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**Industry Viewpoint: FSMA adds new data collection and reporting requirements**

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By

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On Nov. 15 the FDA released the Final Rule on FSMA Section 204, which contains the long-awaited regulations on record keeping for products on the Food Traceability List.

For those already doing case traceability (PTI), you are half-way there. The new additional information requirements include the introduction of Critical Tracking Events and corresponding Key Data Elements, and the need for a written Traceability Plan. The high-level summary is below with details available on the [FDA website under FSMA](#).

The Critical Tracking Events for produce include the following:

- Harvesting: "...activities that are traditionally performed on farms for the purpose of removing raw agriculture commodities from the place they are grown or raised and preparing them for use as food."
- Receiving: "...an event in a food's supply chain in which a food is received by someone other than a consumer after being transported (e.g., by truck or ship) from another location. Receiving includes receipt of an intracompany shipment of food from one location at a particular street address of a firm to another location of the firm at a different street address.
- Cooling: "...active temperature reduction of a raw agricultural commodity using hydrocooling, icing (except icing of seafood), forced air cooling, vacuum cooling, or a similar process."
- Initial Packing: "...packing a raw agricultural commodity, other than a food obtained from a fishing vessel, for the first time.
- Transformation: "... an event in a food's supply chain that involves manufacturing/processing or changing a food (e.g., by commingling, repacking, or relabeling) or its packaging or packing, when the output is a food on the Food Traceability List. Transformation does not include the initial packing of a food or activities preceding that event
- Shipping: "an event in a food's supply chain in which a food is arranged for transport (e.g., by truck or ship) from one location to another location. Shipping does not include the sale or shipment of a food directly to a consumer or the donation of surplus food. Shipping does include sending an intracompany shipment of food from one location at a particular street address of a firm to another location at a different street address of the firm."

The Key Data Elements have some specifics by CTE, but the common elements include: the location of activity, the commodity and variety if applicable, date, reference document. At the Initial Packing, Traceability Lot Code and the product description must be included.

A written Traceability Plan is required for all items on the FTL must include a description of the procedures you use to maintain the required records, including the format and the location of the records. This plan must include the following:

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- A description of the procedures you use to identify foods on the FTL that you manufacture, process, pack or hold
  - A description of how you assign traceability lot codes to foods on the FTL, if applicable
  - A statement identifying a point of contact for questions regarding your traceability plan and records
  - If you grow or raise a food on the FTL (other than eggs), a farm map showing the areas in which you grow or raise such foods. The farm map must show the location and name of each field in which you grow a food on the FTL, including geographic coordinates and any other information needed to identify the location of each field or growing area. This information only need to be provided to the initial packer, and can be a web link if applicable.
  - You have to update your traceability plan as needed to ensure that the information reflects your current practices and to ensure compliance with the rule
  - You must retain your previous traceability plan for two years after you update the plan

Realizing some retailers, distributors and grower-shippers have not implemented case traceability and even those who have will need to add capabilities to capture and report for these requirements. The FDA will start enforcing these new mandates in January 2026.

*Todd Baggett is the founder and CEO of [RedLine Solutions](#), a Santa Clara, CA-based company that helps grower-shippers and distributors drive operational efficiency by managing inventory and traceability. RedLine has been providing solutions for managing receiving, packing, and cooler management for over 25 years. RedLine's cloud-based MyProduce.com enables companies to manage traceability and inventory control across one or more locations. Baggett is the co-chair of the PTI Technology Working Group, where he plays a key role in defining and revising the PTI best practices and is the author of Produce Traceability for Dummies.*

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