
Summary

On November 15, 2022 the FDA issued a final rule on food traceability designed to facilitate faster identification and rapid removal of potentially contaminated food from the market, resulting in fewer foodborne illnesses and/or deaths. Foods subject to the requirements of the final rule appear on the Food Traceability List (FTL), which includes fresh cut fruits and vegetables, shell eggs, and nut butters, as well as certain fresh fruits, fresh vegetables, ready-to-eat deli salads, cheeses, and seafood products.

At the core of the final rule is a requirement that those who manufacture, process, pack or hold food on the FTL maintain records including Key Data Elements (KDEs) related to Critical Tracking Events (CTEs). Covered firms and farms, retail food establishments and restaurants will be required to provide information to the FDA within 24 hours, or some reasonable time to which the FDA agrees. The compliance deadline is **July 20, 2028**.

Background

Congress enacted FSMA in response to changes in the global food system and in the understanding of foodborne illness and its consequences. FSMA aimed to shift the focus of federal regulators from responding to contamination to preventing it.

In Section 204, Congress directed FDA to improve the tracking and tracing of food through the supply chain by establishing additional recordkeeping requirements for facilities handling certain foods frequently associated with foodborne illness outbreaks — with the intent of enabling more efficient removal of products from the market in the case of an outbreak leading to a recall. The goal was to shorten the time it takes for a product to be traced from retailers and distributors back to where it originated.

The new requirements identified in the final rule are intended to allow for faster identification and rapid removal of potentially contaminated food from the market, resulting in fewer foodborne illnesses and/or deaths.

Policy Recommendation

Provide standards for the formatting of data and work with industry to determine flexibilities to enable compliance for third-party logistics providers (3PLs) in the perishable food industry.

GCCA members are committed to ensuring consistent and reliable traceability information for products within the supply chain, but challenges remain. The lack of data standardization in the final rule creates a situation where each customer storing product in a 3PL warehouse may require a different data entry format. This creates complexity for GCCA members and also for FDA who will need to understand all different data sequences when performing recalls or tracebacks.

The rule also requires product tracing and lot code and lot code sourcing, which effectively results in case-level tracking. Ability to comply will depend on warehouse management system sophistication and may require costly and lengthy upgrades or, in some cases, even full replacements.