Final Rule: Food Traceability

The FDA final rule on Requirements for Additional Traceability Records for Certain Foods (Food Traceability Final Rule) establishes traceability recordkeeping requirements, beyond those in existing regulations, for persons who manufacture, process, pack, or hold foods included on the & } } d Œ] o] š Ç >] • š ~ & d > • X d Z ( ] v o Œ µ o] • l r Ç Food u ‰ } v v š Safety Blueprint and implements Section 204(d) of the FDA Food Safety Modernization Act (FSMA). The new requirements identified in the final rule will allow for faster identification and rapid removal of potentially contaminated food from the market, resulting in fewer foodborne illnesses and/or deaths.

At the core of this rule is a requirement that persons subject to the rule who manufacture, process, pack, or hold foods on the FTL, maintain records containing Key Data Elements (KDEs) associated with specific Critical Tracking Events (CTEs) and provide information to the FDA within 24 hours or within some reasonable time to which the FDA has agreed.

The final rule aligns with current industry best practices and covers domestic, as well as foreign firms producing food for U.S. consumption, along the entire food supply chain in the farm to table continuum.

Because the Food Traceability Final Rule requires entities to share information with other entities in their supply chain, the most effective and efficient way to implement the rule is to have all persons subject to the requirements come into compliance by the same date. The compliance date for all persons subject to the recordkeeping requirements is Tuesday, January 20, 2026.

New Webinar: FDA Foodborne Outbreak Response Improvement Plan

On April 12, 2022, the FDA held a webinar on the Foodborne Outbreak Response Improvement Plan. The webinar was attended by more than 1,600 registrants and discussed the Improvement Plan, as well as the independent review } (š Z & [• • š Œ µ š µ Œ o v (µ v s capacity to support, participate in, or lead multistate foodborne illness outbreak investigation activities. Watch a recording of the webinar

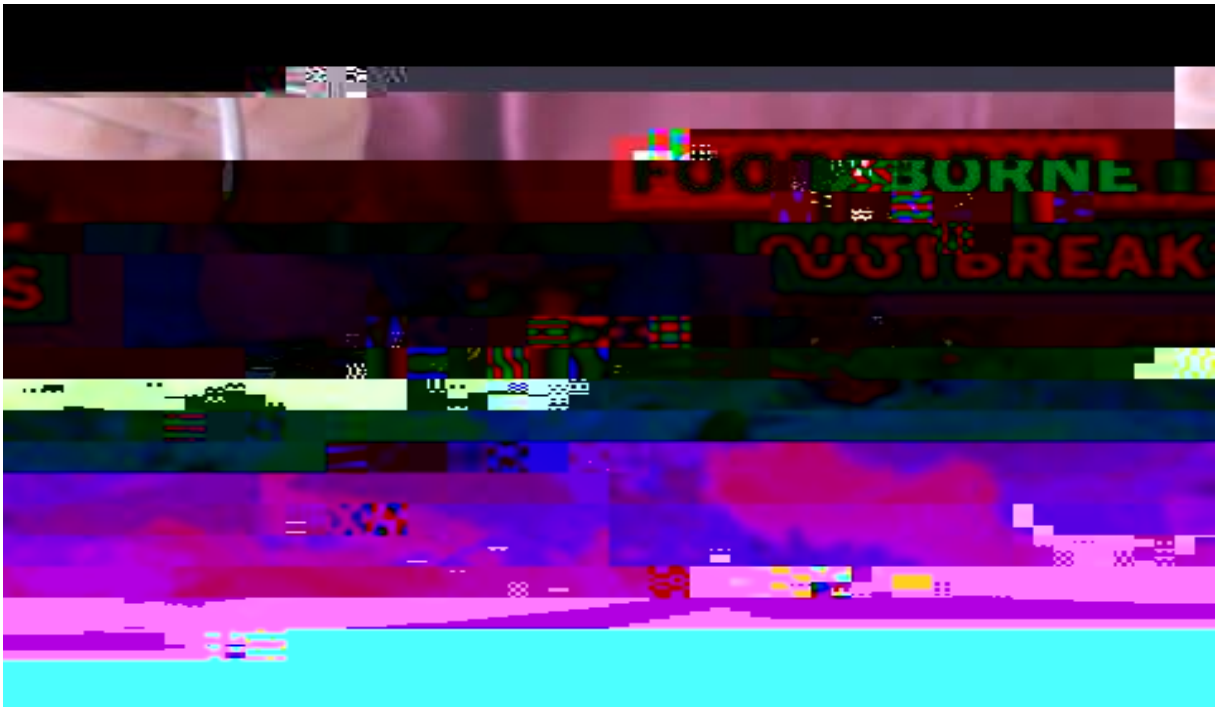
What is the Foodborne Outbreak Response Improvement Plan?

In December 2021, the FDA released the Foodborne Outbreak Response Improvement Plan to enhance the speed, effectiveness, coordination, and communication of investigations into outbreaks of foodborne illness. The goal is to improve our ability to identify the sources and causes of foodborne illness outbreaks. This Foodborne Outbreak Response Improvement Plan is]vš v š}Á}ŒI]v }v NewEraofSmarter Food Safety Blueprint, which outlines specific approaches the FDA will take over the next decade to address food safety in the rapidly changing food system. It focuses on tech-enabled traceability, root cause analysis, outbreak data, and operational improvements.

The plan, which is focused on outbreaks associated with human food, is divided into four priority areas:

- Tech-enabled product traceback, focusing on ways to routinely digitize the process of tracing foods to their source.
- Root cause investigations, working to systemize, expedite and share the results of FDA investigations into the cause of a food contamination.
- Analysis and dissemination of outbreak data to increase the transparency of outbreak investigations.
- Operational improvements to streamline processes and create performance measures.

New Video: How FDA Investigates Foodborne Illness Outbreaks



In October 2022, FDA released a new video which describes the complex steps taken by FDA, along with CDC and local, state, and international public health authorities, in responding to outbreaks in FDA-regulated food products. The video explores how the CDC works with public health authorities to learn more about what might be making consumers sick, and then if an FDA-regulated food product is identified, how the FDA investigates the cause of the outbreak and work with industry to remove any potentially contaminated product from store shelves.

New Report: Reagan-Udall Foundation Report

In July 2022, FDA Commissioner Dr. Califf commissioned an external [illegible] Human Foods Program. The external evaluation conducted by an expert panel facilitated by the Reagan-Udall Foundation was asked to assess the processes, procedures, resourcing, and organizational structure for the Foods Program. On December 6, 2022, the panel released its findings and recommendations to the agency. The Commissioner will form a group of agency leaders to advise on how to best implement and operationalize the findings and ensure that the program obtains the resources, tools, and visibility it warrants