Rule. The implementation complexity stems from both the number of products the rule implicates, the reliance on other entities' compliance to ensure your own obligations are met, and the need to evaluate new technologies and systems, and the desire to ensure interoperability. As explained below, these challenges highlight the need for greater flexibility in the Traceability Rule, specifically related to the use of traceability lot codes, and more time to perform pilot projects and implement the Traceability Rule's requirements.

The Need for Greater Flexibility

First, industry and consumers would benefit from being able to provide a range of lot codes rather than a single lot code for products. Most of the products on retail stores must travel through a distribution center before reaching the store shelves and distribution centers are struggling to find feasible ways to trace single lot codes through their operations without

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implementing case-level tracking. Because distribution centers already have strong visibility into their product's path through the supply chain, allowing a range of traceability lot codes would ease the complexity without hindering FDA's ability to complete an efficient traceback investigation.

The Need for Pilot Projects

For industry to successfully implement the Traceability Rule, pilot projects must be completed to evaluate whether different entities in the supply chain can coordinate with each other to ensure compliance and whether the goals of the Traceability Rule – more efficient and effective traceback investigations - can be met. Quite simply, pilot projects can explore what gaps in implementation need to be addressed before significant investments in technology, recordkeeping systems, training and more have been made. Pilot projects also would enable industry and the agency to explore alternative solutions that reduce the burden on industry while protecting public health. In order for the learnings from these pilot programs to be effectively implemented, the compliance date should be two years after their completion.

The Need for An Extension to the Compliance Date

Given the complexity of the Traceability Rule, the need to educate the supply chain, the need to identify and evaluate new technologies and new recordkeeping systems, and the desire to ensure our systems are interoperable, more time is needed to comply with the rule. Considering the investments we have made thus far and the planned investments that are needed for compliance, we need to ensure we get it right. Additional time for compliance will help us do so.

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,

Reynolds W. Cramer
Chief Executive Officer
Fareway Stores Inc.

October 25, 2024

To the Reagan Udall Foundation,

On behalf of FishWise, please accept the following comments on the FDA's Final Rule on Requirements for Additional Traceability Records for Certain Foods (FSMA Section 204).

FishWise is a non-profit organization focused on sustaining ocean ecosystems and the people who depend on them by transforming global seafood supply chains. For over 20 years, we have acted as trusted advisors to individual companies and their suppliers and leaders in coalitions that drive change across supply chain actors. Through a consultative approach, FishWise supports retail and mid-supply chain companies to leverage traceability practices and technologies for identifying and mitigating various risks linked to seafood production. We work directly with companies to improve electronic data collection and traceability for seafood products in alignment with comprehensive environmental sustainability and social responsibility policies. Our close collaboration with seafood retailers, mid-supply chain companies, and producers has resulted in a rich body of experience from which FishWise, our partners, and our colleagues may draw lessons to advance the field of seafood traceability.

As a result, we know firsthand that the diversity of species, harvest methods, and global supply chains for seafood result in unique food safety risks and traceability challenges for these products compared to agricultural products - including risks resulting from illegal fishing. Illegal, unreported, and unregulated (IUU) fishing results in catch entering the supply chain without proper accountability, increasing risks of mislabeling seafood and the potential mishandling of products. End-to-end, electronic, and interoperable traceability is the industry's best practice and allows for documenting seafood products' legal origins *and* proper handling.

FishWise's seafood traceability efforts align with the FDA's New Era of Smarter Food Safety Blueprint's first core element to support end-to-end traceability with interoperable and electronic systems. While we are pleased to see electronic traceability as a requirement under this rule, we recognize that for the success of Rule 204, there are several foundational needs FishWise recommends the FDA address.

Alignment of Key Data Elements

FishWise is encouraged by the continued momentum to prioritize electronic and end-to-end traceability via Rule 204. We agree that standardized data collection streamlines internal records and promotes interoperability throughout the supply chain. However, many import requirements already collect a subset of this data from the seafood industry (e.g., Seafood Import Monitoring Program, NOAA's Fisheries Certificate of Origin, and Certificate of Admissibility). A review of the information currently collected against the information in FSMA Section 204 would likely reveal that a fair amount of product information is already collected. Where key data elements (KDEs) required under this rule overlap with information collected under others, alignment will improve efficiency and the cost-effectiveness of compliance. With

the standardization and alignment of KDE formats, companies can more readily adapt their existing data management systems, resulting in improved opportunities for data interoperability. **For the KDEs required for seafood produced from a fishing vessel or aquaculture by FSMA Section 204, FishWise recommends aligning KDE definitions *and* formats as outlined by NOAA.**

Standardized, open, and industry-wide nomenclature is encouraged to prevent confusion and harmonize existing procedures, protocols, and data collection practices. The seafood industry is moving towards standardization of KDEs as outlined in the Global Dialogue on Seafood Traceability (GDST) Core Normative Standards. FishWise encourages the seafood industry to align with the GDST, continuing the momentum towards traceability best practices of electronic, end-to-end, and interoperable systems. In addition to GS1 and the 3-Alpha Seafood Species Code (§ 1.1310(1)), **FishWise recommends the FDA include a reference to GDST's existing Core Normative Standards for relevant information required for seafood in FSMA Section 204**.

Aligning KDEs across traceability systems simplifies data collection throughout the supply chain, making traceability a more efficient process with fewer opportunities for errors. Alignment of KDEs would also give the industry a clearer understanding of what data they should track, which documents they will be asked to provide for compliance, and what information to request from their supply chain.

Harmonization Across U.S. Programs

While FishWise recognizes the importance of FSMA Section 204 in enhancing traceability for certain high-risk foods, the effectiveness of this rule can be significantly amplified by harmonizing it with other U.S. government import programs. Harmonization across programs has the potential to streamline regulatory processes, reduce redundancies, lessen the paperwork and reporting burden on the seafood industry, and foster a more cohesive and efficient approach to food safety and import controls.

Aligning FSMA Section 204 with existing import programs like SIMP or other CBP initiatives would create a unified regulatory framework. Currently, different agencies have overlapping or slightly varied data requirements for seafood importation, which leads to confusion and increased compliance costs for companies. Reducing redundancy in data requests and better leveraging already-collected data can lower the burden and cost on businesses, particularly small companies with limited resources. A harmonized approach would enhance the traceability and transparency of imported food products and offer the ability to leverage a more comprehensive dataset to quickly identify and respond to agency needs (e.g., food safety, legality, or origin).

Intragovernmental Coordination

FishWise has and will continue to advocate for better interagency communication and coordination - regardless of program. An essential component of this recommendation is standardizing how FSMA Section 204 operates along with other programs and best practices

within the seafood industry. Seafood supply chains are global and complex, resulting in several U.S. governmental agencies having jurisdiction over seafood products as they enter the country. Creating feedback loops between agencies can foster a culture of regular dialogue to share program updates and lessons learned. This dialogue can identify areas where further capacity building or support might be needed across the industry and ultimately work to remove data-sharing barriers to improve program management and enforcement.

Improved supply chain transparency and effective traceability practices of products are the foundation of regulations governing seafood products. As these regulations and rules continue to evolve, it is necessary to have intergovernmental coordination between agencies (e.g., NOAA, CBP, DOL, and FDA). **FishWise urges the FDA to create Memorandums of Understanding to identify compliance barriers and facilitate interagency coordination between partner agencies implementing documentation and inspection programs for seafood products.**

For example, suppose the FDA progresses to an automated data collection system. In that case, it will be more efficient if done in alignment with existing government traceability platforms such as CBP's Automated Commercial Environment (ACE). FishWise encourages the FDA to consider what automated verification can be built into these existing electronic systems. When information is requested by several entities, ensuring that data is recorded in one electronic and interoperable platform will help the industry submit the information and allow it to be accessed by the agencies needing to view it for more comprehensive analyses.

While Rule 204's mandate is to address food safety in high-risk products, improved interagency coordination would facilitate better data sharing across agencies looking to implement a whole-of-government approach to addressing egregious issues in the seafood sector, such as mislabeling, illegal fishing, and human and labor rights abuses.

Industry Engagement

To comply with FSMA Section 204 effectively, companies need tools and resources that enable operational consistency, standardized processes, and regular communications with the FDA. As seen from FishWise's past six years of engaging with U.S. government agencies and the private sector to find common ground around SIMP, ambiguity and lack of prescriptiveness can harm a company's ability to comply with import regulations. FishWise is aware of multiple interpretations of Rule 204, which undermines a company's efforts to accurately assess whether its existing systems or protocols are sufficient for compliance.

Given the global nature and complexity of seafood supply chains, chain of custody records can vary widely in their content, structure, language, and necessity for trade. Consistent, up-to-date information on regulatory expectations and changes will be necessary to complement the industry's efforts to meet regulatory requirements. Although FSMA Section 204 aligns with current industry best practices, it will require some companies to invest in upgrading or adopting completely new systems. Regular engagement (e.g., a community of practice) whereby companies can ask questions, share suggestions, offer solutions, and receive updated guidance

would go a long way in supporting compliance and enhancing clarity around the final rule. This proactive approach ensures that industry stakeholders are well-informed and equipped to meet compliance standards, reducing the risk of unintentional violations and enhancing overall food safety. Moreover, this kind of regular dialogue can foster a collaborative environment where the FDA can use industry feedback to refine its guidance and support materials and trainings, making them more relevant and user-friendly.

FishWise strongly encourages the FDA to prioritize routine engagement with companies to increase the awareness and understanding of FSMA Section 204 and consider facilitating public-private partnerships to foster cross-sector learning.

FishWise thanks the Reagan Udall Foundation for allowing FishWise the opportunity to provide input and for its excellent work to date to support the FDA's mission. We also thank the U.S. government for taking the leadership on this critical topic of addressing food safety and food traceability. We believe a holistic, collaborative approach to these issues has the potential to create a strong foundation of transparency and coordination that will allow for aligned information sharing and fundamental change in seafood supply chains.

Sincerely,

Sara G. Lewis
Director of Programs
FishWise

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,

Stephanie Harris
Chief Regulatory Officer and General Counsel

Hilary Thesmar, PhD, RD, CFS
Chief Science Officer and SVP Food and Product Safety

10/24/2024

Dear Reagan-Udall Foundation for the FDA,

Thank you for facilitating a public meeting on the FDA Food Traceability Rule and providing the opportunity to offer written comments on implementation of the rule.

I am Dr. Jennifer McEntire, Founder of Food Safety Strategy, LLC. Although my firm recently began working with the Reagan-Udall Foundation on a produce safety dialogue, that work is completely unrelated to the Foundations work on food traceability. Additionally, my comments reflect my personal views and do not necessarily reflect those of any clients of Food Safety Strategy, LLC.

My comments focus on 3 main points:

- FDA should retain the current compliance date while continuing to work with the breadth of the industry to increase awareness and test implementation options
- FDA should assess and quantify how different variables impact the ability to successfully trace a product back to its origin.
- FDA should issue guidance without delay and should encourage the use of globally recognized standards to facilitate interoperability.

Background and Qualifications

My background is in microbial food safety and I began working in food traceability in 2008 when, as part of FDA's contract with my then employer, the Institute of Food Technologists, we were tasked to gather background information and assess the state of the food industry with respect to traceability. Our expert panel, under my leadership, coined the terms and described the concepts of "Critical Tracking Events" and "Key Data Elements" which are now in ubiquitous use, including as key elements of the FDA Food Traceability Rule. In 2011, after the passage of the Food Safety Modernization Act, IFT was again contracted to work on traceability, this time conducting the pilots referenced in Section 204 of the Act.

Over the past 16 years I have evaluated how traceability information is managed in scores of food companies (from farms to distribution centers) and have seen dozens of demonstrations of software technologies. I have also helped support many companies through recalls and outbreak situations. I've given numerous webinars and fielded countless questions on the rule and the topic in general. I have written numerous articles on this topic, and in 2019 co-edited with Andrew Kennedy "Traceability: From Binders to Blockchain". While the challenges noted by many industry representatives during the public meeting are real, the challenges that persist during tracebacks (as part of outbreak investigations) are also real. I remain hopeful that FDA and the food industry can work together to swiftly identify the source of an outbreak. While I am optimistic that the implementation of the traceability rule will help, the food safety community (industry and regulators) must not forget that rapid tracebacks and public health protection are better measures of success than strict regulatory compliance.

Retain the Compliance Date but be Reasonable

Without a clear timeline and milestones for the industry to develop a functional, practical product tracing system, it is difficult to justify the need for "more time". During the public meeting, only the

National Grocers Association indicated the amount of time they felt was needed for their members to comply. FDA should retain the current compliance date in order to maintain industry momentum, but should go beyond the 'educate before and while we regulate' to have meaningful collaboration with the industry to assess if approaches that may not meet the letter of the rule still meet the intent of the rule.

The rise and fall of traceability as a hot topic seems to coincide with two things: devastating outbreaks (e.g., spinach in 2006, tomatoes/peppers in 2008, PCA in 2008/09, romaine in 2018) and FDA action (e.g., FSMA related pilots in 2011/12, proposed and final rules). Establishing supply-chain wide traceability is a daunting task, and without a deadline, may be deferred because it is otherwise overwhelming. Thus, a deadline and the expectation of compliance can help push progress.

It seems FDA recognizes the enormity of the challenges, and also sees that parts of the rule are ambiguous and need additional interpretation. FDA must be reasonable in their expectation for compliance while also requiring companies to demonstrate a good faith effort in helping regulators identify the source of an outbreak.

Assess Factors that Influence Public Health Benefits

FDA should do a better job communicating why this rule exists, and the impact the rule will have on public health.

Buried in the IFT pilot report is a section that assessed the public health benefits of improved speed of tracebacks. IFT was provided with the timelines of several real traceback investigations and determined if illnesses might have been avoided if the tracebacks had occurred faster (e.g., 50% less time). In some cases it mattered, and in others it didn't. Beyond the "reactive" benefit of improved traceability (e.g., avoiding exposures in order to avoid additional illnesses), FDA should also speak to the benefit of pinpointing the source of contamination in order to investigate how contamination might have occurred, in the hopes that similar situations can be avoided in the future.

With the improvements that have been made to the outbreak investigation process (e.g., clinical diagnostics, whole genome sequencing, epidemiology, and traceback), FDA should support a new analysis that determines the key factors and rate limiting steps that influence how an outbreak unfolds. Because FDA cannot influence the epidemiological part of the investigation, an analysis should assess factors that are exclusive to the traceback, beginning with the scope of a records request. This should include the granularity of recordkeeping (e.g., the ability to definitively know which lots were sent from a DC to a store) as well as processes not addressed by the rule (physical commingling of fruit and vegetable RACs, etc.). A sensitivity analysis should guide FDA's focus to practices or rule requirements that have the greatest impact on a traceback investigation.

Guidance is Needed

FDA is to be commended for providing numerous resources on their website, including helpful FAQs. However, there are areas of the rule where additional interpretation and clarification is needed, and questions around implementation outside the scope of the rule where guidance can serve an important role. FDA is notoriously slow in issuing guidance and this must be avoided if FDA wants the food industry to comply.

One area where guidance can help the industry is around standards and interoperability. While the statute appropriately restricts FDA from forcing the industry to adopt one type of system for recordkeeping, the public meeting panelists and commentators made clear that industry members must collaborate and systems must work together so that traceability information can be efficiently shared. If a supplier needs to devote resources to sharing KDEs in a dozen different ways to accommodate a dozen different customers, or if customers are receiving KDEs in a multitude of formats and ways based on the suppliers, the burden of this rule will increase. Compliance will suffer. In contrast, if standards are adopted there can still be flexibility, competition and innovation within the marketplace while facilitating the flow of KDEs (often cited examples include the ability to use a debit card at any bank and many retail stores, and the ability of a land line phone with one provider to call a cell phone on another provider). Industry may align on a path forward without input from FDA, but encouragement from the Agency will likely accelerate the process.

FDA must not let perfection be the enemy of good. Technology will change and approaches to implementation will change. Guidance can be updated to address changes. FDA should not wait until all questions have been received. Please get "version 1" out as quickly as possible. If this is not a priority for the Agency it will not be a priority for the industry.

Thank you for the opportunity to comment and I anxiously await additional information from FDA on this topic. Please reach out with any questions or if additional information would be useful.

Best regards,

Jennifer McEntire, Ph.D.

Hello, my name is Jessica Marino, and I am the Food Safety Manager at Four Seasons Produce. We are a wholesaler and distributor of fresh produce. Most of our products are on the FTL.

First, I would like to thank FDA for this opportunity to offer feedback regarding FSMA 204 and how it will impact our business. As the law is currently written, there are no warehouse management systems that have the capacity to provide FDA with the information they are requiring. Pallets received come in with multiple grower lots. Additionally, to utilize space and efficiencies, grower lots will also be commingled within our warehouse storage slots. As the rule is written, it appears as though FDA is expecting case level traceability. Our company, as with most distribution centers, is struggling to find labor. Our building has limited space, and it is expensive to store in refrigeration. Therefore, to achieve what FDA is asking for would be overburdensome as it would require extra storage space, labor, and time to implement. All these measures will also increase cost per case which will then be carried over to the consumers, who as you know, are experiencing record food inflation prices.

As a distribution center, each year we are pulled into several of our supplier-initiated recalls. Since we are aware of commingling lots, we always recall more product than what is involved in the recall to ensure that all implicated product is accounted for. We notify our retail customers of the recall and to pull affected product from store shelves. We will send two electronic notifications asking for a recall effectiveness questionnaire to be completed. This form verifies product has been pulled from the market and there are no consumer reported health incidents. Sales associates will follow up with those customers we have not heard back from. However, with every recall we still have several stores that refuse to reply to us. I would imagine that product remains on the shelf. However, as a distribution center, this is outside the scope of our control. Time and time again, I have heard the concern of recalled product remaining on store shelves. FSMA 204 has nothing in it that would solve this issue. Also, the FDA has not addressed the unethical practice utilized to manage shrink at the retail level in which stores will take old produce and place it in newly received product cases to return the product to the distribution centers. This act alone nullifies all traceability.

We have heard that FDA may be open to the idea of allowing an algorithm for distribution centers such as ourselves to utilize for traceability data in lieu of case level scanning. We are in favor of this practice as this is what we currently employ during a recall or investigative process. This algorithm, while recalling a small additional amount of product that may not be implicated, is the most effective tool. Under FSMA 204, our preference would be to continue with our current practice of utilizing this algorithm for traceability purposes. We do not believe that FDA should mandate what this algorithm looks like, nor should the algorithm be patented or monetized. With the use of an algorithm, we have concern over what advanced ship notifications will look like. We are envisioning an ASN to essentially be a BOL with traceability lot codes listed. We anticipate the generation of such a document will be time-consuming and may incur excessive costs for technology.

The FDA appears to heavily rely on distribution centers to ensure compliance with FSMA 204. As a distribution center, we frequently source products from smaller suppliers who lack the resources to implement TLCs, which shifts the compliance burden onto us. This makes it increasingly challenging for distribution centers to continue purchasing FTL products from smaller suppliers, potentially pushing them out of the marketplace and driving them to sell their products on the black market without traceability practices and oversight.

Once again, thank you for the allowance of industry comments. We are hopeful that FDA will take these concerns seriously and amend your requirements accordingly.

Most sincerely,

_____

Jessica Marino | Food Safety Manager | Four Seasons Produce, Inc.

The Global Language of Business

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October 25, 2024

Reagan-Udall Foundation for the Food and Drug Administration
1333 New Hampshire Avenue NW
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Washington, DC 20036 USA

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

To Whom It May Concern,

GS1 US appreciates the opportunity to comment on the Reagan-Udall Foundation's FDA's Virtual Public Meeting on the FDA's Final Rule on Requirements for Additional Traceability Records for Certain Foods. For the last 50 years, GS1 Standards have served as the global language of business, enabling the movement and "visibility" of products within supply chains in more than 25 industries across 150 countries. This includes food and beverage production, foodservice, and retail grocery sectors in the United States. In addition, GS1 Standards facilitate the traceability of food and food ingredients to minimize and prevent food safety risks. With feedback from industry experts and stakeholders in mind, we believe GS1 Standards offer practical solutions to the challenges raised during the public meeting. Below is an outline of how GS1 Standards can address the key topics:

1. **Traceability Lot Codes and Labeling**

The FDA's Final Rule mandates the use of traceability lot codes to ensure each lot of food can be accurately tracked and traced from the source to the destination. GS1 US's suggested approach to traceability lot codes and labeling is to leverage GS1 Standards. At a minimum, we recommend considering the Global Trade Item Number (GTIN), an

internal batch/lot code, and the GS1-128 barcode, which provides a framework for assigning and sharing traceability lot codes. Additionally, the Global Location Number (GLN) enhances the visibility of product locations, and the Electronic Product Code Information Services (EPCIS) facilitates data sharing across the supply chain. The GLN lets businesses know who is involved in transactions and where things are located throughout the supply chain, as well as where a product is initially packed, manufactured, transformed, etc. By uniquely identifying parties and locations, a GLN helps optimize processes and provide greater visibility to business transactions and events worldwide. These standards ensure that each product is uniquely identified and can be traced throughout the supply chain. GS1 Standards offer a globally recognized and standardized format for capturing traceability lot codes and traceability lot code sources, simplifying this complexity.

- **Global Trade Item Number (GTIN**): A GTIN is a GS1 identification key that uniquely identifies a trade item. Trade items are physical goods or services that are ordered, priced, or invoiced at any point in the supply chain. By assigning trade items with GTINs, a company can uniquely identify their product or service globally.

- **GS1-128 Barcode:** GS1-128 barcodes can encode multiple pieces of detailed product information such as GTIN, batch/lot, and expiration date, making them beneficial in shipping, receiving, and warehouse scanning environments. With a single scan of a GS1-128, supply chain partners (ex., shipper, distributor, fulfillment center) can capture this detailed information to support supply chain efficiency and product traceability, helping sellers become better prepared for recalls.

- **2D Barcodes:** Two-dimensional barcodes (2D) appear as small grids made up of dark and light spaces. These types of data carriers are smaller in physical size but can carry larger amounts of product data than the GS1-128 barcode, given they have an even greater capacity to hold information. A common example of a 2D barcode is a QR code. When scanned, 2D barcodes provide information about products such as GTIN, batch lot numbers, manufacturing plant, weight, expiration date, and much more.

- **Global Location Number (GLN):** The GLN is a globally unique GS1 Identification Key used to identify parties and locations that are used in business transactions throughout the supply chain. The GLN allows users to answer the questions "who" and "where" within their organization and those entities and physical or digital locations in which they interact throughout the supply chain.

- **GS1 Electronic Product Code Information Services (EPCIS):** EPCIS facilitates the sharing of Critical Tracking Event data by enabling trading partners to capture and share information about the physical movement and status of products, as they travel throughout the supply chain—not only within and between locations in a single enterprise, but also between trading partners and ultimately to consumers. EPCIS answers the "what, where, when, why, and how" questions that provide accurate and detailed product information. This visibility data is aimed at providing all parties involved with the creation, management, and transfer of products an interoperable representation of supply chain events as they occur.

Leveraging GS1 identification, capture and share standards enables companies to streamline traceability compliance with the Final Rule, as well as improve their overall supply chain visibility. The ability to embed multiple pieces of data, including GTIN, batch or lot number, and expiration date within a single barcode allows for accurate tracking even as products move through complex supply chains with many trading partners. By leveraging GS1 Standards, trading partners can ensure they are maintaining greater flexibility in handling different types of products and shipments.

GS1 US EPCIS Recommendations for FSMA 204 Critical Tracking Events

Mapping of Critical Tracking Events and Key Data Elements to GS1 Standards

2. Warehouse Management Systems and Technology

One of the significant challenges industry faces is proprietary systems and the lack of interoperability. These systems often tend to operate in silos, making it difficult to exchange information across the supply chain. Without a common data language, companies may find it difficult to effectively share information or interpret the information they receive from their trading partners, which can hinder traceability and real-time visibility. By adopting data standards such as GS1 Standards, industry can bridge the gap, enable seamless data sharing, and improve traceability. GS1 Standards serve as a tool to address the complexities introduced by the Final Rule, and the structured nature of the standards provides seamless and interoperable data sharing. By incorporating GS1 Standards into warehouse management systems and technology, warehouses ensure they can efficiently capture product traceability data to achieve operational efficiency and regulatory compliance.

Industry faces challenges handling mixed lots in pallets, which may cause additional complexities. The GS1-128 barcode simplifies this process by capturing multiple data points, such as traceability lot code. Advance Ship Notices (ASN) can be sent prior to the

physical pallet arriving, detailing the quantities of each traceability lot code inside a pallet identified with a Serial Shipping Container Code label. This ensures that complex shipments can be accurately tracked and traced. As industry evolves, 2D barcodes provide further opportunities to simplify these processes. The increased data capacity in a smaller barcode makes 2D barcodes ideal for traceability at the case level. Electronic Data Interchange (EDI) bridges the gap between companies and systems and uses standardized business messages to enable trading partners to communicate in a common language. EDI helps companies conduct electronic commerce efficiently and accurately. EDI supports the transmission of ASNs and other transactional data between trading partners, reducing manual processes and errors.

3. Implementation Schedule and Awareness

Several public comments emphasized the need for more time to develop interoperable data standards and raise awareness, particularly among smaller businesses. GS1 US is committed to supporting the industry by offering educational resources, pilot programs, and tools to facilitate the adoption of GS1 Standards. Our experience in other sectors, including healthcare and retail, demonstrates that early engagement and collaboration across the supply chain are essential for success.

GS1 US offers detailed guidelines and best practice documents to assist companies in integrating GS1 Standards into their operations. These resources provide step-by-step instructions and practical advice on how to implement GS1 Standards effectively, ensuring compliance with regulatory requirements.

Recognizing the need for industry-wide awareness of the Final Rule, GS1 US, along with seven other leading organizations, formed the Food Industry FSMA 204 Collaboration to tackle the challenges posed by FSMA Rule 204. The Collaboration includes the Association of Food and Drug Officials (AFDO), FMI – The Food Industry Association (FMI), GS1 US, Institute of Food Technologists (IFT), International Foodservice Distributors Association (IFDA), International Foodservice Manufacturers Association (IFMA), International Fresh Produce Association (IFPA) and National Association of State Departments of Agriculture (NASDA). The Collaboration strives to ease the burden of compliance and equip industry with the tools and knowledge needed to enhance transparency, improve food safety recalls, and meet regulatory requirements.

4. Pilot/Concept Testing

The use of GS1 Standards, barcodes in particular, has been a cornerstone of supply chain efficiency for five decades. Since the first barcode scan in 1974, GS1 has been leading the way in providing global data standards that enable businesses to identify, capture,

and share information seamlessly across the supply chain. The long history of the use of barcodes by industry demonstrates the lasting value of GS1 Standards in enhancing traceability and efficiency across numerous sectors, including the food industry.

Feedback during the virtual public meeting highlighted the importance of testing traceability solutions before full-scale implementation. GS1 Standards have been successfully used in pilot programs across various sectors. These pilots demonstrate the effectiveness of GS1 Standards in handling complex supply chain challenges, including interoperability and data exchange. GS1 US encourages pilot programs and concept testing to validate the effectiveness of GS1 Standards in real-world scenarios. These pilots help identify potential challenges and opportunities for improvement, ensuring that the standards meet the specific needs of the industry. By collaborating with industry stakeholders, GS1 US can facilitate successful pilot projects that demonstrate the value of GS1 Standards in enhancing traceability and compliance. This proactive approach allows for adjustments and refinements to be made before large-scale rollouts, ensuring that all parties—from small businesses to large corporations—are equipped to meet the FDA's traceability requirements.

In recent years, GS1 US has continued to address traceability challenges as they emerge through collaborative pilots and case studies. One example is the Leafy Green Traceability Pilot, which was conducted with key industry partners to test traceability procedures using GS1 Standards to track romaine lettuce from point-of-sale back to the grower. The pilot demonstrated how industry could share product information in a standardized format and accelerate their response to recalls. The Leafy Green Traceability Pilot is a practical example of how industry can collaborate to streamline traceability efforts and meet regulatory requirements.

In conclusion, GS1 Standards offer a comprehensive solution for addressing the FDA's food traceability requirements. We are committed to supporting industry in adopting these standards and achieving greater traceability, transparency, and efficiency in the food supply chain. By leveraging GS1 Standards, companies can enhance their traceability systems, improve operational efficiency, meet consumer demands, and ensure compliance with regulatory requirements.

Sincerely,

Maggie Lyons
Vice President, Government Relations
GS1 US
MLyons@gs1us.org

October 25, 2024

The Reagan-Udall Foundation
1333 New Hampshire Ave NW
Suite 420
Washington, DC 20036
finalrule@reaganudall.org

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:

Hy-Vee, Inc. appreciates the opportunity to provide comments on The Reagan-Udall Foundation's (RUF) Virtual Public Meeting on the Food and Drug Administration's (FDA) Final Rule on Requirements for Additional Traceability Records for Certain Foods (the Traceability Rule). As an employee-owned company operating more than 570 retail business units across nine Midwestern states – Illinois, Indiana, Iowa, Kansas, Minnesota, Missouri, Nebraska, South Dakota and Wisconsin – Hy-Vee is directly impacted by the Traceability Rule's requirements, and we have been working diligently to meet the compliance deadline. Through our collaboration with our supply chain partners to bring our operations into compliance, we have identified several hurdles and challenges impacting our industry.

Since the final rule was published in November 2022, we have been working diligently to educate our supply chain partners and to identify and implement our compliance strategy. The food industry is committed to enhancing traceability throughout the supply chain as demonstrated by the hundreds of millions of dollars that have already been invested in Traceability Rule compliance efforts. Notwithstanding these efforts, more work and more financial investment is needed before compliance can be achieved.

At this time, the biggest challenge facing industry is the overwhelming complexity involved in implementing the Traceability Rule. The implementation complexity stems from both the number of products the rule implicates, the reliance on other entities' compliance to ensure your own obligations are met, and the need to evaluate new technologies and systems, and the desire to ensure interoperability. As explained below, these challenges highlight the need for greater flexibility in the Traceability Rule, specifically related to the use of traceability lot codes, and more time to perform pilot projects and implement the Traceability Rule's requirements.

<u>The Need for Greater Flexibility</u>

First, industry and consumers would benefit from being able to provide a range of lot codes rather than a single lot code for products. Most of the products on retail stores must travel through a distribution center before reaching the store shelves and distribution centers are struggling to find feasible ways

to trace single lot codes through their operations without implementing case-level tracking. Because distribution centers already have strong visibility into their product's path through the supply chain, allowing a range of traceability lot codes would ease the complexity without hindering FDA's ability to complete an efficient traceback investigation.

The Need for Pilot Projects

For the industry to successfully implement the Traceability Rule, pilot projects must be completed to evaluate whether different entities in the supply chain can coordinate with each other to ensure compliance and whether the goals of the Traceability Rule – more efficient and effective traceback investigations – can be met. Pilot projects can explore what gaps in implementation need to be addressed *before* significant investments in technology, recordkeeping systems, training and more have been made. Pilot projects also would enable the industry and the agency to explore alternative solutions that reduce the burden on the industry while protecting public health. For the learnings from these pilot programs to be effectively implemented, the compliance date should be two years after their completion.

The Need for An Extension to the Compliance Date

Given the complexity of the Traceability Rule, the need to educate the supply chain, the need to identify and evaluate new technologies and new recordkeeping systems, and the desire to ensure our systems are interoperable, more time is needed to comply with the rule. In light of the investments we have made thus far and the planned investments that are needed for compliance, we need to ensure we get it right. Additional time for compliance will help us do so.

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

Sincerely,

Stacey Johnson
Senior Vice President, Government Relations & Corporate Compliance
Hy-Vee, Inc.

iFoodDS

By Electronic Submission

October 25, 2024

Jim Jones, MS
Deputy Commissioner for Human Foods
U.S. Food and Drug Administration

c/o Susan C. Winckler, RPh, Esq.,
Chief Executive Officer,
Reagan-Udall Foundation
FinalRule@reaganudall.org

Dear Sir:

iFoodDS appreciates the opportunity to share its views during the Reagan-Udall Foundation's Industry Roundtable Series and associated public meeting held October 7, 2024, covering the FSMA Final Rule on Requirements for Additional Traceability Records for Certain Foods Top-Line Learnings Summary. iFoodDS is a leader in food supply chain traceability solutions for the fresh food industry. We launched iFoodDecisionSciences, Inc. in 2013 following years of food safety consulting. Our expansion continued with the acquisition of HarvestMark in 2020, a company well-known as the leading provider of food traceability software and food quality management solutions.

Today, iFoodDS makes it easier for companies in the food industry to deliver wholesome, fresh, high-quality products with the best solutions for connected traceability, quality and food safety.

Our consulting subsidiary, New Era Partners, helps enterprises navigate the complexities of the FDA's Food Traceability Rule, FSMA 204, to smooth the path to compliance.

Awareness: More outreach from FDA to covered entities and clarification of enforcement strategy is needed. We have found many FTL food producers are still unaware of the rule. Less than two-minute videos shared to social media from official FDA accounts explaining the rule and pointing to resources would benefit this entire industry. Also, guidance on how the two traceability rules interact with each other - the BT Act of 2002 (Subpart J) and FSMA 204 (Subpart S).

TLC & Labeling: The retail industry is beginning a multi-year transition from 1D to 2D barcodes. Covered entities will benefit from incorporating the TLC into 2D case barcodes, however the technology is not fully tested yet and best practices have not been established.

Warehouse Management Systems: Most retail and foodservice distribution center warehouse management systems are not currently designed to handle supplier provided traceability lot code and source. For the foreseeable future, these systems will need to compute or estimate lot codes based on inventory and receiving records for most shipments. In the future, product identification technology may enable distribution centers to capture TLC from each case delivered to restaurants and retail stores, but this will require a significant investment of time and money by producers and distributors. We recommend FDA provide guidance allowing last-mile distributors with the flexibility to use both methods to keep and provide traceability lot code information. If the TLC is calculated, we recommend that FDA and subsequent recipients are notified. We also recommend that retail stores and restaurants be allowed to keep receiving records based on either the calculated TLCs provided by the distributor or the actual TLCs from the food packaging (if available). We do not believe that this will impact FDA's ability to trace back to the source because the number of lot codes or sources that must be physically inspected is a function of convergence between multiple traceback legs. In other words, most lot codes are filtered out because investigators are comparing TLC Sources or TLCs provided by different supply chain owners across multiple distribution centers. Rarely is an outbreak limited to one distribution center.

Technology: Rather than dive straight into technology implementation, we recommend the Learn-Plan-Do-Review methodology developed by New Era Partners. Many companies that manage distribution centers are waiting for FDA's decision on how to handle traceability lot codes in situations where they are not readily available on food packaging. This impacts their suppliers and customers.

Pilots: We do not feel that the industry needs to wait for FDA to execute pilots. There are many organizations who already have deep experience in performing pilots, including GS1 and IFT's Global Food Traceability Center. We recommend that the industry pilot 2D and electronic data carriers in parallel with TLC calculation methods, recognizing that both will be needed.

Public-Private Partnership: We recommend the Reagan-Udall foundation host free quarterly public meetings covering: FDA updates, industry pilots, panel discussions, Q&A sharing.

Implementation Schedule: The first year of the rule should be considered a Stabilization period, similar to what was implemented for the Drug Supply Chain Security Act (drug traceability). It should be made clear that the industry should begin operating as if the rule is being enforced, but with the understanding that FDA's goal for the year is allowing time for participants to work out the inevitable technical challenges.

Warehouse Management System Capability

Scan or Calculate? The question before FDA and the food industry is whether the rule requires the selector to identify the precise traceability lot code selected from a barcode or human readable text on the food packaging or if it is sufficient to calculate the traceability lot codes that could have been selected from the warehouse location based on inventory and receiving records.

Even when most foods are identified with traceability lot code in machine readable format, the calculation method is useful for filling in gaps. Conversely, electronic data capture from food packaging can be used to validate and improve calculation algorithms. Therefore, we see that that the answer to Scan or Calculate? is **Scan *AND* Calculate**.

RECOMMENDATION for FDA Industry Guidance Language on TLC Calculation:

"Recognizing that:

1. The FSMA Final Rule on Requirements for Additional Traceability Records for Certain Foods does not require that food packaging be marked with the traceability lot code.[1]
2. The majority of FTL food packaging (cases, inner packs, saleable items) are currently marked with either ITF-14 barcodes that have high read rates but do not include the traceability lot code or are marked with GS1-128 barcodes that may include the traceability lot code but have unacceptably low read rates.
3. Most food distribution centers do not capture supplier provided traceability lot code from food packaging during receiving, order selection, or delivery.

Food distribution centers[2] may calculate traceability lot codes for FTL foods that could reasonably[3] be selected during order selection based on business records (receiving, inventory, order selection records). This information may be kept in shipping records, provided to subsequent recipients, and shared to FDA in the form of a sortable spreadsheet. If one elects to calculate traceability lot code, the calculation method and any audit or verification methods should be described in the traceability plan under 1.1315(a)(1)[4]. Below is an example of an acceptable shipping record with multiple traceability lot numbers and an indication that the lot numbers were calculated. This notification will assist receivers and FDA with how to use this information."

Quantity	UOM	Product Description	Traceability Lot Code*	TLC Source Reference
10	Cases	Iceberg Lettuce	AAA BBB	FFRN: 12345 FFRN: 45678
5	Cases	Tomatoes	CCC DDD	FFRN: 78901 FFRN: 23456

**** The traceability lot codes shown were calculated rather than captured from food packaging. Traceability lot codes shown on food packaging may differ from this listing.***

Subsequent recipients of FTL foods from distribution centers may either record the calculated traceability lot codes received from food distribution centers or may record actual traceability lot codes marked on food packaging. The method used and any audit or verification methods should be noted in the subsequent recipient's traceability plan.

Persons who manufacture, process or pack FTL foods are strongly encouraged to develop and implement improved FTL food identification methods that will enable precise, reliable traceability lot code capture by food distributors during order selection or delivery.

[1] https://www.fda.gov/food/food-safety-modernization-act-fsma/traceability-lot-code
[2] Locations that primarily receive FTL foods on pallets and ship to RFEs and restaurants by the case, inner pack, or saleable item.
[3] At minimum, a 1% chance that the traceability lot code has been selected
[4] https://www.ecfr.gov/current/title-21/part-1/section-1.1315#p-1.1315(a)(1)

Comments on FSMA 204 Implementation: Reagan-Udall Foundation for the FDA

October 25, 2024

Reagan-Udall Foundation for the Food and Drug Administration

Submitted via: *FinalRule@reaganudall.org*

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

Institute of Food Technologists (IFT) & Global Food Traceability Center (GFTC)

IFT is a non-profit scientific organization with over 11,000 individual members in over 90 countries, who along with dedicated IFT staff, are committed to creating and upholding a scientifically sound society focused on overcoming barriers to feed our future safely. IFT provides scientific, technical, and career development resources for advancing the science of food and its application across the global food and agricultural systems.

IFT's Global Food Traceability Center (GFTC) provides the global food system stakeholders resources, standards, and vision to help improve food safety, diminish risk, avert devastating health consequences and economic loss through enhanced food supply chain traceability. Together, the Institute and its Center believe that science is essential to ensuring a global food supply that is sustainable, safe, nutritious, and accessible to all.

Overview

Formed by IFT following the completion of multiple task orders for the US FDA (Food and Drug Administration) and playing a key advisory role in the creation of the Food Safety Modernization Act (FSMA) through conducting pilots and generating a thorough report of recommendations[1], the GFTC has collaborated with broad sectors of the food industry, aiding various private and public stakeholders in their traceability initiatives since 2013.

This work informs GFTC's knowledge base on advances in identifier technology, stakeholder needs throughout the supply chain, and the challenges in globally integrated food supply systems. With extensive experience working with a diverse range of stakeholders, including small and medium-sized businesses, foreign suppliers, and producers, the GFTC is uniquely positioned to provide valuable insights and recommendations on the implementation of the Food Traceability Rule.

Our expertise is built on a foundation of rigorous research, pilot studies, and collaboration with industry leaders and regulatory bodies. The GFTC has been actively involved in numerous initiatives aimed at enhancing food safety and traceability across the supply chain. Our work aligns closely with the objectives of the Food Safety Modernization Act (FSMA) and the FDA's efforts to improve traceability and reduce the incidence of foodborne illnesses.

Feedback on Key Themes from Reagan-Udall Foundation's Report

Awareness and Education

Through our global engagement with covered entities, the GFTC has observed, in alignment with The Reagan-Udall Foundation's findings, that there is a lack of awareness regarding the Food Traceability Rule and its specific requirements in certain segments of the food system. This issue seems to be particularly pronounced among small and medium-sized businesses, foreign suppliers, and independent organizations. The responsibility for informing impacted parties about the Rule has predominantly fallen to industry associations, food system conveners, and pre-competitive platforms. However, this approach has inadvertently resulted in communication gaps, especially for covered entities that may not be connected to these networks, leaving them unaware of their obligations under the Rule.

To address this concern, it would be beneficial for the FDA to consider adopting a more proactive strategy to reach entities that may not currently engage with these organizations. Furthermore, enhancing support for the associations and platforms that have taken responsibility for disseminating this critical information is essential. This should include not only domestic stakeholders but also international industry associations. Engaging with foreign-based exporter associations, particularly in sectors like produce and seafood that account for a significant portion of U.S. food imports, would be especially impactful. Outreach efforts with these associations may provide an efficient way to connect with a broad range of impacted stakeholders through an established and familiar platform. By equipping these organizations with the necessary tools and resources, the FDA can facilitate effective

[1] McEntire and Bhatt. 2012. Pilot Projects for Improving Product Tracing along the Food Supply System – Final Report. Available from: https://www.ift.org/-/media/gftc/pdfs/ift_fda_producttracingpilotsfinalreport.pdf?la=en&hash=0C3519FD083651860AF89835E1A517AC413C6AF0.

implementation of the Rule, ensuring that both U.S. companies and foreign suppliers are prepared to meet compliance requirements.

In light of this, the GFTC recommends the FDA invest in comprehensive educational programs, providing clear guidance and examples, and publishing case studies on successful implementation. Such initiatives will help ensure that all stakeholders fully understand their responsibilities under the Rule.

Implementation of Traceability Lot Codes (TLCs)

The requirement to utilize and share TLCs presents both opportunities and challenges. While the rule does not mandate case-level labeling, many industry players believe that such detailed tracking will be necessary to meet compliance. The lack of standardization in TLCs, combined with the potential for damaged or unreadable labels, could hinder effective traceability. Adopting a standardized format will present challenges, particularly in the early stages of adoption and implementation. Many solution providers may need to make adjustments to their systems to accommodate the new lot code requirements, which could entail upfront costs for certain providers. Similarly, supply chain actors would likely need to modify or augment their existing lot coding practices, which would require resources and operational changes.

However, the development of clear guidelines on TLC generation, sharing, and storage is essential to minimize confusion and errors and promote interoperability in the long-term. Currently, many organizations utilize multiple lot codes, which can create confusion between trading partners. A standardized format would make it easier to quickly identify the TLC on documents, case labels, and other materials where multiple lot codes are used. Additionally, a unified format would foster interoperability among traceability solution providers. By supporting a single standard, solution providers could streamline their systems, potentially lowering the overall cost of implementation for the industry.

Although a regulatory mandate on TLC format may not be practical, the growing demand for standardization indicates that guidance from the FDA would be well received by industry stakeholders. We recommend that the FDA work collaboratively with industry members and technology providers to establish a recommended format for TLCs. This approach would facilitate smoother implementation for companies seeking to standardize TLCs across their supply chains and provide a unified framework for software providers to integrate into their systems without the constraints of a fixed compliance deadline.

Warehouse Management System Capabilities

Distributors managing a vast array of FTL items stated that they face operational challenges in adapting their warehouse management systems (WMS) to comply with the new requirements. However, modern systems are available that can handle the amount and variation of data required for compliance. It is important to note that investing in technology to support business functions offers numerous benefits beyond compliance, including improved supply chain visibility and efficiency, reduced recall costs, enhanced regulatory compliance, and improved risk assessments.

Technology and Data Integration

In light of the Food Traceability Rule, various technology systems—including data management, warehouse management, enterprise resource planning, and traceability systems—have the potential to

support compliance effectively. However, it is essential for industry stakeholders to carefully evaluate these systems in terms of functionality, capacity, and connectivity with both internal and external systems.

As the industry navigates the implementation of the Rule, it has become clear that improvements in data management processes and enhanced integration of existing systems may be beneficial. This presents an opportunity for businesses to invest in new or upgraded technologies that not only facilitate compliance but also enhance overall operational efficiency. By prioritizing these investments, organizations can benefit from improved data accuracy, streamlined processes, and increased supply chain visibility. However, decisions regarding new or additional technology can be complex, costly, and time-consuming for companies. The GFTC recommends that the FDA develop resources to assist organizations in adopting new technology or adapting existing systems. These resources could include best practice guidelines for crafting technology-specific Requests for Proposal, How-To guides for collaborating with technology vendors, or generic implementation guidance, which could be developed through the FDA's New Era of Smarter Food Safety initiative.

Beyond aiding compliance with the Food Traceability Rule, investing in technology that facilitates data collection, reporting, and adherence to regulations prepares organizations to meet statutory demands while also enabling them to utilize data for improved decision-making, risk management, and food safety.

Public-Private Partnerships (PPP)

The establishment of a public-private partnership could significantly bolster implementation efforts. By facilitating collaboration between industry stakeholders and regulatory bodies, such a partnership could ensure consistent data standards and address common challenges. However, it’s essential to clearly identify the role of the Public-Private Partnership (PPP), the FDA's involvement, and involve all affected stakeholders in developing best practices. These stakeholders include the conveners and ongoing collaborative initiatives, some that were set up to support traceability well before the final FSMA 204 rule was announced, and include the Global Dialogue on Seafood Traceability, the Global Food Traceability Center, the Produce Traceability Initiative, and GS1’s FSMA 204 working group, among others. Evaluating the current framework of these efforts is essential to ensure that a PPP complements and enhances them, rather than risking duplication of efforts. Furthermore, for a Public-Private Partnership to function efficiently, it is essential to clarify the level of cost-sharing—whether financial or in-kind—among industry, the FDA, and subject matter experts. This ensures that the industry does not incur additional costs beyond what is currently expected during implementation.

Implementation Schedule and Phasing

The GFTC holds that altering the timeline for when the rule applies to whom at this stage will generate confusion and delay initiatives aimed at minimizing the effects of food-borne illnesses. Maintaining the current schedule is essential for implementing timely and effective food safety strategies. Instead of staggering the compliance date, the FDA should consider utilizing discretionary enforcement to work collaboratively with the industry beyond the implementation phase. This approach would allow for flexibility and support as businesses adapt to the new requirements, while still maintaining the ability to enforce the law against organizations that show no intent to comply. Delaying the Rule would

unnecessarily extend the risk to consumers and detract from the urgency of improving food safety where it is most needed.

Closing

The Food Traceability Rule represents a transformative step toward enhancing food safety. However, effective implementation will require concerted efforts in education, technology integration, and stakeholder collaboration. By addressing the identified challenges, it is possible to achieve a traceable food system that benefits industry, regulators, and consumers alike. Please contact Blake Harris, GFTC's Technical Director (bharris@ift.org) if GFTC can be of further assistance.

October 25, 2024

By Electronic Submission

Reagan-Udall Foundation for the FDA
1333 New Hampshire Ave. NW, Ste. 420
Washington, DC 20036
FinalRule@reaganudall.org

Re: Reagan-Udall Foundation Roundtables and Virtual Public Meeting on FDA's Food Traceability Rule

To Whom It May Concern:

The International Foodservice Distributors Association ("IFDA") is pleased to submit these comments in response to the Reagan-Udall Foundation's ("the Foundation") roundtable series and virtual public meeting regarding FDA's Final Rule on Requirements for Additional Traceability Records for Certain Foods ("traceability rule" or "the rule"). IFDA is a non-profit trade association that represents businesses in the foodservice distribution industry. Our industry delivers approximately 33 million cases of food and related products to more than 1 million professional kitchens across America every day. As part of this work, foodservice distributors receive and ship thousands of foods on FDA's Food Traceability List ("FTL") on a daily basis and are therefore significantly affected by the traceability rule. IFDA appreciates the Foundation's efforts to examine the practical challenges posed by the traceability rule and to work with stakeholders to identify solutions to those challenges.

Foodservice distributors are deeply committed to food safety and have a proven track record of providing FDA with critical traceback information in a timely manner. Due to both the volume of foods they handle and their central role in the supply chain, foodservice distributors likely assist with more traceback investigations than any other segment of the supply chain. As a result, foodservice distributors have developed highly effective tracking and tracing systems to ensure they have robust records identifying the source, internal movement, and recipient of all products they handle.

IFDA appreciates the core objectives of the traceability rule, and our members continue to dedicate significant time and resources to building traceability programs to comply with the rule's requirements. We remain concerned, however, that certain components of the rule are overly complex and place undue burdens on industry, especially foodservice distributors and operators. Our members are particularly challenged by the de facto case-level tracking the rule imposes on distributors and the rule's current implementation schedule. While we appreciate that the Foundation's Top-Line Learnings Summary from the Industry Roundtable Series ("Top-Line Summary")[1] highlights some of these issues, our comments below provide additional

[1] Reagan-Udall Foundation, Industry Roundtable Series on the FSMA Final Rule on Requirements for Additional Traceability Records for Certain Foods, Top-Line Learnings Summary (Sept. 2024), https://reaganudall.org/sites/default/files/2024-09/Food%20Traceability%20Top-Line%20Summary%20090424_0.pdf.

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important details on the immense burdens these challenges place on industry and identify practical solutions that will allow FDA to resolve these issues while preserving the rule's main goals.

I. The traceability rule imposes a burdensome and costly de facto case-level tracking requirement.

As reflected in the Top-Line Summary, multiple stakeholders, including IFDA, have expressed concerns that "labeling and tracking *at the case-level* [will be] essential to generate" the records required by the traceability rule and that "much of the industry interprets [the rule's requirement that the TLC and TLC source be shared with recipients] to mean that *every case of food must be labeled and scanned* to produce the data FDA may request of downstream entities to trace a lot through the supply chain."[2] The Top-Line Summary further notes that most warehouse management systems are not currently capable of capturing this sort of case-level data and that reconfiguring systems to allow for this capability could "require years to implement" and "potentially require significant increases in labor, equipment, and space, with significant associated costs."[3] These findings underscore IFDA's longstanding concern that, by requiring entities to maintain and pass forward shipping key data element ("KDE") records that reflect *only* the specific traceability lot codes ("TLCs") included in each shipment, the rule imposes a de facto case-level tracking requirement on distributors.

This issue becomes readily apparent when considering the operational structure followed by nearly all foodservice distributors, which involves: (1) receiving products from suppliers in multi-case pallets, which may contain cases from multiple different traceability lots; (2) pulling individual cases from pallets directly or from pick slots; and (3) assembling customer orders using products pulled from pallets and/or pick slots. Because pallets and pick slots typically contain cases associated with different traceability lots, customer shipments may contain products from multiple traceability lots. Thus, to comply with the rule's requirement that shipping KDEs reflect *only* the specific TLCs included in each shipment, distributors will need to determine the precise TLC associated with each case on the pallet, track the particular case and its TLC through the distribution facility, and then track which cases, and thus which TLCs, are pulled from each pallet or pick slot and included in an order. In short, the only way for distributors to comply with the rule's current requirements is to engage in case-level tracking. Additionally, determining which TLC is associated with each case on a mixed-lot pallet or pick slot requires readable, scannable labels with lot codes correctly embedded on each case, which suppliers are not required to provide under the rule.

As the Top-Line Summary suggests, this case-level tracking requirement will place immense—and costly—burdens on distributors, who will need to fundamentally reconfigure their warehouses, processes, and/or warehouse management systems in order to comply with the rule, particularly given that cases are not required to be labeled with the TLC. In doing so, distributors will need to identify and implement new technological solutions—solutions that are expensive to implement, are neither comprehensive nor segmented by industry, take time to assess, and may not be widely adopted or available until well after the rule's current compliance deadline. Implementing such changes is a resource-intensive, multi-year endeavor and will result in increased costs being passed on to the end consumer. It will be tremendously challenging to achieve these changes by January 20, 2026, and doing so will be cost-prohibitive for many distributors. The impacts of these burdensome requirements will be

[2] Top-Line Summary at 3-4 (emphasis added).

[3] Top-Line Summary at 4.

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disproportionately felt by small- and mid-sized distributors, many of whom do not have the resources to immediately restructure their core operations.

In fact, based on ongoing discussions with members, IFDA estimates that one-time program implementation costs—including everything from data management, software development, and hardware procurement to supplier and customer readiness activities and warehouse management system upgrades or replacements—could total up to approximately 10 million dollars for a mid- to large-sized foodservice distributor. In addition to these upfront costs, we estimate foodservice distributors would have annual costs associated with gathering, tracking, and sending KDEs, that would amount to a range of approximately 34 cents to 1 dollar for every case that is subject to the rule, potentially adding up to hundreds of millions to billions of dollars in annual, ongoing costs for foodservice distributors.

As also reflected in the Top-Line Summary, stakeholders have already identified practical solutions that would resolve this issue without requiring fundamental changes to the rule's structure. These include proposals that would give certain entities in the supply chain, including foodservice distributors, the flexibility to pass forward a reasonable range of possible TLCs associated with shipments in circumstances where passing forward shipping KDEs for each individual TLC would not be possible without engaging in case-level tracking. IFDA is confident that such flexibilities would significantly reduce the burdens outlined above while still providing FDA with quick access to the information needed to carry out efficient traceback investigations. IFDA urges FDA to consider adopting these added flexibilities well in advance of the rule's compliance date.

II. The rule's current implementation schedule fails to account for downstream entities' reliance on upstream entities.

IFDA remains concerned that the rule's current compliance timeframe will not afford industry sufficient time to develop and implement traceability programs and align with the upstream supply chain partners on whom entities will rely to ensure full compliance with the rule. IFDA's perspective is consistent with the stakeholder views reflected in the Top-Line Summary, which notes that "many [roundtable participants] suggested a staggered implementation schedule might offer greater efficiency and compliance" due, in part, to the fact that "each sector of the supply chain (the purchaser) [will rely] on information provided by the prior sector participant (the supplier)" to pass forward information required under the rule.[4] IFDA urges FDA to consider certain modifications to the rule's compliance timeframe, including the adoption of a staggered implementation schedule that extends the compliance date for each subsequent downstream sector in the supply chain.

The need for a staggered implementation schedule becomes apparent when considering the degree to which entities throughout the supply chain, including foodservice distributors, must rely on their upstream supply chain partners to pass forward the information necessary to ensure compliance with the rule. Consider, for example, a single foodservice distributor who receives thousands of products from hundreds of different suppliers on any given day. When developing a traceability program, the distributor must work with each individual supplier to determine (a) how the supplier will identify whether the foods it supplies are subject to the traceability rule, (b) how the supplier plans to provide KDE records for each covered food, and (c) how those records can be incorporated into the distributor's own recordkeeping system. For instance, when receiving salsa from a supplier, the distributor will need to work with the manufacturer first to determine whether the salsa is covered by the rule (e.g., whether it

[4] Top-Line Summary at 6.

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contains fresh tomatoes, fresh herbs, fresh-cut vegetables, and/or other FTL ingredients and, if so, whether the product has undergone processing that would exempt it from the rule). If the product is subject to the rule, the distributor will then need to work with the supplier to identify how the supplier will provide KDE records for the product. Only after receiving this information will the distributor be able to assess whether and how the supplier's records can be incorporated into the distributor's own recordkeeping systems and whether the distributor needs to modify its recordkeeping systems to accommodate the supplier.

Put simply, distributors will not be able to finalize their own traceability programs unless and until they have full visibility into how their suppliers will comply with the rule. Even then, distributors will need time to adapt their traceability programs to align with their suppliers' practices. This same pattern will be replicated at all stages of the supply chain (e.g., manufacturers will rely upon their ingredient suppliers to provide required records, and retailers and restaurants will rely upon the distributors from whom they source products to provide such records). While foodservice distributors continue to take significant steps to coordinate with their suppliers ahead of the rule's compliance date, the practical reality is that it will be virtually impossible to achieve full, industry-wide alignment by January 20, 2026. This is particularly true given that some upstream entities likely will not finalize their traceability programs until just before the compliance date, leaving downstream entities with virtually no time to adapt and finalize their own programs.

FDA can resolve this issue by implementing a staggered, sector-by-sector implementation schedule, starting with entities at the beginning of the supply chain. This could involve, for example, retaining the January 20, 2026, compliance date for growers and harvesters, but then providing for a series of extended compliance dates for manufacturers, then distributors, and then retail food establishments. This will give downstream entities the opportunity to align with their supply chain partners and proactively ensure they have access to the information they need to comply with the rule.

This staggered approach would not be without precedent. For example, under the Drug Supply Chain Security Act ("DSCSA"), which established new traceability requirements for prescription drugs, FDA has, over the course of the DSCSA's 10-year compliance window, implemented a staggered, sector-by-sector implementation schedule, starting with manufacturers and followed by repackagers, distributors, and then dispensers.[5] This model reflects the practical challenges associated with imposing multifaceted, interdependent requirements across an entire supply chain and could serve as a helpful precedent as FDA considers how it might restructure the food traceability rule's implementation schedule.

III. FDA should work with stakeholders to conduct pilot programs to assess potential implementation challenges.

The Top-Line Summary acknowledges that industry stakeholders have encouraged FDA to work with industry to conduct pilot programs to assess implementation of the rule across various sectors and segments of the food supply chain.[6] IFDA firmly agrees that FDA, state and local regulators, and industry would all benefit from the completion of well-designed pilot programs. These programs would help all stakeholders assess the real-world application of the rule, identify challenges, and implement solutions to facilitate compliance. The completion of pilot programs should be viewed as an essential prerequisite for effective implementation of the

[5] *See* Federal Food, Drug, and Cosmetic Act § 582 (21 U.S.C. § 360eee–1).

[6] Top-Line Summary at 5.

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rule, since the results of such programs will provide valuable learnings for all stakeholders. We thus urge FDA to partner with industry to conduct pilot programs and to delay implementation of the rule pending completion of those pilots.

IV. FDA should increase its efforts to enhance awareness of the rule among key stakeholders.

IFDA shares in the concerns reflected in the Top-Line Summary regarding low levels of awareness and understanding of the rule among key stakeholders.[7] IFDA is especially concerned about low levels of awareness among the state and local regulators who, in many cases, will be tasked with enforcing the rule. IFDA is also concerned about the lack of awareness or preparation among certain upstream and downstream partners, which will significantly affect foodservice distributors' ability to comply, and among small- and medium-sized businesses that may not have the resources to develop complex compliance programs. Stakeholders have consistently raised these concerns since issuance of the final rule, and similar concerns were noted in a January 2024 report issued by the Government Accountability Office.[8]

To address these concerns, IFDA urges FDA to take a broad-based, sustained approach to engaging with stakeholders, particularly those who may not be receiving FDA's current communications. As part of these efforts, we encourage FDA to issue its anticipated draft guidance on the rule. It is essential that these materials be published well in advance of the rule's compliance date so that stakeholders can rely on them while developing their traceability programs.

* * *

IFDA appreciates the opportunity to provide these comments and would be pleased to provide the Foundation and FDA with any additional information that might be helpful as the agency works toward implementation of the rule.

Respectfully submitted,

Mala Parker

Mala Parker
Vice President, Policy & Government Affairs

[7] Top-Line Summary at 3.

[8] *See* GAO, Food Safety: FDA Should Finalize Plans to Implement Its Rule to Help Trace Source of Outbreaks, GAO-24-106563, at 35 (noting that "[s]takeholders representing nonfederal regulatory partners stressed that FDA needs to improve coordination with, and guidance to, nonfederal regulatory partners to ensure consistent enforcement of the food traceability rule across jurisdictions.").

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October 24, 2024

Submitted by Ed Treacy
etreacy@freshproduce.com

International Fresh Produce Association (IFPA) is a 501(c)(6) non-profit trade association representing the entire fresh produce supply chain. With over 3,000 member companies in 54 countries, IFPA represents seed and fertilizer companies, grower/shippers, processors, distributors of specialty crops, food service, retail and quick serve restaurants. We estimate that greater than 90% of fresh produce and floral sold in the US in grocery stores or in food service establishments has been "touched" by at least two IFPA member companies. The mission of IFPA and its members is to grow a healthier world, and this project will contribute to this goal.

The following are IFPA's comments on FDA's Final Rule on Requirements for Additional Traceability Records for Certain Foods submitted to the Reagan-Udall Foundation.

1. We strongly urge the FDA to approve the IFPA proposal submitted to FDA on behalf of the fresh produce industry, to allow Distribution Centers that service Restaurants and Retail Stores to use their Warehouse Management System to calculate the Traceability Lot Code for shipments to Restaurants and Retail Stores. This proposal will save more than 8 million labor hours and $250 million a year and facilitate timely implementation of the changes required in distribution centers for FSMA 204 compliance. In addition, many distribution centers will have to be expanded to accommodate the decrease in order picking productivity that capturing Traceability Lot Code at time of order assembly would result in. In absence of approval of this proposal, many companies are stalled in their efforts in implementing the necessary changes for FSMA 204 compliance. Other companies will be purchasing capital equipment and planning on facility expansions that will be unnecessary if the approval was approved. Any opposition or objection to this proposal are not based on the technical or operational merits of the proposal. These objections have been made without the full understanding of the proposal.
2. We believe the FDA should consider extending the deadline for FSMA 204 compliance reduced to the Produce Terminal Market Operators. Additionally, the FDA should reduce the Key Data Elements the Produce Terminal Market Operators are required to capture store and share as many, many Terminal Market Operators have no receiving, inventory or shipping systems. The manual tracking, storing and sharing of the required KDE's would reduce the speed of their business, increase their labor cost and make some operations unviable.

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3. IFPA urges FDA to suspend the Traceability Lot Code Source/ Traceability Lot Code Source Reference requirement until pilots are conducted to validate if the inclusion of TLC Source will reduce traceback time and narrow the impact of recalls. We believe that the value of the FDA investigators of having the TLC Source information is far less than the cost to the industry of capturing, storing and sharing this KDE.
4. IFPA suggest the FDA partner with the U.S. Customs & Border Protection to inform the importer of every Food Traceability List item to make them aware of FSMA 204 and the required Key Data Elements that they will have to provide effective January 20, 2026. This effort should start as soon as possible as the awareness of FSMA 204 Final Rule is very low among foreign exporters.
5. We suggest that FDA increase their efforts to increase awareness of the small businesses who will have to comply with the Final Rule. Awareness is very low among small businesses. Most small businesses do not engage with any trade associations and are not aware of FSMA 204 and or their compliance requirements.
6. We request FDA publish guidance on how what steps to the receiver should take when the Traceability Lot Code is provided, and the Traceability Lot Code Source/TLS Source Reference is not provided by the shipper. FDA have previously advised *"the receiver should ask the source to provide the complete information required of the shipper under §?1.1340(b)"* which is impractical. Many receipts are performed during outside of normal business hours on the second and third shift and on weekends and holidays. As well, contacting the shipper at the time of the receipt is impractical and will impede the receiving process greatly. We suggest when the Traceability Lot Code is provided, and the Traceability Lot Code Source/TLS Source Reference is not provided by the shipper, the shippers contact information be used as the Traceability Lot Code Source.
7. We request FDA to publish guidance for Terminal Market Operators to clarify how they should record shipments to non-consumer cash and carry customers who do not provide their contact information.
8. We request FDA to provide guidance when a case of FTL product is being received and the case has a label has a Traceability Lot Code, but the commodity or variety are incorrect.

Submitted by Ed Treacy
etreacy@freshproduce.com

National Confectioners Association
ALWAYS A TREAT

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October 25, 2024

Submitted via email to FinalRule@reaganudall.org

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

RE: FDA's Final Rule on Requirements for Additional Traceability Records for Certain Foods

To Whom It May Concern:

The National Confectioners Association ("NCA") appreciates the opportunity to provide comments regarding the U.S. Food and Drug Administration's ("FDA" or "the Agency") Final Rule on Requirements for Additional Traceability Records for Certain Foods ("Final Rule"). We appreciate the Regan-Udall Foundation hosting the industry roundtable series on the Final Rule, as well as the virtual public meeting to hear additional insights regarding questions and challenges with the implementation of the Final Rule.

NCA is the leading trade organization for the $48 billion U.S. confectionery industry. NCA advocates for an environment that enables candy makers to thrive and works to ensure that chocolate, candy, gum and mints are celebrated for their contributions to culture, society, the economy and everyday moments of joy. The industry employs nearly 58,000 workers in more than 1,600 manufacturing facilities across all 50 states and supports an additional 635,000 jobs in related fields. The U.S. confectionery industry has made a commitment to making safe food, increasing transparency, providing more portion guidance options and educating consumers about the role of confectionery in a happy, balanced lifestyle.

NCA shares FDA's goals in implementing Section 204 of the FDA Food Safety Modernization Act. We recognize the potential public health benefits associated with efficient traceback investigations during recalls and foodborne illness outbreaks that, when executed quickly, facilitate the efficient removal of the affected food from the market. Although the Final Rule represents a crucial step toward enhancing the safety and transparency of the food supply chain, several challenges must be addressed to ensure its successful and equitable implementation across the diverse landscape of the food industry.

The overarching challenge our members are facing is the complexity of the Final Rule driven by the collaboration it requires across supply chain entities. Although industry is actively taking steps to navigate this complexity, such as educating supply chain partners, evaluating new traceability technologies, and improving internal data management systems to meet the compliance deadline,

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more time is needed before compliance can be achieved in a manner that benefits public health. The challenges explained below highlight the need for more time to implement the Final Rule.

Challenges of Implementing Traceability in a Complex and Diverse Food Supply Chain
One of the fundamental challenges in implementing the Final Rule is the inherent complexity of the food supply chain. The food industry is diverse, encompassing various sectors from small producers to large multi-national manufacturers. Each of these entities have different capabilities for adopting new traceability requirements. The different capabilities mean that the challenges facing small and medium-sized companies can be very different than those facing large, multinational companies. For example, small companies might still rely on manual or paper-based systems, which can be difficult to integrate into the more sophisticated digital platforms that the rule envisions. In contrast, larger companies might have sophisticated platforms in place but could still need to make significant investments in new technologies to upgrade those systems throughout the supply chain (national and international) to meet the Final Rule's requirements.

Further, the Final Rule requires collaboration across the entire supply chain. Individual companies cannot comply in isolation, as traceability requires tracking data from farms to retailers. Our members are working with their upstream and downstream partners to share information related to the high-risk foods identified by the Agency. However, some supply chain partners are requesting traceability data for more products than those included on the Food Traceability List (FTL). The expansion of traceability requirements to non-FTL products creates a significant burden for businesses now tasked with collecting and sharing data often in different formats, depending on the partner's specific requirements for both FTL and non-FTL products. The expanded request for traceability obligations for non-FTL products could affect some businesses disproportionately.

Challenges Related to Data Interoperability and Data Standardization
Another critical challenge in implementing the Final Rule is the need for data interoperability and data standardization. Because the Final Rule requires data to be transferred throughout the supply chain, it is critical that the various data systems are compatible and can receive and maintain this data. Industry is currently working with supply chain partners and technology vendors to standardize tracking practices and create interoperable systems to facilitate data transfers. However, there are still vast differences in recordkeeping systems throughout the supply chain. Ensuring that these systems can communicate with each other is vital for an effective traceability network. For example, a confectionery manufacturer making products containing nut butters must ensure that traceability systems can communicate among their suppliers of nuts and nut butters, the manufacturers of the finished product, the subsequent storage and transportation facilities, distributors, and retailers. Each of these entities will need to be able to store traceability information in the same format, necessitating data standardization and interoperability.

Many stakeholders struggle to share or exchange data in a standardized format because of existing practices. This lack of standardization not only complicates compliance efforts but also increases operational costs, as businesses must adapt systems to meet varying data demands. This can lead to breakdowns in traceability, which can increase the time needed to trace the source of an outbreak, delaying the identification and containment of contaminated products.

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We urge FDA to work closely with the food industry to take additional steps to help facilitate industry adoption of traceability capabilities to meet the Final Rule's requirements. This could involve encouraging the use of standards that allow for the integration of various systems, such as warehouse management systems, enterprise resource planning software, and/or point-of-sale platforms. Additionally, FDA should facilitate and/or participate in discussions or workshops with technology vendors and the food industry to help the development of interoperable and standardized data formats that facilitate data exchange/communication among systems.

Further, we encourage FDA to issue clear guidance on the protection of proprietary business information and personal data as traceability systems increasingly require sharing of detailed supply chain information across partners.

Pilot Testing

To determine whether more efficient and effective traceback is possible, FDA should continue to engage with industry on pilot programs that test collaborative traceback capabilities among stakeholders across different segments of the supply chain. By involving manufacturers, processors, and retailers in these pilot projects, it will be possible for all stakeholders to evaluate the effectiveness of various traceability solutions and identify potential roadblocks and gaps in implementation that should be addressed before significant investments in technology, recordkeeping, and training are made. These pilots would also serve to explore alternative solutions that could reduce the burden on the food industry while protecting public health.

* * *

Given the complexity of the Final Rule, the need to collaborate across the supply chain, the time needed to identify and evaluate new recordkeeping platforms or upgrade existing systems, and the need to ensure those systems are interoperable, more time is needed for the industry to comply with the Final Rule. While the industry has made progress toward compliance, additional time is required to develop and adopt data standards that ensure consistency and compatibility across different platforms and supply chain partners. By fostering greater collaboration among stakeholders and offering more time for compliance, FDA can make the Final Rule more feasible for the food industry and more protective of public health. We encourage FDA and the Reagan-Udall Foundation to continue engaging with various stakeholders across the food supply chain, technology providers, and broader public, to refine the traceability framework for a safer and more transparent food system.

NCA appreciates the opportunity to submit these comments. Please do not hesitate to contact NCA at farida.mohamedshah@CandyUSA.com or 202-534-1492 with any questions you may have regarding these comments.

Sincerely,

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Farida Mohamedshah, MS, CNS
Senior Vice President, Scientific & Regulatory Affairs
National Confectioners Association

NATIONAL FISHERIES INSTITUTE

October 25, 2024

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

Submitted via email to finalrule@reaganudall.org

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

Dear Sir or Madam:

The National Fisheries Institute ("NFI") is pleased to have the opportunity to submit written comments for the record in response to the Reagan-Udall Foundation's virtual public meeting addressing FDA's Food Traceability Rule.

NFI is the leading trade association for the seafood community in the United States. NFI, a nonprofit, and its members support and promote sound public policy based on ground truth science. Because the majority of seafood products are on FDA's Food Traceability List, NFI's members have a vested interest in a successful implementation of FDA's new rule – Requirements for Additional Traceability Records for Certain Foods.

NFI is grateful that the Reagan-Udall Foundation has provided this opportunity for stakeholders to address concerns and challenges with implementing the requirements of this new regulation. In addition to the statement that we provided during the public meeting (included as Attachment A), we would like to add these additional comments regarding Implementation.Schedule.™ .Awareness¡

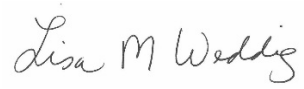
NFI is aware that FDA is preparing draft guidance to outline the agency's interpretation of some aspects of the rule and supply chain scenarios that are not clearly elaborated in the rule. For example, the determination of when a raw agriculture commodity ("RAC") would no longer be considered a RAC is key to understanding the exemption for commingled RACs. This "gray area" is directly applicable to those firms at the beginning of the seafood supply chain who need to determine how they will comply with the regulation. While the Food Traceability Rule Resources already developed by the agency are very useful, there

are still many questions the must be addressed to provide industry with a clear path forward for implementation. And this clear path forward would be facilitated with additional time for implementation once the draft guidance is available.

NFI acknowledges that FDA has already indicated that the first year of compliance will be a time to "educate before and while we regulate." This is the right approach for a rule this complex. But there is now industry customer pressure to ensure complete compliance even prior to January 2026. This is leading firms to look for ready solutions to facilitate transfer of the required KDEs that may not be sustainable for the long term. Interoperability necessary to support the transfer of the required KDEs to multiple supply chain partners using multiple technology platforms will take collaboration and will not be achieved by January 2026.

Thank you for considering these comments.

Sincerely,



Lisa M. Weddig
Chief Food Safety Officer
National Fisheries Institute

Attachment A

FDA's Final Rule on Requirements for
Additional Traceability Records for Certain Foods
Virtual Public Meeting
October 7, 2024

NFI's Public Comments

Good afternoon. I am Lisa Weddig, Chief Food Safety Officer with the National Fisheries Institute. National Fisheries Institute is the leading trade association for the seafood community in the United States. NFI, a nonprofit, and its members support and promote sound public policy based on ground truth science.

This might be an understatement, but the Food Traceability Rule is complex. While it may not seem like it with a simple read, once one tries to figure out how to comply, the challenges are revealed. The expectations are simple: have a traceability plan, maintain records of KDEs at specific CTEs, pass forward certain KDEs when shipping products, use traceability lot codes to link CTEs, and provide FDA with certain records - including an electronic sortable spreadsheet - when requested.

We often say that implementing this rule is more challenging than implementing the landmark "Seafood HACCP" regulation in the mid 1990s. The seafood industry had two advantages with the implementation of that rule that are not relevant to the Food Traceability Rule.

First, there was a concerted effort on the part of FDA, state agencies, university and SeaGrant extension programs, and industry trade groups -- through the Seafood HACCP Alliance -- to develop and provide the widespread training and resources necessary to educate the industry and to ensure that no one was left behind. These efforts started even before the rule was finalized. While a standardized Food Traceability Rule curriculum is in development through the Food Safety Preventive Controls Alliance, those materials are not expected to be completed until early 2025 – leaving less than one year before the January, 2026, implementation date.

Second, Seafood HACCP could be internalized within a company. There was little need for companies to collaborate with suppliers and customers. The Food Traceability Rule is different. Companies cannot move forward without knowing how their suppliers will pass forward KDEs, including the illusive Traceability Lot Code and Lot Code Source as internal IT systems were not originally designed to do this, or how their customers expect to receive the applicable KDEs. It is an endless chain of challenges as each company is now making

internal decisions and expending resources (both time and money) that may not later be accepted by the next step in the supply chain.

NFI has spent the last year and 10 months providing the awareness, understanding, and resources necessary to help our members implement the rule requirements. This includes addressing the misconceptions associated with the requirements of the rule. But there is still much more to accomplish.

First, NFI has about 200 members who are impacted by this rule. There are 20 times that number of seafood companies in the US alone -- and this does not account for the size of the global food industry covered by this rule. Awareness and understanding can only go so far with "a friend telling two friends and so on and so on."

Second, there are still many questions about the rule that will – hopefully - be clarified through guidance. Without FDA's guidance, some companies are currently at a standstill. Answers to questions on the scope of exemptions, for example, will allow companies to fully start implementing the rule requirements.

All this to say, a three-year implementation period, while at first might have seemed generous, simply does not allow sufficient time for awareness, outreach, understanding and then finally executing the rule's requirements in an effective manner. There is still much work to be accomplished that cannot be achieved by January 2026.

Thank you for this opportunity to provide public comments.

October 25, 2024

The Reagan-Udall Foundation
1333 New Hampshire Ave NW
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finalrule@reaganudall.org

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:

Thank you for the opportunity to provide comments on The Reagan-Udall Foundation's Virtual Public Meeting on the Food and Drug Administration's (FDA) Final Rule on Requirements for Additional Traceability Records for Certain Foods (traceability rule).

Founded in 1919, the National Restaurant Association is the leading business association for the restaurant industry, which is comprised of nearly 1 million restaurant and foodservice outlets and a workforce of 15 million employees. Together with 52 state associations, the National Restaurant Association creates a network of professional organizations dedicated to serving every restaurant through advocacy, education, and food safety.

Food safety is the restaurant industry's top priority, and we are committed to increasing traceability throughout the supply chain. Since the FDA's final traceability rule was published in 2022, the National Restaurant Association has worked diligently to educate our members on the rule's requirements, timelines, exemptions, and compliance strategies. However, a number of challenges remain for many of our members who are working to comply with the rule.

Due to the complexity and breadth of the FDA's traceability rule, the Association believes that adequate flexibility, increased compliance time and the ability to conduct pilot projects will ensure that the restaurant industry can best comply with the requirements of the rule.

Pilot Projects

In order to ensure that the food supply chain can properly coordinate and successfully implement all elements of the FDA's traceability rule, pilot projects should be conducted across the supply chain. These pilot projects will help determine how each link in the supply chain can coordinate to ensure compliance. The complexity and level of information sharing and coordination by the rule is unprecedented, and these projects will help us identify and remedy any pitfalls or gaps in implementation before the supply chain makes significant investments in new systems, technology, and training.

We support the establishment of at least three pilot projects in coordination with restaurants, retail food establishments, and distribution centers to determine gaps in process and implementation. Results of the pilots could help the Agency and the food supply chain create solutions to ensure that the rule is as effective as possible in order to protect our food supply.

Increased Compliance Timeline

Given the complexity of the Traceability Rule, more time is needed to ensure compliance with the rule. For example, if pilots are conducted, appropriate time is needed to implement any learnings and solutions that are identified. Additionally, the food supply chain is still working to evaluate new technologies and recordkeeping systems and ensure that different entities' systems are capable of working together to comply with the rule in a timely manner.

Restaurants are the last stop in the supply chain before food products reach consumers. Our members and suppliers are currently making the appropriate investments necessary for compliance with the rule but it's imperative that the entire supply chain communicates in order for all supply chain entities, especially those downstream like restaurants, can comply.

Additional time will allow that communication to occur and ensure that we can adequately implement the rule and protect public health.

Increased Flexibility

Finally, the FDA's traceability rule requires tracking the specific lot codes associated with a particular product on the food traceability list. In many situations, a restaurant receives a pallet with several food items organized by cases that could come from a variety of different lot codes. However, since the rule was finalized, food distribution centers have reported that they are struggling to trace individual lot codes without implementing case-level tracking.

Therefore, allowing a range of traceability lot codes would reduce the complexity of the rule without impeding the Agency's ability to conduct an effective and efficient traceability inquiry.

We appreciate the opportunity to provide comments on this important issue and thank the Reagan-Udall Foundation for their engagement in this effort.

Sincerely,

Laura Abshire

Laura Abshire
Director of Food and Sustainability Policy
National Restaurant Association

October 25, 2024

Jim Jones
Deputy Commissioner for Human Food
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

RE: Food Safety Modernization Act (FSMA) Section 204 Implementation Challenges for Retailers and Distributors

Dear Reagan Udall Foundation for the FDA,

On behalf of the National Grocers Association (NGA), thank you for the opportunity to provide oral and written comments to inform FDA's implementation of the Final Rule on "Requirements for Additional Traceability Records for Certain Foods."

NGA is the national trade association representing retail and wholesale grocers that comprise the independent sector of the food retail and distribution industry. An independent retailer is a privately owned or controlled food retail company operating in a variety of formats. Independents are the true "entrepreneurs" of the grocery industry and dedicated to their customers, associates, and communities. Much of NGA's membership is comprised of family-owned and family-operated small businesses. Nearly half of NGA's members are single-store operators, and another quarter operate less than five stores. Independent retail and wholesale grocers are an important part of America's economy. Independent community grocers account for 33 percent of all grocery sales, exceeding $250 billion, and more than 1 million American jobs. We are inherently tied to the strength and vitality of the markets we serve – at the heart of local communities and the U.S. economy. Having often been in the business for generations, independent grocers are dedicated to their customers, associates, and communities.

We write to update you on the challenges our industry is facing while working to implement FSMA Section 204 ("the Final Rule"). A summary of these key issues is provided below.

Traceability Lot Code (TLC) Management

A significant challenge with the Final Rule is effectively managing lot code information. This new piece of data that does not have an industry standard is not integrated into software used to manage distribution centers, warehouses, or retailer stores.

Integration involves unique difficulties in managing large data sets, compounded by technical obstacles in receiving lot code details from suppliers, tracking them within warehouse management systems, and dealing with technological constraints in storing and processing these codes at the retail level. For retailers, receiving and managing products from manufacturers and distributors adds complexity, and for all parties—manufacturers, distributors, and retailers—effectively managing lot codes throughout the supply chain remains a significant hurdle.

When warehousing, shipping, or receiving products, NGA members rely on suppliers to provide Key Data Elements and TLC. The FDA food regulations do not limit the ways that this information can be obtained in order to track and trace products effectively. While this flexibility is beneficial in some situations, it results in a wide variance of how suppliers share information. Lot codes can be supplied and managed digitally, using new artificial technology tools, or managed manually. Most suppliers utilize a variety of methods to share lot codes and Key Data Elements with customers. Examples of ways suppliers share this information include a Bill of Lading, product invoice, or through an electronic data interchange (EDI), email, or scannable barcode.

While a supplier may use a specific electronic system for lot codes, it doesn't guarantee compatibility with systems used for warehouse management or retail inventory management. Managing supplier paperwork and updates across various systems updates can be a full-time job, largely due to lack of standardization. This lack of standardization complicates processes such as internal document updates (e.g., Bill of Lading). Often it is difficult to keep documents updated, or distributors and retailers have to rely on suppliers to enter product documents independently for each customer.

Emerging artificial intelligence technology has the potential to read electronic versions of paper documents (scanned or uploaded into a system) and fill in the lot coding information, but it is still in the early stages, unreliable, and expensive. At this time, it is not a widespread compliance solution.

- For distributors, most Warehouse Manage Systems (WMS) do not have do not have fields for storing lot codes or they generate new lot codes rather than using supplier-provided ones. This issue is compounded by lack of standardization requiring distributors to navigate multiple Electronic Data Interchange (EDI) systems, often managing six or seven different platforms from suppliers.

- For small retailers, the burden is even bigger. Many lack digital tools to accept and integrate lot codes into their systems, relying heavily on suppliers for information transfer. Even when retailers invest in electronic recordkeeping systems, the cost and effort to upgrade and integrate them with supplier systems are significant. For those involved in product transformation, advanced lot coding equipment and formula management systems require substantial investments in both time and resources.

In addition to managing lot codes digitally, they can be received in a paper format and manually typed into the warehouse management system or retail inventory control system. This process comes with a high potential for human errors and incurs significant expenses, compounded by the challenges of sourcing human resources in a tight labor market.

In *Appendix A* we outline the challenges our members face in managing lot codes across their supply chain, each requires resources and time to resolve. Retailers have the capability to trace food back to its source without a traceability lot code. The requirement to include this additional data is making compliance with the rule overly burdensome without contributing to improved food safety. We ask that FDA grant flexibility on the traceability lot code and focus on reaching foods impacted by foodborne pathogen outbreaks.

Supplier Coordination and Education

The implementation of this rule is wholly dependent on the ability of suppliers to provide the required information to their customers. FDA has underestimated the complexity of supplier education needed to understand the nuance required in this rule. This complex rule impacts hundreds of thousands of retailers and even more suppliers and manufacturers. When creating a completely new system and operating procedures from the ground up it takes time and coordination. Many suppliers and retailers, especially those that are not members of trade associations, are not aware of this rule and are not participating in the preparation processes. This is making it difficult for retailers to know if they are going to be able to continue working with certain suppliers and/or if they are exempted from the rule.

We ask that the FDA begin communicating about this rule to the food industry and throughout all of its channels and touches with different food-related companies to raise awareness of the forthcoming deadline and compliance requirements. NGA believes that FDA should reconsider a phased-in implementation, starting with primary producers so that subsequent distributors (regardless of the number of levels of distribution), of products subject to the Food Traceability List (FTL), can learn and adapt to what kinds of data they will be receiving, and how that data can be organized and stored.

Outstanding Technical Questions

While the FDA has diligently answered numerous questions, special circumstances continually arise where NGA members are unsure about whether or not an item needs to be tracked or special circumstances where it is unclear if the rule should be applied. This ambiguity is creating confusion. For example, often, retail establishments need smaller amounts of certain items, so they may ship cases, racks, or totes that have two or more different products inside a single shipping unit. Some foods have "kill steps" but distributors and retailers have no way of knowing that, and some foods have ingredients on the FTL, but the only way of knowing is by opening the case. This essentially results in requiring case-level and sometimes item-level tracking for these products, which is not feasible for retailers.

Determination is so complicated that some distributors and retailers are asking suppliers to label whether their foods require tracking under the rule, which adds time and complexity to the process but is necessary for compliance. We ask that the FDA provide more guidance around what to do in cases when retailers and distributors are unsure if traceable foods are included in the case.

Limited Information on Enforcement Mechanism

As we near the compliance date, NGA is uncertain about the enforcement mechanisms FDA intends to use to enforce this rule. Understanding how traceable events will be enforced with help with the design of solutions and determining how best to implement the rule. We ask the FDA to provide guidance as to how recalls will look so our members and the industry can comply accordingly.

Timeline is Unachievable

The U.S. food system supplies food for the over 333 million Americans every day. To feed everyone, our industry relies on a complex yet efficient chain of stakeholders who must work together to master logistics and safety throughout the supply chain. The FDA traceability requires a dramatic change in every step of this system, and we ask for additional time and flexibility to get the job done right.

Distributors work both with suppliers and retailers meeting demands from both directions. Many distributors are receiving demands from technology companies on behalf of suppliers and manufacturers that require different technical configurations, lot code styles, and processes for sharing data. Due to the lack of standardization, the complexity of this rule is expanding exponentially for those that aggregate and distribute food throughout the country. Finally, they are having to rework all of their legal agreements with every supplier, customer, and technology provider to ensure compliance that works within their systems. Additionally, we have many distributor members that have multiple FSMA regulations to comply with that also require integration into the data sharing and recordkeeping system. This cannot be done in a three-year timeframe, and we urge you to provide more time.

While we acknowledge the benefits of traceability, it's vital for the retail sector to be given more time to adapt to these changes. We ask the FDA to address our concerns and consider the limitations we are attempting to work through outlined in Appendix A. We also urge the FDA to conduct industry pilots before full-scale implementation and reconsider the potential for a phased approach to address limitations with supplier communication. As a result of these challenges, NGA requests FDA extend the compliance deadline to January 1, 2032, to allow retail establishments adequate time to adapt to these regulations ensuring effective implementation and enhanced food safety without compromising operational efficiency or incurring excessive costs.

Conclusion

NGA is appreciative of FDA's effort to address this important issue and together with our members, we share the same goals of ensuring the integrity and safety of our food supply chain. NGA looks forward to continuing to work collaboratively with the FDA to build on the many successful systems and practices already employed throughout the food distribution system that will allow us to achieve our shared public health goals.

October 24, 2024

The Reagan-Udall Foundation
1333 New Hampshire Ave NW
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Washington, DC 20036
finalrule@reaganudall.org

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

Dear Sir or Madam:

The National Retail Federation appreciates the opportunity to provide comments on The Reagan-Udall Foundation's (RUF) Virtual Public Meeting on the Food and Drug Administration's (FDA) Final Rule on Requirements for Additional Traceability Records for Certain Foods (the Traceability Rule).

By way of background, the National Retail Federation (NRF) passionately advocates for the people, brands, policies and ideas that help retail succeed. From its headquarters in Washington, D.C., NRF empowers the industry that powers the economy. Retail is the nation's largest private-sector employer, contributing $5.3 trillion to annual GDP and supporting more than one in four U.S. jobs — 55 million working Americans. For over a century, NRF has been a voice for every retailer and every retail job, educating, inspiring and communicating the powerful impact retail has on local communities and global economies. nrf.com

We represent numerous food retailers, including chain restaurants, grocery stores, and convenience stores, that will be directly impacted by the Traceability Rule's requirements. We were involved early in the rule's life cycle, organizing a representative working group of our members to review the rule when originally proposed and submit comments for the record with our suggestions for improvements. We noted that the U.S. food supply chain is enormously complex, and we proposed that the traceability rule should take into consideration this significant diversity and publish a final rule which prioritized flexibility. Unfortunately, our suggestions did not seem to be reflected in the final rule. Since the final rule was published in November 2022, we have been working diligently to educate our members about the rule and its requirements for food retailers. Food retailers have spent significant resources on preparation for compliance, but we are concerned that some segments of the supply chain will not be ready by the compliance deadline in January 2026.

There is overwhelming complexity involved in implementing the Traceability Rule stemming in part from the number of products the rule implicates as well as the fact that each segment's compliance is dependent on the accuracy and compliance of each preceding segment in the chain. Further, compliance across the supply chain will rely heavily on new technologies which need to

be evaluated and tested, and the entire system must be interoperable. These challenges highlight the need for greater flexibility in the Traceability Rule, specifically related to the use of traceability lot codes, and more time to perform pilot projects and implement the rule's requirements.

The rule should permit the provision of a range of lot codes rather than a single lot code for products. Most of the products in retail stores must travel through a distribution center before reaching the store shelves and distribution centers are struggling to find feasible ways to trace single lot codes through their operations without implementing case-level tracking. Because distribution centers already have strong visibility into their product's path through the supply chain, allowing a range of traceability lot codes would ease the complexity without hindering FDA's ability to complete an efficient traceback investigation.

We strongly suggest that pilot projects must be completed to evaluate whether different segments in the supply chain can coordinate with each other to ensure compliance and whether the goals of the Traceability Rule – more efficient and effective traceback investigations - can be met. Pilot projects can explore what gaps in implementation need to be addressed to avoid chaos when the compliance deadline takes effect. Pilot projects also would enable the supply chain and the agency to explore alternative solutions that reduce burdens while protecting public health. For the learnings from these pilot programs to be effectively implemented, the compliance date should be two years after their completion.

We continue to be concerned that word of the Traceability Rule's existence still seems not to have made its way to all participants in the food supply chain – particularly those at the supply chain's front end, i.e., small growers and farmers. We worry that the inability of some players to comply with the Traceability Rule, for whatever reason – lack of awareness, technical hurdles, compliance costs – will lead to chaos when the rule takes effect. If one or more links in the supply chain are not in compliance, it will filter through the entire chain, leading to mistakes, errors and failures. The solution to this problem is more time. Given the complexity of the Traceability Rule, the need to continue educating the supply chain, the need to identify and evaluate new technologies and new recordkeeping systems, and the desire to ensure systems are interoperable, more time is needed to comply with the rule.

Thank you for this 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,

M. Scott Vinson
Vice President, Government Relations, Food & Energy Policy

October 25, 2024

Reagan-Udall Foundation for the Food and Drug Administration
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Washington, D.C. 20036

RE: Food Safety Modernization Act's Requirements for Additional Traceability Records for Certain Foods

Oceana, the largest international conservation organization solely focused on protecting the world's oceans, works to promote seafood traceability, keep illegally sourced products out of the supply chain, and ensure that our seafood is safe, legally caught, and honestly labeled.

We appreciate the opportunity to provide comments to the Reagan-Udall Foundation regarding the upcoming implementation of the Food and Drug Administration's (FDA) Final Rule on Requirements for Additional Traceability Records for Certain Foods. It is critical that the Rule go into effect in January 2026 to provide consumers and seafood buyers with more confidence in what they are eating. Oceana strongly opposes any efforts to delay and weaken the implementation of this Rule.

Key concerns with delaying the Food Traceability Rule include:

- Undermining public health and safety by impeding transparency and accountability in our food supply chains.
- Jeopardizing the integrity of the 2010 Food Safety Modernization Act.
- Potentially increasing the risk of foodborne illness outbreaks and their associated costs.

According to a recent Gallup poll, American consumers' confidence in the government's ability to protect the food supply has dropped to a record low of 57%[1]. This is unsurprising as each year about 48 million Americans, or one in six people, fall ill from foodborne illness, with 128,000 hospitalizations and 3,000 deaths.[2] A recent National Institute of Health (NIH) study estimated the 2023 costs of foodborne illness in the U.S. to be $75 billion.[3] Of that, foodborne illnesses linked specifically to seafood have annual costs of $360 million.[4]

Continuing to wait for fully traceable supply chains puts more consumers at risk. In October 2024 alone, there have been multiple accounts of mass foodborne illness: over 250 people ate food contaminated with *Shigella*; over 700 waffle products were recalled

due to possible *Listeria* contamination on October 18; and a multi-state outbreak involving *E. coli* and fast food hamburgers started on October 22 with 49 cases and 1 death thus far.[5-8] There is also an ongoing recall of over seven million pounds of meat contaminated with *Listeria* that started mid-July, which affects 19 states, includes 59 cases, and is the largest *Listeria* outbreak in the U.S. since 2011.[9-10]

Seafood is the most heavily traded food commodity in the world, with intricate supply chains that are often very opaque, making products difficult to trace in the event of an outbreak. Annually, around 260,000 people in the U.S. get sick from contaminated fish—the most common food category associated with foodborne illness outbreaks.[11] NOAA has estimated that more than 79% of the seafood consumed in the U.S. is imported.[12] Another factor further complicates the path to markets and the reliability of the products sold: a significant amount of illegal and unreported seafood is laundered into the supply chain, with as much as 31% of the global marine catch illegally caught or not reported.[13] Illegally caught seafood escapes basic management and traceability controls: illegal fish are unsafe fish.

Mislabeling

Quick recalls are also crucial in cases of mislabeling; on October 17 over 13,000 cases of Minute Maid zero sugar lemonade were recalled due to mislabeling as they were actually full sugar.[14] Seafood is also frequently subject to mislabeling and species substitution.[15] A global review of more than 200 seafood fraud investigations found seafood mislabeling on every continent except Antarctica, with 1 in 5 samples mislabeled. 58% of these seafood swaps included fish with species-specific health advisories, including parasites, environmental contaminations, and aquaculture drugs.[16] Specific hazards included risks of histamine or scombrotoxin poisoning found in certain tuna-related species; ciguatera, a natural toxin in some reef fish; tetrodotoxin found in certain pufferfish species; and gempylotoxin, a natural toxin found in escolar and oilfish.[17] These problematic fish were mislabled as safer alternatives. The Food Traceability Rule would significantly reduce the risk of illness dues to mislabeling by require traceability lot code (TLC) requirements for all finfish and many other types of seafood, some of which are also associated with those histamines and toxins, and would be crucial to ensuring seafood safety.

Pilot Studies

To support best practices for traceability, the FDA tasked the Institute of Food Technologists (IFT) starting in 2008 to undertake four pilot studies to understand the barriers in tracing a food item from the point of illness backwards to its source at a farm or production facility. IFT found that improved traceability would reduce outbreak response

time, protect up to 800 consumers during each outbreak from illnesses, and save consumers and hospitals $18,000-$14,000,000 per outbreak. Each day that an outbreak continues can cost at minimum $1,053 but can at times exceed $277,000.[18] The FMSA Final Rule on Requirements for Additional Traceability Records for Certain Foods was based on these extensive pilot studies.

Additional pilot studies would be duplicative, they are only meant to delay food traceability standards for years to come. In three of the four pilot studies, FDA found that standard TLC information was necessary to track an outbreak and perform quick recalls, and that keeping TLC data for two years was critical in that system. Furthermore, although electronic records may be more expensive initially than paper ones, this higher cost is crucial to protect public health and reduce foodborne illnesses. Additional studies are unnecessary and are an inefficient use of funds when the existing data shows the importance and necessity of TLCs.

Recommendations

The FDA noted as early as 2006 that food tracebacks in outbreaks were often unsuccessful due to a lack of uniform data and gaps in recordkeeping, including the fact that farms and restaurants were not required to keep records at that time.[19] Delaying or weakening these requirements would set food safety standards back almost 20 years. TLC requirements for restaurants, food retailers, and warehouses are critical to protecting the public from foodborne illnesses.

Removing the TLC requirement for any entity handling food such as restaurants and grocery stores would severely hamper efforts to trace foodborne illnesses, as over 60% of foodborne illnesses in the U.S. happen at restaurants.[20] Traceability requirements under the Rule will ensure consumers can be confident in their purchases, help stop seafood fraud, and keep illegally caught fish out of the U.S. market. Establishing traceability systems capable of documenting that all seafood that enters the U.S. market complies with legal, health, and safety requirements is critical to prevent future outbreaks of foodborne illness.

The food industry has been aware of these upcoming changes for nearly 15 years, giving industry members ample time to adjust their practices. Establishing a system to collect and maintain all data required under the Food Traceability Rule by the January 2026 compliance date is both feasible and necessary. To ensure food traceability and protect consumers from foodborne illness, Oceana recommends the FDA require all entities associated with high-risk foods--including restaurants, retailers, and warehouses--keep TLC information for two years and comply with this Rule by January 20, 2026.

Sincerely,

Dr. Marla Valentine
Director, Illegal Fishing and Transparency
Oceana

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October 25, 2024

Submitted via email to FinalRule@ReaganUdall.org

The Reagan-Udall Foundation
1333 New Hampshire Ave NW
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Washington, DC 20036
finalrule@reaganudall.org

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:

The Peanut and Tree Nut Processors Association (PTNPA) is an association of members whose mission is to proactively advance the nut industry through professional networks, advocacy, and education. PTNPA represents business owners, operators, management, and food safety professionals in the peanut and tree nut industry. PTNPA member companies, ranging from large global organizations to small, family-owned small businesses that shell, process, salt and/or roast peanuts and tree nuts. In addition, our member companies are also those who supply equipment and services that are critical to our industry. PTNPA has members in every state in the nation and many from around the world. Our member companies represent employers for millions of people and generate billions for our global economy.

PTNPA appreciates to opportunity to provide comments in response the Reagan-Udall Foundation's (RUF) 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 Traceability Rule). With nut butters included on FDA's Food Traceability List (FTL), PTNPA's members are part of one of the supply chains heavily impacted by the Traceability Rule. Because of this, our members have been actively engaged in efforts to implement the rule from its publication. Based on these efforts and the topics discussed in the Reagan-Udall Foundation's roundtable report and virtual public meeting, we want to take this opportunity to provide comments related to the rule's implementation schedule. Specifically, PTNPA urges FDA to postpone the Traceability Rule's compliance date. Additional time is needed in order for (1) industry to align on data standards for information being transferred among entities, (2) compliance solutions to be tested before companies invest in new systems and technology, and (3) entities not covered by the rule, but required to comply with its requirements by retailers, to be engaged in the implementation process.

1. **Industry needs more time to align on traceability data standards and to evaluate technology solutions to ensure information moves smoothly through the supply chain.**

At the heart of the Traceability Rule is the need to streamline traceback investigations to help identify and respond to foodborne illness outbreaks efficiently and effectively. For this goal to be met, industry needs to ensure not only that each entity is compliant with the basic requirements of the Traceability Rule, but also that information moves through the supply chain seamlessly. For this to happen, industry needs to adopt flexible data standards that provide structure and uniformity in the way information is communicated, while still allowing companies to tailor their records to their business needs. Industry also needs time to evaluate, purchase, and implement technology systems that can enhance the storage and sharing of traceability records. We are aware of industry efforts to align on data standards and PTNPA urges FDA to participate in these discussions to ensure that the work being completed will in fact result in a traceability landscape that facilitates the agency's public health goals. Because these efforts to standardize traceability data and ensure it is interoperable remain ongoing, FDA should delay the rule's compliance date to allow consensus to be reached on standards and the implementation of these standards to take effect. This compliance approach will help ensure that industry is not only compliant, but that this compliance meets the Traceability Rule's public health objectives in a meaningful way.

2. **Compliance strategies should be tested through pilot programs before industry makes investments in technology solutions.**

Because compliance with the Traceability Rule relies on entities successfully receiving traceability records from their suppliers and passing traceability records forward, it will be impossible to know whether implementation has been successful unless implementation is tested through pilot programs. Most PTNPA members have concluded that in order to comply with the Traceability Rule's requirements investments will need to be made to enhance and expand their recordkeeping systems. Because technology systems take time to implement, companies are beginning to make substantial investments in new solutions without any guarantee that these solutions will be interoperable with their supply chain partners and meet FDA's public health goals. In order to help ensure that industry resources are being focused on effective and comprehensive compliance solutions, FDA should complete pilot programs designed to identify pain points and shortcomings in the rule's structure and industry's compliance strategies. These pilots need to be completed with sufficient time for industry to communicate these learnings and implement systems that solve any identified problems. PTNPA requests that FDA extend the compliance deadline to allow industry to complete these much needed pilot programs before they are required to make significant investments in traceability solutions.

3. **Additional time is needed to engage entities not covered by the rule but required to comply with its requirements by retailers.**

The Traceability Rule imposes complex requirements on covered entities and requires supply chain partners to interact and collaborate in new and challenging ways. The challenges associated with implementation have been compounded by certain retailers announcing that they will expect all suppliers to provide traceability records for all foods, not just the foods identified on the FTL. This announcement has expanded the scope of the rule's impact and will require entities that have not previously been engaged in discussions surrounding the rule to become educated on the rule's requirements quickly. In order for the implementation of the traceability rule to be cohesive, these

companies need to participate in the current, ongoing compliance efforts so that data standards and compliance strategies reflect the feedback of all members of the supply chain. If these entities are not engaged going forward, there is a risk that multiple different compliance strategies that are not interoperable will be developed, which would undermine the public health goals of the rule. Because retailers have only recently announced an intent to require entities to provide traceability records for all products, additional time is needed to engage with and educate those entities not previously considered covered by the Traceability Rule.

* * *

PTNPA appreciates the opportunity to submit these comments and both FDA and the Reagan-Udall Foundation's continued engagement on the effectiveness and implementation of the Traceability Rule. We look forward to continued collaboration going forward and please do not hesitate to contact PTNPA with any questions you may have regarding these comments.

Respectfully Submitted,

Jeannie Shaughnessy, Chief Executive Officer
Peanut and Tree Nut Processors Association
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Alexandria, VA 22301

October 25, 2024

Submitted via email to FinalRule@ReaganUdall.org

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1333 New Hampshire Ave NW
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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:

PepsiCo, Inc. ("PepsiCo") appreciates the opportunity to submit comments on the Reagan-Udall Foundation's Virtual Public meeting concerning the U.S. Food and Drug Administration's ("FDA") final rule Requirements for Additional Traceability Records for Certain Foods (the "Traceability Rule"). PepsiCo is a global food and beverage leader with net revenues of more than $91 billion and a product portfolio that includes 23 brands that generate more than $1 billion each in annual retail sales. Our main businesses – Quaker, Gatorade, Frito-Lay, and Pepsi-Cola – make hundreds of foods and beverages that are loved throughout the world. PepsiCo is dedicated to producing the safest, highest-quality, and best-tasting beverages and foods in every part of the world. Developing and maintaining robust food safety programs is how we assure safety for every package, every day, in every market.

PepsiCo is committed to food safety and regulatory compliance and takes its responsibility to facilitate traceback investigations and respond to potential outbreaks seriously. This commitment has included a particular focus on ensuring comprehensive traceability for our products throughout our systems. With the implementation of the Bioterrorism Act's one-up, one-back traceability requirements for nearly 20 years, PepsiCo has developed expertise in conducting traceback investigations with a high degree of accuracy for both recalls and other quality matters. PepsiCo has taken this a step further and is an industry leader in the use of SmartLabel to communicate with consumers at the point of sale and in their homes if a product is recalled. As a result of these efforts, scanning the on-pack QR code allows consumers and retailers to receive detailed information on the recall and the manufacturing and product code dates that are impacted.

Consistent with our commitment to food safety and traceability, PepsiCo has been a leader in the efforts to implement Section 204 of the FDA Food Safety Modernization Act (FSMA). Even before the publication of the final rule, in partnership with 14 trade associations and FDA, PepsiCo led the industry in working together on a series of workshops to help develop the Traceability Rule. Then, following the publication of the final Traceability Rule, PepsiCo has been a driving force in industry's implementation efforts through the development of industry resources, collaborating with supply chain partners, participating in meetings between FDA and industry (particularly with respect to direct store delivery (DSD) systems), and assisting in standing up the public-private partnership – the Partnership for Food Traceability – to facilitate and drive collaboration. We participated in the Reagan-Udall Foundation's roundtables on the Traceability Rule and are committed to supporting and participating in the newly formed Partnership for Food Traceability. As demonstrated by these efforts, PepsiCo has

been working diligently to implement the Traceability Rule, however we have encountered significant challenges that are hindering our ability to implement the rule in a way that fully realizes FDA's goal of improving public health through more efficient traceback investigations. Below we outline our key concerns and share our recommendations for improving implementation of the Traceability Rule.

Key Concerns Regarding Traceability Rule Implementation

PepsiCo is committed to implementing the Traceability Rule, but we are concerned that the implementation of the rule in its current timeline will result in costly patchwork data systems that do not in fact make traceback investigations more efficient. For example, large food manufacturers like PepsiCo have complex internal manufacturing and warehousing networks. Today, we have systems in place that give us full visibility into how foods move through our network of facilities before being released to the control of a supply chain partner. The Traceability Rule mandates that traceability records be maintained for all intracompany shipments, which requires major system and process changes as it drives the need to do case and individual package scanning within our diverse product delivery networks in an extremely complex omni-channel market.

Although some warehouse management and ERP systems within industry can carry the Traceability Rule's records today, many of the major platforms are undergoing updates to carry additional data to support FSMA 204. Within PepsiCo, we have systems and processes to understand the flow of goods within our internal network and the ability to extract as needed. The new regulation will require new information sources to be created to comply with the requirements of the Traceability Rule. Essentially, we are creating and installing a new system that requires hardware and software to be able to tie all of these existing data points within our intracompany shipments. This additional parallel system that must be built and the labor to track all intracompany critical tracking events is the driver of our significant costs in order to ensure compliance. Additionally, many companies across the industry today, based on their operational size and complexity, may not even have a warehouse management system in place. Given many of these systems are likely redundant, there is no guarantee that this effort and investment will actually drive improvement in FDA's ability to conduct traceback investigation, as no new capabilities are achieved.

Strategies for Improving the Implementation of the Traceability Rule

Similar to others in the industry and as was discussed in the virtual public meeting, in order to effectively implement the Traceability Rule, PepsiCo will need to invest significant capital to overhaul its technology and recordkeeping systems. Current estimates go beyond what was outlined in the rule's impact analysis and PepsiCo alone expects to spend tens of millions on compliance efforts. Because of this significant investment, it is incredibly important that we are able to implement the right system the first time and not rush too quickly into insufficient systems that achieve compliance without effectiveness. To prevent this from happening, we urge FDA to pursue the following recommendations to improve implementation activities.

- **Provide Compliance Guidance for Industry.** Since the issuance of the final rule, FDA has been collaborating with industry to understand implementation challenges and the impact of the rule on manufacturing and logistics operations. We urge FDA to issue formal guidance documents in line with these conversations to help provide direction to industry as it works through its implementation process.

- **Engage in Pilot Programs.** FDA should facilitate a pilot program that includes packaged food manufacturing to better understand the interoperability of systems, the current status of data standards, and ensure the rule is being implemented in a manner that does in fact meet FDA's goal of improving traceback investigations.

- **Exempt Intracompany Shipments.** We urge FDA to provide an exemption for intracompany shipments. As discussed above, PepsiCo and other packaged food manufacturers are currently able to track products moving through internal systems efficiently. Imposing the traceability requirements on intracompany shipments is adding a substantial burden to manufacturers without providing a demonstrated benefit to public health.

- **Focus Only on High Risk Foods.** Recently, some retailers have announced an expectation that all suppliers will provide records required under the Traceability Rule for all foods, regardless of whether the foods are on the Food Traceability List. Although we appreciate the spirit of these requirements at driving more transparency and consistency, we urge FDA to discourage this practice. The FSMA mandate required FDA to identify and implement a solution that would improve traceability for foods that present the greatest risk to consumers. With the limited resources available for traceability enhancement, it is important that these resource be focused in the areas of the truly greatest importance – the highest risk foods. FDA should discourage retailers from implementing business requirements that drive resources and attention away from the foods that will provide the greatest public health benefit.

- **Extend the Compliance Date to Allow for Concept Testing.** Given the substantial investments implementing the rule will require, FDA needs to provide additional time for companies to fully vet and test compliance programs to ensure they meet the public health goals of the Traceability Rule. This is particularly important in light of industry's efforts through the Partnership for Food Traceability to align on key cross-cutting issues such as data standardization.

We believe that these efforts will help ensure the fully implemented Traceability Rule meets FDA's needs by measurably improving the effectiveness of traceback investigations. Considering the immense pressures to keep costs low for consumers and our desire to use our resources most efficiently to improve food safety, these strategies should be implemented before companies begin making large, formal investments in traceability programs. Therefore, FDA should provide an extension to the compliance deadline to accommodate the completion of the pilot projects and other initiatives before investments in new systems and technology are required.

* * *

Thank you for the opportunity to comment on this important rule. In addition to these comments, PepsiCo also supports the comments submitted by our trade association partners, the Consumer Brands Association and FMI, the Food Industry Association. Please do not hesitate to contact us if we can provide any further information.

Sincerely,

John S. Philips
SVP Customer Supply Chain & Global Go-To-Market

Sarah Meyer-In
VP Quality & Food Safety, PepsiCo Foods North America

SpartanNash
THE FOOD SOLUTIONS COMPANY

October 25, 2024

The Reagan-Udall Foundation
1333 New Hampshire Ave NW
Suite 420
Washington, DC 20036
finalrule@reaganudall.org

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:

SpartanNash appreciates the opportunity to provide comments on The Reagan-Udall Foundation's (RUF) Virtual Public Meeting on the Food and Drug Administration's (FDA) Final Rule on Requirements for Additional Traceability Records for Certain Foods (the Traceability Rule). As a retail and wholesale food solutions company, SpartanNash is directly impacted by the Traceability Rule's requirements, and we have been working diligently to meet the compliance deadline. Through collaboration with our supply chain partners, we have identified numerous hurdles and challenges impacting the industry. SpartanNash supports the comments provided by FMI, The Food Industry Association. We are also taking this opportunity to highlight concerns of our own and a request of the FDA.

Since the final rule was published in November 2022, we have been working to educate our upstream vendors and our independent retail customers to define and implement a compliance strategy. The food industry is committed to enhancing traceability throughout the supply chain, as demonstrated by the hundreds of millions of dollars that have already been invested in Traceability Rule compliance efforts. We continue to evaluate emerging technology to meet the needs of our company as well as those of our independent retail customers. Notwithstanding these efforts, more work and more financial investment is needed from the industry before compliance can be achieved across the entirety of the supply chain.

As you know, the food supply chain is a complex network of companies that must work together to ensure that safe and affordable food reaches store shelves every day. No single company alone can comply with the requirements of the Traceability Rule unless and until all supply chain partners are able to pass forward the required information. Accurate records must be maintained throughout the supply chain, and SpartanNash must depend on our suppliers to implement these practices first, which can have an impact on our own compliance efforts. Given these complexities and the necessary

SpartanNash
THE FOOD SOLUTIONS COMPANY

measures that must be made throughout the supply chain, the food industry as a whole needs additional time to ensure proper compliance with the Traceability Rule.

At this time, the biggest challenge facing our industry is the overwhelming complexity involved in implementing the Traceability Rule. The implementation complexity stems from the number of products the Traceability Rule implicates, the reliance on other entities' compliance to ensure our own obligations are met, the need to properly evaluate new technologies and systems both for security and practical ease of use, and the desire to ensure interoperability.

Given this complexity of the Traceability Rule, the need to: educate both our vendors and our independent retail customers; identify and evaluate new technologies and new recordkeeping systems; and ensure our systems are interoperable…means that more time is needed to comply. In light of the investments we have made thus far and the planned investments that are needed for compliance, it's imperative we get things right. Additional time for compliance will help us further ensure our vendors and independent retail customers are able to make this journey with us.

We truly 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. It is our hope that this process results in a revised timeline that will ultimately provide a better, safer result for all constituencies involved.

Sincerely,

James Lilly
Vice President
SpartanNash Government Affairs
850 76th St SW
Byron Center, MI 49315

October 25, 2024

The Reagan-Udall Foundation
1333 New Hampshire Ave NW
Suite 420
Washington, DC 20036
finalrule@reaganudall.org

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:

Sprouts Farmers Market appreciates the opportunity to provide comments on The Reagan-Udall Foundation's (RUF) Virtual Public Meeting on the Food and Drug Administration's (FDA) Final Rule on Requirements for Additional Traceability Records for Certain Foods (the Traceability Rule). As a grocery store, Sprouts is directly impacted by the Traceability Rule's requirements and we have been working diligently to meet the compliance deadline. Through our collaboration with our supply chain partners to bring our operations into compliance, we have identified a number of hurdles and challenges impacting our industry. Sprouts supports the comments provided by FMI, The Food Industry Association. In these comments we will discuss these challenges and our requests of FDA.

Since the final rule was published in November 2022, we have been working diligently to educate our supply chain partners and to identify and implement our compliance strategy. The food industry is committed to enhancing traceability throughout the supply chain as demonstrated by the hundreds of millions of dollars that have already been invested in Traceability Rule compliance efforts. Notwithstanding these efforts, more work and more financial investment is needed before compliance can be achieved.

At this time, the biggest challenge facing industry is the overwhelming complexity involved in implementing the Traceability Rule. The implementation complexity stems from both the number of products the rule implicates, the reliance on other entities' compliance to ensure your own obligations are met, and the need to evaluate new technologies and systems, and the desire to ensure interoperability. As explained below, these challenges highlight the need for greater flexibility in the Traceability Rule, specifically related to the use of traceability lot codes, and more time to perform pilot projects and implement the Traceability Rule's requirements.

<u>The Need for Greater Flexibility</u>

First, industry and consumers would benefit from being able to provide a range of lot codes rather than a single lot code for products. Most of the products on retail stores must travel

through a distribution center before reaching the store shelves and distribution centers are struggling to find feasible ways to trace single lot codes through their operations without implementing case-level tracking. Because distribution centers already have strong visibility into their product's path through the supply chain, allowing a range of traceability lot codes would ease the complexity without hindering FDA's ability to complete an efficient traceback investigation.

The Need for Pilot Projects

In order for the industry to successfully implement the Traceability Rule, pilot projects must be completed to evaluate whether different entities in the supply chain can coordinate with each other to ensure compliance and whether the goals of the Traceability Rule – more efficient and effective traceback investigations - can be met. Quite simply, pilot projects can explore what gaps in implementation need to be addressed *before* significant investments in technology, recordkeeping systems, training and more have been made. Pilot projects also would enable industry and the agency to explore alternative solutions that reduce the burden on industry while protecting public health. In order for the learnings from these pilot programs to be effectively implemented, the compliance date should be two years after their completion.

The Need for An Extension to the Compliance Date

Given the complexity of the Traceability Rule, the need to educate the supply chain, the need to identify and evaluate new technologies and new recordkeeping systems, and the desire to ensure our systems are interoperable, more time is needed to comply with the rule. In light of the investments we have made thus far and the planned investments that are needed for compliance, we need to ensure we get it right. Additional time for compliance will help us do so.

* * *

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,

Carlos Rojas
Vice President - Enterprise Risk Management

United Egg Producers
Leadership by Egg Farmers for Egg Farmers

UEP OFFICERS
Mike West
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Chad Gregory
President and CEO

J.T. Dean
Vice Chairman

Sherman Miller
Treasurer

Sandra Lausecker
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UEP STAFF
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President and CEO

Tabitha McCoy
Director of Finance

Oscar Garrison
Sr. VP, Food Safety

Dr. Larry Sadler
Sr. VP, Animal Welfare

DC Offices
Louie Perry
Cornerstone Govt Affairs

Randy Green
Watson Green LLC

October 24, 2024

Reagan-Udall Foundation for the Food and Drug Administration
1333 New Hampshire Avenue, N.W., Suite 420
Washington, D.C. 20036

Dear Sir or Madam:

These comments are submitted on behalf of United Egg Producers (UEP) regarding the document entitled "Industry Roundtable Series on the FSMA Final Rule on Requirements for Additional Traceability Records for Certain Foods: Top-Line Learnings Summary" (the "summary). UEP is a farmer-owned cooperative whose members independently produce and market more than 90 percent of all eggs in the United States.

The Reagan-Udall Foundation for the FDA (the "foundation") has performed a valuable service in soliciting and interpreting the concerns of FDA-regulated food industries about the final traceability rule. In these comments, we will list the concerns that have been expressed to us by egg producers. In the course of doing so, we will comment on some of the major themes in the summary.

Our members generally market their eggs directly to food retailers, food service chains and consumer packaged goods companies. As the final rule's effective date approaches, egg producers and their customers are trying to work out the best approaches to comply with the rule in a practical way.

- **The rule is complex and some of its requirements are ambiguous** when applied to specific, real-world situations. Better understanding on the part of both food producers and their customers is needed. Thus, we concur with the summary's section on **"Awareness,"** notably its statements that there is currently "low awareness of the rule and its specific requirements across the food system …" We also agree that there are "multiple interpretations of the final rule …" which create uncertainty about whether a supplier's plan for compliance is adequate.
    - *Specifically, the rule allows for data to be maintained within the supply chain (§ 1.1455 (b)) and does not mandate that KDEs "move" with the product when the customer and supplier have agreed upon the data staying with the supplier. However, the regulated industry and its customers clearly do not understand that this a viable option as demonstrated by comments made during the webinar. UEP believes that this allowance should be made crystal clear in any guidance document made available to the industry.*

IEC
Council Representative

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- *UEP believes that FDA should move rapidly to issue additional guidance documents to assist industry in implementation and compliance, and should announce a delay in the compliance date (currently January 20, 2026) until one year after all such documents have been issued.*

- Some retail customers have told suppliers that they will **apply the final rule's requirements to all foods,** not simply those on the Food Traceability List (FTL). UEP fully realizes that FDA cannot prevent companies from going beyond the final rule's requirements, but applying the final rule to products that FDA did not intend to cover may result in additional expense and impractical requirements. We believe that the summary's section on **"Public/Private Partnership"** may be helpful in this regard. We concur that a "PPP, which might include state regulators and public health agencies, could facilitate collaboration to support implementation, and could help build consistency …" In addition, we encourage the establishment of additional pilot programs as described in the summary's section entitled **"Pilots (Concept-Testing)."**
  - *UEP believes that FDA should move expeditiously to establish a public-private partnership and to carry out additional pilot programs, including at least one involving shell eggs.*
- In addition to applying the final rule to foods not on the FTL, some customers **are establishing requirements that go well beyond those in the final rule.** Once again, we understand that the FDA does not control customer behavior, but when some customers, applying the final rule, establish different requirements than other customers, it becomes much more difficult for suppliers to design systems that ensure traceability compliance consistently across their entire enterprise. Thus, **the additional requirements make overall supplier compliance more challenging, and also risk turning food traceability into a point of competition among industry participants.**
  - *UEP believes FDA should encourage industry to implement the final rule in a pre-competitive fashion and in a consistent way across all supply chains. From this standpoint, the public-private partnership discussed in the foundation's summary report would be helpful.*

In conclusion, UEP again commends the foundation for its work to make industry concerns known to FDA. We encourage the foundation to continue working with industry and the agency to enhance communication and encourage active engagement among all parties to implement the final rule responsibly and practically.

Sincerely,

Oscar Garrison
Senior Vice President Food Safety Regulatory Affairs

October 25, 2024

The Reagan-Udall Foundation
1333 New Hampshire Ave NW
Suite 420
Washington, DC 20036
finalrule@reaganudall.org

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:

US Foods, Inc. ("US Foods") appreciates the opportunity to provide comments on The Reagan-Udall Foundation's (RUF) Virtual Public Meeting on the Food and Drug Administration's (FDA) Final Rule on Requirements for Additional Traceability Records for Certain Foods (the Traceability Rule). As a foodservice distributor, food manufacturer, and retailer, US Foods is directly impacted by the Traceability Rule's requirements, and we have been working diligently to meet the compliance deadline. Through our collaboration with our supply chain partners to bring our operations into compliance, we have identified a number of hurdles and challenges impacting industry. US Foods supports the comments provided by FMI, The Food Industry Association. In these comments we will discuss these challenges and our requests of FDA.

Since the final rule was published in November 2022, we have been working diligently to educate our supply chain partners and to identify and implement our compliance strategy. The food industry is committed to enhancing traceability throughout the supply chain as demonstrated by the hundreds of millions of dollars that have already been invested in Traceability Rule compliance efforts. US Foods has assembled a cross-functional team and made strong progress in creating capabilities to ensure compliance with the Traceability Rule. Through our scoping efforts across the various Food Traceability List product categories, we identified countless unique supply chain scenarios for which we are developing compliance solutions, and we have made a material investment in additional technology to support these solutions. Notwithstanding these efforts, more work and more financial investment is needed before compliance can be achieved. We view pragmatic testing to be the best way to ensure industry can create highly effective and efficient compliance solutions.

At this time, the biggest challenge facing industry is the overwhelming complexity involved in implementing the Traceability Rule. The implementation complexity stems from both the number of products the rule implicates, the reliance on other entities' compliance to ensure your own obligations are met, and the need to evaluate new technologies and systems, and the desire to ensure interoperability. As explained below, these challenges highlight the need for greater flexibility in the Traceability Rule, specifically related to the use of traceability lot codes, and more time to perform pilot projects and implement the Traceability Rule's requirements.

<u>The Need for Greater Flexibility</u>

First, industry and consumers would benefit from being able to provide a range of lot codes rather than a single lot code for products. Most of the products on retail stores must travel through a distribution center before reaching the store shelves, and distribution centers are struggling to find feasible ways to trace single lot codes through their operations without implementing case-level tracking. Because distribution centers already have strong visibility into their product's path through the supply chain, allowing a range of traceability lot codes would ease the complexity without hindering FDA's ability to complete an efficient traceback investigation.

<u>The Need for Pilot Projects</u>

In order for industry to successfully implement the Traceability Rule, pilot projects must be completed to evaluate whether different entities in the supply chain can coordinate with each other to ensure compliance and whether the goals of the Traceability Rule – more efficient and effective traceback investigations - can be met. Quite simply, pilot projects can explore what gaps in implementation need to be addressed *before* significant investments in technology, recordkeeping systems, training and more have been made. Pilot projects also would enable industry and the agency to explore alternative solutions that reduce the burden on industry while protecting public health. In order for the learnings from these pilot programs to be effectively implemented, the compliance date should be two years after their completion.

<u>The Need for An Extension to the Compliance Date</u>

Given the complexity of the Traceability Rule, the need to educate the supply chain, the need to identify and evaluate new technologies and new recordkeeping systems, and the desire to ensure our systems are interoperable, more time is needed to comply with the rule. In light of the investments we have made thus far and the planned investments that are needed for compliance, we need to ensure we get it right. Additional time for compliance will help us do so.

* * *

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,

Charlie Loes
Senior Director, Supply Chain Data and Technology
US Foods

| US Foods |

9399 W. Higgins Road | ROSEMONT, IL 60018 | **USFOODS.COM** |

Wakefern
FOOD CORP.®

October 25, 2024

The Reagan-Udall Foundation
1333 New Hampshire Ave NW
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Washington, DC 20036
finalrule@reaganudall.org

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:

Wakefern Food Corp.(Wakefern) appreciates the opportunity to provide comments on The Reagan-Udall Foundation's (RUF) Virtual Public Meeting on the Food and Drug Administration's (FDA) Final Rule on Requirements for Additional Traceability Records for Certain Foods (the Traceability Rule). As a Retailer and Wholesaler, Wakefern is directly impacted by the Traceability Rule's requirements and we have been working diligently to meet the compliance deadline. Through our collaboration with our supply chain partners to bring our operations into compliance, we have identified a number of hurdles and challenges impacting industry. Wakefern supports the comments provided by FMI, The Food Industry Association. In these comments we will discuss these challenges and our requests of FDA.

Since the final rule was published in November 2022, we have been working diligently to educate our supply chain partners and to identify and implement our compliance strategy. The food industry is committed to enhancing traceability throughout the supply chain as demonstrated by the hundreds of millions of dollars that have already been invested in Traceability Rule compliance efforts. Notwithstanding these efforts, more work and more financial investment is needed before compliance can be achieved.

At this time, the biggest challenge facing industry is the overwhelming complexity involved in implementing the Traceability Rule. The implementation complexity stems from both the number of products the rule implicates, the reliance on other entities' compliance to ensure your own obligations are met, and the need to evaluate new technologies and systems, and the desire to ensure interoperability. As explained below, these challenges highlight the need for greater flexibility in the Traceability Rule, specifically related to the use of traceability lot codes, and more time to perform pilot projects and implement the Traceability Rule's requirements.

The Need for Greater Flexibility

First, industry and consumers would benefit from being able to provide a range of lot codes rather than a single lot code for products. Most of the products on retail stores must travel through a distribution center before reaching the store shelves and distribution centers are struggling to find feasible ways to trace single lot codes through their operations without implementing case-level tracking. Because distribution centers already have strong visibility into their product's path through the supply chain, allowing a range of traceability lot codes would ease the complexity without hindering FDA's ability to complete an efficient traceback investigation.

The Need for Pilot Projects

In order for industry to successfully implement the Traceability Rule, pilot projects must be completed to evaluate whether different entities in the supply chain can coordinate with each other to ensure compliance and whether the goals of the Traceability Rule – more efficient and effective traceback investigations - can be met. Quite simply, pilot projects can explore what gaps in implementation need to be addressed *before* significant investments in technology, recordkeeping systems, training and more have been made. Pilot projects also would enable industry and the agency to explore alternative solutions that reduce the burden on industry while protecting public health. In order for the learnings from these pilot programs to be effectively implemented, the compliance date should be two years after their completion.

The Need for An Extension to the Compliance Date

Given the complexity of the Traceability Rule, the need to educate the supply chain, the need to identify and evaluate new technologies and new recordkeeping systems, and the desire to ensure our systems are interoperable, more time is needed to comply with the rule. In light of the investments we have made thus far and the planned investments that are needed for compliance, we need to ensure we get it right. Additional time for compliance will help us do so.

* * *

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,

Mike Stigers
President

The following Wakefern Food Corp. member companies also wish to support this letter:

Gerrity's Supermarket, Inc
Greenfield's ShopRite
Joseph Family Markets LLC d/b/a ShopRite of Canton Connecticut
Inserra Supermarkets
Price Rite Marketplace
Ravitz Family Markets ShopRites
ShopRite, Supermarkets, Inc.
Waverly Markets, LLC

October 25, 2024

The Reagan-Udall Foundation
1333 New Hampshire Ave NW
Suite 420
Washington, DC 20036
finalrule@reaganudall.org

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:

United Natural Foods, Inc. (UNFI) appreciates the opportunity to provide comments on The Reagan-Udall Foundation's (RUF) Virtual Public Meeting on the Food and Drug Administration's (FDA) Final Rule on Requirements for Additional Traceability Records for Certain Foods (the Traceability Rule). As a wholesale distributor that also operates retail grocery banners and owns private labels, UNFI is directly impacted by the Traceability Rule's requirements, and we have been working diligently to meet the compliance deadline. Through our collaboration with supply chain partners to bring our operations into compliance, we have identified several implementation barriers impacting our operations and UNFI's supply chain partners. In these comments we will discuss those challenges and our requests of FDA. Along with our specific concerns outlined in this letter, UNFI supports the comments provided by FMI, The Food Industry Association.

UNFI is committed to improving food safety and enhancing traceability throughout the supply chain as demonstrated by the millions of dollars we have already invested in Traceability Rule compliance efforts. Since the final rule was published in November 2022, we have been working diligently to educate our supply chain partners and to develop our compliance strategy. UNFI has established an internal product traceability working group dedicated to evaluating our internal systems and processes and updating warehouse management systems to prepare for compliance. Across our distribution network, UNFI is in constant discussion with its retail grocery customers as well as product suppliers to assess their capabilities and better understand how existing data management systems will or could be incorporated to achieve compliance. With over 30,000 customers and over 10,000 suppliers, this requires ample time and resources. While UNFI is working diligently to meet the January 2026 compliance date, additional time for more planning, education, and implementation is critical to ensure all traceability systems throughout the supply chain are effective and interoperable.

At this time, the biggest challenge facing industry is the overwhelming complexity involved in implementing the Traceability Rule. The implementation complexity stems from the reliance on other entities' compliance to ensure our own obligations are met, and the need to evaluate many new technologies and systems. Further, interoperability of I.T. systems throughout the supply chain are crucial. As explained below, these challenges highlight the need for greater flexibility implementing the Traceability Rule, specifically related to the use of traceability lot codes, and more time to perform pilot projects and share best practices throughout the supply chain. We strongly believe addressing these concerns will allow us to implement the Traceability Rule's requirements as Congress intended under the *Food Safety Modernization Act,* effectively preventing foodborne illnesses, and improving human health through modernized processes and greater consumer transparency.

The Need for Greater Flexibility

First, industry and consumers would benefit from being able to provide a range of lot codes rather than a single lot code for products. Most of the products in retail stores must travel through a distribution center such as UNFI's before reaching the store shelves. As one of the largest wholesale distributors of food products in North America, tracing individual lot codes through our vast distribution network is complex and would require implementing case level tracking. Because we already have strong visibility into our products' paths through the supply chain, allowing a range of traceability lot codes would ease the compliance burden without hindering FDA's ability to complete an efficient traceback investigation.

The Need for Pilot Projects

For industry to successfully implement the Traceability Rule, it is recommended that multiple pilot projects, sanctioned and evaluated by FDA, be completed to gauge whether different entities in the supply chain can coordinate with each other to ensure compliance and whether the goals of the Traceability Rule— more efficient and effective traceback investigations— will be achieved. Pilot projects will help us identify what gaps exist in implementation of the rule that need to be addressed *before* significant efforts in technology, recordkeeping systems, training and more are made. Pilot projects also would enable industry and FDA to explore alternative solutions that reduce the burden on industry while still protecting public health. For the learnings from these pilot programs to be effectively implemented, we are recommending the compliance date should be no sooner than two years after completion of the pilots.

The Need for An Extension to the Compliance Date

Given the complexity of the Traceability Rule, the need to educate the supply chain, the need to identify and evaluate innovative technologies and new recordkeeping systems, and the desire to ensure our systems are interoperable, our most pressing request is more time to comply with the rule before enforcement begins. Considering the investments we have made thus far and the future investments we know will be needed for compliance, we are committed to achieving full compliance with FSMA Rule 204 in the right way. Additional time for all supply chain entities covered will ensure we are able to do so.

* * *

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,

Tehzin Chadwick
Senior Vice President, Safety

October 25, 2024

Reagan-Udall Foundation for the Food and Drug Administration
FDA Traceability Rule (FSMA 204)
1333 New Hampshire Ave, NW, Suite 420
Washington, DC 20036

Re: Comments on the Implementation of the FDA's Final Rule on Requirements for Additional Traceability Records for Certain Foods (FSMA 204)

To Whom It May Concern:

Founded in 1926, Western Growers Association represents local and regional family farmers growing fresh produce in Arizona, California, Colorado, and New Mexico. Our members and their workers provide half the nation's fresh fruits, vegetables, and tree nuts, including half of America's fresh organic produce. We appreciate the opportunity to provide written comments following our verbal remarks at the October 7, 2024, public meeting on the U.S. Food and Drug Administration's (FDA) Final Rule on Requirements for Additional Traceability Records for Certain Foods, under Section 204 of the FDA Food Safety Modernization Act (FSMA).

The produce industry has long been committed to improving traceability, with the Produce Traceability Initiative (PTI) leveraging GS1 standards as a prime example. As our members prepare to comply with the rule, we want to stress the importance of leveraging current frameworks, systems, and investments. We respectfully submit comments to the Reagan-Udall Foundation for the Food and Drug Administration and focus on three key areas: interoperability, compliance, and implementation.

Interoperability

Interoperability of traceability technology throughout the supply chain is of paramount importance to ensure faster identification and swift removal of potentially contaminated food from the marketplace. If interoperability is not adopted, industry will be slow to comply and FDA's goal to protect public health through effective and efficient traceback investigations will continue to be hampered. We urge FDA to support a framework that improves interoperability by identifying data formats and standards that allow different systems to communicate, share, and use traceability data effectively. Interoperability and integration together are crucial for effectively implementing the final rule across the food supply chain. We urge FDA to promote data standardization across the supply chain to enable systems to communicate seamlessly and avoid the need to implement redundant and costly systems.

Without interoperability, upstream suppliers such as fresh produce growers, packers, and shippers, are being forced to adopt multiple systems and redundant practices to meet demands

from different downstream buyers. Our members report that this is already occurring, with some having to upload information into new different systems. Implementing data standards that build off existing frameworks would help minimize the need for multiple data systems and prevent the additional cost burden imposed by the final rule. Current cost components for PTI compliance, for instance, include expenses for supplies like stickers and scanners, software development for the scanner program within a specific system, general and administrative labor for programming, as well as labor for stickering each box at the field level. With FSMA 204 compliance, additional costs include additional labor for stickering pallets at the cooler level, supplies for pallet sticker numbers, software for additional scanners at the cooler, and general and administrative labor for scanner programming development. The more complexity that is added to this process the more burdensome it will become and data standardization ensuring interoperability would help prevent compliance with the final rule from becoming prohibitively burdensome.

Additionally, many companies already face challenges with partially integrated systems, leading to high costs and operational difficulties associated with upgrading systems and processes. We urge the FDA to consider the economic viability of various-sized operations and to prioritize a unified, interoperable framework to support efficient traceability. This includes prioritizing both interoperability and integration to prevent unnecessary costs and redundancies and to ensure a harmonized system across the entire food supply chain that enhances food safety and facilitates traceback investigations.

Compliance Approach

We support regulatory compliance efforts to enhance the ability to quickly and accurately trace foods that may be implicated in a foodborne illness outbreak. Outbreak investigations generally start at the local level, with public health officials first working to understand possible food vehicles, then seeking to illuminate the supply chain pathways of those products in the hope that a common source is found. Thus, retail stores and restaurants where consumers shop and eat represent the first node in an investigation. As the first step in the investigation, efficient traceback depends on the availability of key information at these points in the supply chain. The absence of even the most plain and simple information at these points can result in a slower identification of the source and cause of an outbreak. Given our members' commitment to public health, which requires strong traceability programs, our members have largely embraced the PTI. However, PTI adoption has lagged among "last mile" entities such as retailers and distribution centers which receive granular, lot-specific information in a standardized format (using the GS1 system of application identifiers, communicated in a standardized GS1 128 barcode) but fail to record this information.

Additionally, fresh produce buyers are increasingly demanding FSMA 204 compliance for all fresh produce, not just those items on the Food Traceability List (FTL). Expanding FSMA 204 requirements beyond the FTL items without consistent standards in place further complicates

implementation, increases costs, and undermines traceability efforts, particularly if "last mile" entities are not recording the information and do not have it readily available in the event of an outbreak investigation.

We do not support frameworks that disproportionately burden growers, packers, and shippers while offering flexibility to the entities that are the first points of an outbreak investigation: retailers, distributors, and buyers. We urge FDA to develop a fair compliance framework across the entire supply chain. Selective flexibility threatens to fragment the industry's traceability efforts, slows innovation, and ultimately undermines the goal of preventing foodborne illnesses. To be clear, Western Growers does not support unequal approaches at different points along the supply chain and instead advocates for solutions that foster innovation, shared accountability, and a coordinated traceability system across the entire supply chain.

Global Implementation

FSMA 204 affects both domestic and foreign suppliers of food for U.S. consumption. Fresh produce origin can vary widely depending on product type.[1] For instance, suppliers of artichokes, asparagus, and cucumbers rely heavily on imports, with over 70% coming from foreign sources. Leafy greens suppliers, on the other hand, have low import dependency. In order to truly reduce foodborne illnesses, FDA needs to develop a strategy that addresses global implementation.

The rule applies to persons who manufacture, process, pack, or hold certain foods and because coverage under the rule relies on taking physical possession of a certain food, many importers or brokers of produce are not required to maintain traceability records. This structure creates a clear loophole for foreign producers. By excluding brokers and importers from the rule unless they take physical possession of the product, the rule creates an information gap between foreign producers and domestic entities that receive foreign product because these entities do not interact directly, but rather through the broker or importer. Excluding importers and brokers therefore could slow down and even halt traceback investigations because domestic receivers may not have access to the required traceability records. This places an unfair burden on domestic producers, who are required to comply with the traceability requirements. FDA should ensure its enforcement strategy addresses compliance for both domestic and foreign entities, including clear compliance standards and inspections of foreign suppliers.

Additional Considerations

At the panel discussion during the virtual public meeting hosted by the Reagan-Udall Foundation on the implementation of FSMA 204, industry representatives shared key

[1] USDA Economic Research Service (Vegetable & Pulses 2023 Yearbook Tables, Melon Yearbook Tables, and Fruit and Nuts Yearbook Tables).

challenges related to traceability in the fresh produce and seafood sectors and we highlight a few for your consideration.

Johnny McGuire (Nunes Co.) noted the success of the Produce Traceability Initiative, but cautioned against introducing too many new systems that could overwhelm growers. He emphasized the importance of leveraging existing frameworks and improving data interoperability, especially in grower-to-grower transactions, to avoid errors. Jodi Blanch (Gorton's Seafood) pointed out that most seafood is imported and the exemption for importers requires more FDA outreach and training for foreign suppliers. She also emphasized that outdated IT systems pose challenges. Both panelists stressed the need for a standardized and careful approach to technology adoption. Consumer advocates, like Sarah Sorscher (CSPI), underscored the importance of full supply chain traceability for consumer confidence, citing the 2018 romaine lettuce outbreak as an example of how effective lot coding can reduce investigation time.

The panel as a whole emphasized the need for standardization, collaboration, and balancing regulatory compliance with practical, industry-wide solutions to enhance traceability and protect public health. These themes align with Western Growers' perspective on overarching issues associated with the implementation of FSMA 204.

Conclusion

In conclusion, we urge the FDA to work with the food industry to find consistent, interoperable solutions throughout the entire global supply chain, leveraging current systems and addressing gaps in its implementation strategy for foreign firms. Thank you for considering these comments.

Respectfully,

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