

March 13, 2025

Kyle Diamantas
Acting Deputy Commissioner for Human Foods
United States Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Re: Request for compliance date delay of the FDA final rule on Food Traceability and review under Executive Order 14219

Dear Mr. Diamantas,

On behalf of the undersigned associations, we are writing to request an immediate delay of the compliance date for FDA's final rule on Requirements for Additional Traceability Records for Certain Foods ("Traceability Rule" or "final rule"). Our organizations represent a broad spectrum of the food and beverage supply chain, including food processing, manufacturing, distribution, and retail.

The FDA's final rule mandates comprehensive tracking of food products throughout the supply chain and for companies to provide traceability information electronically to the FDA within 24 hours. While our organizations strongly support efforts to improve food safety under the Food Safety Modernization Act (FSMA), we have significant concerns about the feasibility of meeting the final rule's compliance deadline of January 20, 2026, and have raised such concerns since release of the final rule in November of 2022.

FDA's Traceability Rule Should Be Evaluated Under Executive Order 14219

The Traceability Rule is a prime example of regulatory overreach that warrants evaluation under Executive Order 14219, *Ensuring Lawful Governance and Implementing the President's "Department of Government Efficiency" Deregulatory Initiative*. President Trump has consistently emphasized the need to eliminate overly burdensome regulations that impose unnecessary costs without demonstrable public benefits.

While we recognize the FDA's intention to enhance food safety, the Traceability Rule, as currently written, fits within the EO's mandate for review. It imposes significant costs and compliance challenges on industry stakeholders, particularly smaller businesses. It lacks sufficient clarity and enforcement guidance, making compliance difficult and increasing regulatory uncertainty. The rule requires extensive and costly technological overhauls, and we believe that the FDA's requirements have exceeded its statutory mandate under section 204 of FSMA for specific tracking requirements (e.g., case-level tracking).

Notably, the FDA has not conducted full-scale pilot programs to assess whether the rule is achievable or scalable across the entire food supply chain. Without real-world testing, the feasibility and effectiveness of these requirements remain uncertain, further exacerbating industry concerns.

Compliance Concerns Are Well-Documented Across the Supply Chain

Stakeholders across the food industry supply chain have gone on record many times outlining compliance challenges. The January 20, 2026, compliance deadline imposes an unrealistic timeline given the following obstacles:

- **Technological Limitations:** Many industry stakeholders lack the necessary digital infrastructure to comply with the extensive data collection and reporting requirements. Compliance necessitates the implementation of new tracking systems and electronic data storage management and reporting, which are costly and impractical, especially for smaller producers, manufacturers, distributors, and retailers.
- **Lack of FDA Guidance and Clarity on Enforcement:** Industry participants continue to face uncertainty regarding the rule's scope, application, and enforcement mechanisms. Unresolved questions about traceability lot codes, data transmission, and exemptions make compliance difficult.
- **Lot Code Requirements Provide Questionable Benefits:** Implementing traceability lot codes, a central component of the rule, is proving to be a significant hurdle at every step in the supply chain. The industry can track foods without this requirement. The rigid lot code tracking requirement adds layers of complexity without clear evidence of improving food safety outcomes.
- **Disproportionate Burden on Small Businesses:** The FDA estimated that the financial impact on the food industry would be up to \$24.6 billion over 20 years which significantly underestimates the true cost of compliance. The rule presents a significant cost and operational challenge for small and mid-sized farms, manufacturers, distributors, and retailers, who lack the financial and technical resources to overhaul their digital tracking systems or store large amounts of data for the purposes of traceability.

Request for Compliance Delay

The U.S. food system supplies food for over 333 million people in America 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 Rule requires a dramatic change in every step of this system, many of which go beyond the requirements of the law. While we acknowledge the benefits of improved traceability, it's vital for stakeholders in the food industry supply chain to be given more time to adapt to these changes.

We therefore urge the FDA to both evaluate this rule under EO 14219 and extend the compliance date immediately. This additional time will provide the FDA the opportunity to conduct pilot programs to refine the rule's application and identify necessary adjustments, and it will allow businesses to develop and integrate traceability systems without disrupting supply chains. Implementation concerns must be addressed so that food prices can be competitive for American consumers. Such a delay will align with the Administration's goal of reducing unnecessary compliance costs and ensuring regulations are both effective and achievable.

Conclusion

Our organizations share the Administration's goals of ensuring the integrity and safety of our food supply chain. We look 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.

Sincerely,

FMI – The Food Industry Association
International Foodservice Distributors Association
National Association of Convenience Stores
National Fisheries Institute
National Grocer Association
National Restaurant Association
National Retail Federation

CC:

Robert F. Kennedy, Jr., Secretary, Department of Health and Human Services
Heather Melanson, Chief of Staff, Department of Health and Human Services
Heidi Overton, Domestic Policy Council, The White House
Luke Farritor, Department of Government Efficiency Liaison to the Department of Health and Human Services