SAFE FOOD COALITION

1620 I Street, NW, Suite 200, Washington, DC 20006 202-939-1010

September 8, 2025

Martin Makary
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

VIA ONLINE SUBMISSION

RE: Docket No. FDA-2014-N-0053. Requirements for Additional Traceability Records for Certain Foods: Compliance Date Extension

Dear Commissioner Makary:

The undersigned members of the Safe Food Coalition write to express our opposition to FDA's proposed two-and-a-half year delay in the implementation of the final rule, Requirements for Additional Traceability Records for Certain Foods (Food Traceability Final Rule), and to urge you to implement the rule's recordkeeping requirements by a date closer to the previously announced January 20, 2026 compliance date. That compliance date continues to afford industry ample time to prepare, and represents an already long overdue enactment of the Food Safety Modernization Act (FSMA), which Congress passed with broad bipartisan support in 2010 and President Barack Obama signed into law in January 2011.

According to FDA's Federal Register notice, the agency's leadership "think the public health benefits will be greater if the compliance date is delayed by 30 months for all of industry, allowing time to focus on successful implementation of the entire rule throughout the full supply chain."[1] We disagree. Industry should not need more than a decade and a half to implement this critical FSMA provision which has been in the offing for years. Further delay will result in greater than necessary "harm to public health caused by foodborne illness outbreaks" and "adverse impacts on industry sectors affected by these outbreaks," as detailed in the agency's initial rulemaking.[2]

As the agency explained in its initial rulemaking, the food industry "has generally adopted the requirements for one-up, one-back tracing required under" current regulations. This status quo approach to traceability results in preventable foodborne illness and waste. When investigators lack

[1] https://www.federalregister.gov/documents/2025/08/07/2025-14967/requirements-for-additional-traceability-records-for-certain-foods-compliance-date-extension
[2] https://www.federalregister.gov/documents/2020/09/23/2020-20100/requirements-for-additional-traceability-records-for-certain-foods

adequate information to trace a food back in the supply chain to a common source, they cannot identify contaminated foods or ingredients to target in a recall, leading to overbroad recalls or public advisories, such as a 2018 advisory to avoid romaine lettuce from an entire growing region. Likewise, inadequacies in the currently required information have prevented or delayed FDA in tracing foods forward and connecting the dots to discover the underlying cause of a foodborne illness outbreak, particularly "outbreaks that are challenging to resolve, such as those involving multiple foods and foods with multiple ingredients."[3]

Continued delay in requiring compliance with the Food Traceability Final Rule will forestall the considerable benefits to consumers and industry identified by FDA in its rulemaking. It will also run contrary to the expressed intent of Congress and the courts. With FSMA, Congress directed FDA to propose recordkeeping requirements for certain "high risk" foods no later than January 2013. When FDA failed to propose those requirements, Safe Food Coalition member Center for Food Safety sued the agency, leading to a federal court Consent Decree mandating that the agency propose requirements by September 2020, and finalize the rulemaking process by November 2022.[4] The agency's proposal now to delay compliance with its final rule until nearly six years after that court deadline calls into question whether it is indeed exercising "good faith to the complete the actions" set out in its Consent Decree.

The proposed delay undermines investment made by companies across the food supply chain in anticipation of the rule. Retailers including Kroger, Albertsons and Walmart have already implemented traceability programs that incorporate the requirements set out by FDA, and often go further.[5] Without widespread adoption, however, many food manufacturers, processors, packers and retailers will continue to employ inconsistent approaches to product tracing with non-standard data elements. FDA's final rule establishes a consistent approach, specifying "Key Data Elements" along with "Critical Tracking Events" that align with the best practices observed among members of industry. By establishing a standardized and efficient system for traceability, FDA's rule will reap lasting benefits for consumers and the food industry alike, but only if a critical mass of food companies has the confidence to invest in recordkeeping systems that comply with the rule.

The lengthy two-and-a-half year proposed postponing of the agency's rule encourages a small but vocal minority of the rule's opponents to continue their efforts to undermine confidence in the rule, and to defend status quo "one step forward and one step back" traceability programs. Currently, draft appropriations legislation in the U.S. House of Representatives would send FDA back to the drawing board, requiring "at least 4 evaluations or beta tests using multiple products" to identify alternative traceability schemes.[6] These appropriations riders may very well fail, similar to

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[3] https://www.federalregister.gov/documents/2020/09/23/2020-20100/requirements-for-additional-traceability-records-for-certain-foods

[4] Kimbrell, G., & Talbott, R. (2019, June 11). Taking Foodborne Illness Off the Menu. Center for Food Safety. https://www.centerforfoodsafety.org/blog/5622/taking-foodborne-illness-off-the-menu

[5] https://www.grocerydive.com/news/grocers-fsma-food-traceability-preparing-requirements-2026/738201/

[6] https://www.congress.gov/119/bills/hr4121/BILLS-119hr4121rh.pdf

previous legislative attempts to stymie FDA's traceability rule indefinitely.[7] However, the longer FDA puts off implementing the Traceability Rule, its opponents will have more opportunities to sow uncertainty, and ultimately derail common sense traceability requirements.

Thank you for your consideration of these comments.

Center for Food Safety
Center for Science in the Public Interest
Consumer Federation of America
Consumer Reports
Government Accountability Project
Institute for Food Safety & Nutrition Security
Oceana
Stop Foodborne Illness

[7] FMI Applauds Introduction of Legislation to Address Challenges with FDA's Food Traceability Rule. (2024, March 6). The Food Industry Association. https://www.fmi.org/newsroom/news-archive/view/2024/03/06/fmi-applauds-introduction-of-legislation-to-address-challenges-with-fda-s-food-traceability-rule