

## Key Takeaways

### “To the Buyer and Beyond: What the New FSMA Traceability Rule Means for the Produce Industry”

February 23, 2023 | Produce Safety Webinar Series Summaries (#13)

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#### Top 7

- 1) Under the new traceability rule, specific recordkeeping requirements were established for facilities that manufacture, process, pack, or hold certain foods (including farms). These foods are identified in the Food Traceability List, and these requirements are in addition to existing recordkeeping requirements under the 2002 Bioterrorism Act (21 CFR Part 1 Subpart J) that apply to registered facilities. Compliance with the new rule begins January 2026.
- 2) The rule requires that key data elements (including a traceability lot code) must be collected and recorded at critical tracking events.
- 3) The key data elements that must be recorded will vary depending on the critical tracking event.
- 4) Critical tracking events are intended to capture points in the food supply chain when significant changes in the product (like chopping) or in handling of the product (repacking) occur that could impact food safety. These events include harvesting, cooling, initial packing, transforming operations (including repacking), receiving, and shipping.
- 5) A traceability lot code must be assigned to a food that is on the Food Traceability List. This code must uniquely identify a traceability lot within an operation's records. All key data elements for the critical tracking event must be linked to the traceability lot.
- 6) Any operation that is subject to the final rule must establish and maintain a traceability plan. This plan is intended to explain to the FDA how you identify products on the Food Traceability List, whether you are responsible for a critical tracking event, the nature of your traceability lot code, and a person who is a dedicated point of contact about the plan and your records. If you grow or raise food on the Food Traceability List, you must also include a map showing the areas in which you grow or raise food in your plan.
- 7) The traceability records are critical to outbreak investigations, as well as recalls. Operations are required to provide FDA with an electronic sortable spreadsheet of the above mentioned data within 24 hours of a formal request by the FDA. An operation that requires more than 24 hours to provide those data may negotiate for that with the FDA.

## Acronym Key

CDC: Centers for Disease Control and Prevention

FDA: Food and Drug Administration

FSIS: Food Safety Inspection Service

USDA: United States Department of Agriculture

## Additional Reading

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The Produce Traceability Initiative (2023). Home Page. <https://producetraceability.org/>.

U.S. FDA (2022). Food Traceability List.

<https://www.fda.gov/food/food-safety-modernization-act-fsma/food-traceability-list>.

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U.S. FDA (2022). How the Food Traceability Rule works: Produce Supply Chain Example.

<https://www.youtube.com/watch?v=ZcSBvLQ6p6M>.

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