

What is FSMA 204?

The FDA Food Safety Modernization Act (FSMA), was the most sweeping reform of our food safety laws in more than 70 years. FSMA Section 204, finalized in November 2022, establishes additional traceability recordkeeping requirements, beyond those in existing regulations, for certain foods.

This regulation mandates that companies establish and maintain a traceability plan, describing their procedures for maintenance of records under the new requirements. This includes the assignment and capture of traceability lot codes, combined with other identifying data, to link shipments of certain foods in our supply chains. In order to handle the sheer volume of data, the FDA strongly encourages the use of electronic recordkeeping for traceability.

Trustwell's FoodLogiQ Traceability solution is the leading tech-enabled traceability platform for the food industry. Companies can collect, store and share FSMA-compliant traceability data through our cloud-based platform, leveraging industry recognized best practices and standards for food traceability.

Who Has to Comply?

Companies that manufacture, process, pack or hold foods on the Food Traceability List (FTL) are subject to the rule.

What Food is Covered?

The FTL was compiled using the FDA's Risk Ranking Model for Food Tracing as a data-driven science-based decision support tool. The FTL includes foods as they are listed and foods that are using as an ingredient in the same form in which it appears on the list -- such as peanut butter cracker snacks, frozen and breaded finfish patties, etc.



Cheeses
(other than hard cheeses)



Crustaceans
(fresh and frozen)



Cucumbers
(fresh)



Finfish
(fresh and frozen)



Fruits
(fresh-cut)



Herbs
(fresh)



Leafy Greens
(fresh-cut and fresh)



Melons
(fresh)



Molluscan shellfish bivalves
(fresh and frozen)



Nut Butters



Peppers
(fresh)



Ready-to-eat Deli Salads
(refrigerated)



Sprouts
(fresh)



Shell Eggs



Smoked Finfish
(refrigerated and frozen)



Tomatoes
(fresh)



Tropical Tree Fruits
(fresh)



Vegetables other than leafy greens
(fresh-cut)

What Information Needs to be Tracked?

In most cases, enhanced traceability data must be stored for 24 months. And if requested, an electronic sortable spreadsheet containing relevant traceability information must be shared with the FDA within 24 hours of a request (or within a reasonable time to which the FDA has agreed).

The Food Traceability Rule requires companies who manufacture, process, pack, or hold foods on the Food Traceability List (FTL) to maintain and provide records about key data elements (KDEs) for certain critical tracking events (CTEs). Key Data Elements (KDE's) are the attributes and information describing the activity or CTE. Required data will vary depending on the CTE being performed. The records required must also contain the traceability lot code of the food and link to the relevant KDEs.

When Will Businesses Need to Comply?

The compliance date for these enhanced record-keeping requirements is set for January 20, 2026.

Take on FSMA 204

Tech-enabled traceability is essential for competitive food businesses and provides business value beyond FSMA 204 compliance and consumer protection. But making the switch and implementing the essential protocols for success can be a daunting task. Luckily, our team of traceability and regulatory experts are here to help.

With Trustwell's FSMA 204 Professional Services, our team can help you prepare for compliance and learn the essential benefits of a tech-enabled traceability solution, including:

- Understand the full scope of responsibilities for all your foods requiring additional traceability recordkeeping, and how capturing and sharing enhanced traceability data for high-risk foods can protect your customers and your business.
- How to tackle a feasible traceability timeline with aggressive action on the planning and development of traceability programs.
- The many benefits of advanced traceability recordkeeping, and why this essential change in the industry is only the beginning of building a stronger, more transparent food supply chain.



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