

FSMA Final Rule: Requirements for Additional Traceability Records for Certain Foods



- Federal Register Notice (<https://www.federalregister.gov/public-inspection/2022-24417/requirements-for-additional-traceability-records-for-certain-foods>).

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 Food Traceability List (FTL). The final rule is a key component of FDA's New Era of Smarter Food 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.

Compliance Date

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.

Food Traceability List (FTL)

Section 204 of the [FDA Food Safety Modernization Act \(FSMA\)](https://www.fda.gov/food/guidance-regulation-food-and-dietary-supplements/food-safety-modernization-act-fsma) ([/food/guidance-regulation-food-and-dietary-supplements/food-safety-modernization-act-fsma](https://www.fda.gov/food/guidance-regulation-food-and-dietary-supplements/food-safety-modernization-act-fsma)) requires the FDA to designate foods for which additional recordkeeping requirements are appropriate and necessary to protect public health. Additional recordkeeping requirements are outlined in the [Food Traceability Final Rule](https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-final-rule-requirements-additional-traceability-records-certain-foods) ([/food/food-safety-modernization-act-fsma/fsma-final-rule-requirements-additional-traceability-records-certain-foods](https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-final-rule-requirements-additional-traceability-records-certain-foods)), and 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.

The Food Traceability List (FTL) identifies the foods for which the additional traceability records are required. The additional recordkeeping requirements apply to the foods specifically listed on the FTL, and to foods that contain listed foods as ingredients, provided that the listed food that is used as an ingredient remains in the same form (e.g., fresh) in which it appears on the list.

For additional information about the FTL, view the [Food Traceability List \(/food/food-safety-modernization-act-fsma/food-traceability-list\)](/food/food-safety-modernization-act-fsma/food-traceability-list).

Key Features

1. Critical Tracking Events (CTE) (§ 1.1325 through 1.1350)

The final rule identifies Critical Tracking Events (CTEs) for which records containing Key Data Elements (KDEs) will be required. The KDEs required will vary depending on the CTE that is being performed.

The Critical Tracking Events in the final rule are harvesting; cooling (before initial packing); initial packing of a raw agricultural commodity other than a food obtained from a fishing vessel; first land-based receiving of a food obtained from a fishing vessel; shipping; receiving; and transformation of the food.

Below is a brief description of each CTE. For a detailed description of the KDEs that would be required for each CTE, see [Critical Tracking Events and Key Data Elements \(/media/163132/download\)](/media/163132/download). You can also see how the final rule applies in three different supply chain examples below, including the KDEs and CTEs that would be associated with each commodity.

Harvesting

Harvesting applies to farms and farm mixed-type facilities and means activities that are traditionally performed on farms for the purpose of removing raw agriculture commodities (RACs) from the place they are grown or raised and preparing them for use as food.

Cooling

Cooling means active temperature reduction of a raw agricultural commodity (RAC) using hydrocooling, icing (except icing of seafood), forced air cooling, vacuum cooling, or a similar process.

Initial Packing

Initial Packing means packing a raw agricultural commodity (RAC), other than a food obtained from a fishing vessel, for the first time.

First Land-Based Receiver

First Land-based Receiver is the person taking possession of a food for the first time on land directly from a fishing vessel.

Shipping

Shipping is 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.

Receiving

Receiving is 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.

Transformation

Transformation is 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 (FTL). Transformation does not include the initial packing of a food or activities preceding that event (e.g., harvesting, cooling).

2. Traceability Lot Code

Traceability lot code (TLC) means a descriptor, often alphanumeric, used to uniquely identify a traceability lot within the records of the firm that assigned the traceability lot code.

You must assign a traceability lot code to a food on the Food Traceability List (FTL) when you do any of the following: initially pack a raw agricultural commodity (RAC) other than a food obtained from a fishing vessel; perform the first land-based receiving of a food obtained from a fishing vessel; or transform a food. If you receive an FTL food from an entity that is exempt from the final rule, you must assign a TLC if one has not already been assigned (unless you are a retail food establishment or restaurant). Otherwise, you must not establish a new TLC when you conduct other activities (e.g., shipping) for a food on the Food Traceability List.

Once a food has been assigned a TLC, the records required at each Critical Tracking Event (CTE) must include that TLC. All of the Key Data Elements (KDEs), including the TLC, must be linked to the relevant traceability lot.

3. Traceability Plan (§ 1.1315)

If you are subject to the requirements of the final rule, you must establish and maintain a traceability plan containing the following information:

1. A description of the procedures you use to maintain the records you are required to keep under this rule, including the format and location of these records.
2. A description of the procedures you use to identify foods on the Food Traceability List that you manufacture, process, pack, or hold;
3. A description of how you assign traceability lot codes to foods on the Food Traceability List, if applicable;
4. A statement identifying a point of contact for questions regarding your traceability plan and records; and
5. If you grow or raise a food on the Food Traceability List (other than eggs), a farm map showing the areas in which you grow or raise such foods.
 - i. The farm map must show the location and name of each field (or other growing area) in which you grow a food on the Food Traceability List, including geographic coordinates and any other information needed to identify the location of each field or growing area.

- ii. For aquaculture farms, the farm map instead must show the location and name of each container (e.g., pond, pool, tank, cage) in which you raise seafood on the Food Traceability List, including geographic coordinates and any other information needed to identify the location of each container.

4. Additional Requirements (§ 1.1455)

The final rule also requires that:

- Records must be maintained as original paper or electronic records, or true copies; they all must be legible and stored to prevent deterioration or loss. Electronic records may include valid, working electronic links to the information required to be maintained under the rule.
- All records required under this rule, along with any information required to understand the records, must be made available to the FDA within 24 hours after a request is made (or within a reasonable time to which the FDA has agreed).
- Unless exempt from this requirement, an electronic sortable spreadsheet containing relevant traceability information must be provided to the FDA within 24 hours of a request (or within some reasonable time to which the FDA has agreed) when necessary to assist the FDA during an outbreak, recall, or other threat to public health.

Full and Partial Exemptions

The final rule identifies certain exemptions and partial exemptions from the requirements of the final rule. The exemptions are listed in § 1.1305 of the final rule.

A tool is available to help stakeholders determine whether an exemption may apply to their situation. Users identify a topic area and then answer a series of yes or no questions.

- [Exemptions to the Food Traceability Rule \(https://collaboration.fda.gov/tefcv13/\)](https://collaboration.fda.gov/tefcv13/).

Critical Tracking Events and Key Data Elements

The Food Traceability Rule requires persons who manufacture, process, pack, or hold foods on the Food Traceability List (FTL) to maintain and provide to their supply chain partners with key data elements (KDEs) for certain critical tracking events (CTEs) in the food's supply chain. This framework forms the foundation for effective and efficient tracing and clearly communicates the information that FDA needs to perform such tracing.

The information that firms must keep and send forward under the rule varies depending on the type of supply chain activities they perform with respect to an FTL food, from harvesting or production of the food through processing, distribution, and receipt at retail or other point of service. Central to the proposed requirements is the assignment, recording, and sharing of traceability lot codes (TLCs) for FTL foods, as well as linking these TLCs to other information identifying the foods as they move through the supply chain.

[Learn the KDEs \(/media/163132/download\)](#) required for each CTE performed.

Supply Chain Examples

The Food Traceability Rule requires persons who manufacture, process, pack, or hold foods on the Food Traceability List (FTL) to maintain and provide to their supply chain partners specific information – called **Key Data Elements** (KDEs) – for certain **Critical Tracking Events** (CTEs) in the food's supply chain. This framework forms the foundation for effective and efficient tracing of food.

The following examples show the Key Data Elements required for the Critical Tracking Events in three example supply chains – fresh cucumbers, tuna steaks, and soft cheese.

Produce Supply Chain Example

- [Video Presentation \(https://youtu.be/ZcSBvLQ6p6M\)](https://youtu.be/ZcSBvLQ6p6M)  <http://www.fda.gov/about-fda/website-policies/website-disclaimer>
- [Transcript \(/media/163059/download\)](#)
- [Slides \(/media/163054/download\)](#)