

TRACEABILITY BASICS

FDA Food Safety Modernization Act (FSMA) Section 204(d)
Requirements for Additional Traceability Records for Certain Foods (87 Fed. Reg. 70,910)
[Final Rule \(PDF\)](#) [FDA Summary](#)

COMPLIANCE DATE: JANUARY 20, 2026

SUMMARY

The final Traceability Rule establishes recordkeeping requirements for food entities who manufacture, process, pack, or hold foods on the Food Traceability List (**FTL**). It requires that these food entities provide their supply chain partners Key Data Elements (**KDE**) for certain Critical Tracking Events (**CTE**) in the handling of the food.

This rule requires food entities to:

- Create and maintain a traceability plan
- Assign traceability lot codes, record, and share Key Data Elements for all Food Traceability List foods and Food Traceability List containing foods
- Provide records with Key Data Elements to FDA in the case of an outbreak within 24 hours in an electronic sortable spreadsheet
- Comply by January 20, 2026

FOOD TRACEABILITY LIST (FTL)

The FTL includes all foods listed below and foods that contain the foods listed below. The FDA will update this list periodically. Proposed changes will have the opportunity for comment.

- Cheeses, other than hard cheeses, specifically:
 - Cheese (made from pasteurized milk), fresh soft or soft unripened
 - Cheese (made from pasteurized milk), soft ripened or semi-soft
 - Cheese (made from unpasteurized milk), other than hard cheese
- Shell eggs
- Nut butters
- Cucumbers (fresh)
- Herbs (fresh)
- Leafy greens (fresh)
- Leafy greens (fresh-cut)
- Melons (fresh)
- Peppers (fresh)
- Sprouts (fresh)
- Tomatoes (fresh)
- Tropical tree fruits (fresh)
- Fruits (fresh-cut)
- Vegetables other than leafy greens (fresh-cut)
- Finfish (fresh and frozen), specifically:
 - Finfish, histamine-producing species
 - Finfish, species potentially contaminated with ciguatoxin
 - Finfish, species not associated with histamine or ciguatoxin
- Smoked finfish (refrigerated and frozen)
- Crustaceans (fresh and frozen)
- Molluscan shellfish, bivalves (fresh and frozen)
- Ready-to-eat deli salads (refrigerated)

CRITICAL TRACKING EVENTS (CTE)

Below are the Critical Tracking Events that require the food entity to record and share Key Data Elements and possibly assign Traceability Lot Codes:

- Harvesting (raw agricultural products not obtained from a fishing vessel)
- Cooling before initial packing (raw agricultural products not obtained from a fishing vessel)
- Initial Packing (food products not obtained from a fishing vessel)
- First Land-Based Receiver (food obtained from a fishing vessel)
- Shipping
- Receiving
- Transformation

TRACEABILITY LOT CODES

Traceability Lot Codes are used to identify foods as they move through the supply chain. At certain Critical Tracking Events, you will be required to create new Traceability Lot Codes. A Traceability Lot Code must be assigned by a food entity when they:

- initially pack raw agricultural commodities (“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 by manufacturing/processing a food or by changing the food or its packaging or labeling.

Traceability Lot Code Definitions

- **Traceability Lot:** means a batch or lot of food that has been *initially packed* (for RACs other than food obtained from a fishing vessel), *received* by the first land-based receiver (for food obtained from a fishing vessel), or *transformed*.
- **Traceability Lot Code:** means a descriptor, often alphanumeric, used to uniquely identify a traceability lot within the records of the traceability lot code source.
- **Traceability Lot Code Source:** means the place where food(s) was assigned a traceability lot code.
- **Traceability Lot Code Source Reference:** means an alternative method for providing FDA with access to the location description for the traceability lot code source as required under this subpart.

Traceability lot codes should **NOT** be assigned during other critical tracking events like shipping. Shippers and receivers of FTL foods must provide the Traceability Lot Code and other Key Data Elements to the recipients of the food. To avoid disclosing confidential information about their suppliers, instead of directly identifying the Traceability Lot Code Source of an FTL food, the shipper may instead choose to provide a Traceability Lot Code Source Reference, that provides an alternative means for FDA to identify and contact the Traceability Lot Code Source for the food.

KEY DATA ELEMENTS (KDE)

Information requirements vary based on each Critical Tracking Event, starting from harvesting or production through processing, distribution, and retail. Below is a summary of what will be required.

Shipping

- Traceability Lot Code for the food
- Quantity and unit of measure of the food
- Product description for the food
- Location description for the immediate subsequent recipient (other than a transporter) of the food
- Location description for the location from which you shipped the food
- Date you shipped the food
- Location description for the Traceability Lot Code source or the Traceability Lot Code Source Reference
- Reference document type and reference document number (maintain only)

Receiving

- Traceability Lot Code for the food
- Quantity and unit of measure of the food
- Product description for the food
- Location description for the immediate previous source (other than a transporter) for the food
- Location description for where the food was received
- Date you received the food
- Location description for the Traceability Lot Code Source or the Traceability Lot Code Source Reference
- Reference document type and reference document number

Receiving (For food you receive from a person who is exempt from the rule)

- Traceability Lot Code for the food, which you must assign if one has not already been assigned (does not apply to retail food establishments or restaurants if not shipping)
- Quantity and unit of measure of the food
- Product description for the food
- Location description for the immediate previous source (other than a transporter) for the food
- Location description for where the food was received (i.e., Traceability Lot Code Source) and (if applicable) Traceability Lot Code Source Reference
- Date you received the food
- Reference document type and reference document number

Transformation (FTL foods used as ingredients)

- Traceability Lot Code for the FTL food
- Product description for the food to which the Traceability Lot Code applies
- For each traceability lot used, the quantity and unit of measure of the food used from that lot

Transformation (New food produced)

- New Traceability Lot Code for the food
- Location description for where you transformed the food (i.e., the Traceability Lot Code Source), and (if applicable) the Traceability Lot Code Source Reference
- Date transformation was completed
- Product description for the food
- Quantity and unit of measure of the food
- Reference document type and reference document number Traceability Lot Codes

TRACEABILITY PLAN

You must create and maintain a Traceability Plan. Your Traceability Plan must be updated as needed and you must keep your old Traceability Plans for two years. The Traceability Plan must include the following items:

- 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.
- A description of the procedures you use to identify foods on the Food Traceability List that you manufacture, process, pack, or hold.
- A description of how you assign traceability lot codes to foods on the Food Traceability List, 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 Food Traceability List (other than eggs), a farm map showing the areas in which you grow or raise such foods.

ENFORCEMENT

- Failure to comply will be deemed a prohibited act under FSMA.
- Penalties for prohibited acts include all the FDA's enforcement authority, including injunction, criminal prosecution, product seizure, administrative detention, and facility registration suspension or revocation.
- There is presently no authority for FDA to levy fines for violation of the food provisions of the FD&C Act outside of a criminal prosecution.
- The FDA has yet to release a full enforcement plan, but they will likely be working with local food safety agencies to enforce this rule.

EXEMPTIONS

Below is a list of some exemptions that may apply to some retailers.

- Foods regulated by the USDA are exempted.
- Exemptions and partial exemptions for foods that receive certain types of processing. This includes foods that receive certain types of processing:
 - Produce that receives commercial processing that adequately reduces the presence of microorganisms of public health significance.
 - Food that you receive that has previously been subjected to a kill step or that has previously been changed such that the food is no longer on the FTL.

- Food that will be subjected to a kill step by an FTL food entity *other than* a retail food establishment, restaurant, or consumer; or that will be changed by an entity other than a retail food establishment, restaurant, or consumer, such that the food will no longer be on the FTL, provided that the additional requirements laid out in the Final Rule are met.
- Exemption for small retail food establishments and small restaurants. This includes retail food establishments and restaurants with an average annual monetary value of food sold or provided during the previous three (3) year period of no more than \$250,000 on a rolling basis.
- Partial exemption for retail food establishments and restaurants purchasing directly from a farm.
- Partial exemption for retail food establishments and restaurants making certain purchases from another retail food establishment or restaurant. This includes either entity when a purchase is made by a retail food establishment or restaurant from another retail food establishment or restaurant, and the purchase occurs on an ad hoc basis outside of the buyer's usual purchasing practice.
- Exemption for transporters. This includes those who transport food like Instacart.
- Exemption for nonprofit food establishments.

THIRD PARTY RECORD MAINTENANCE

The Final Rule allows food entities to have another entity establish and maintain required records on their behalf, although the person subject to the final rule remains responsible for ensuring the records can be provided onsite to FDA within twenty-four (24) hours of the FDA's request for official review. Electronic records are considered onsite if they are accessible from an onsite location.

RESOURCES

Food Traceability List

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

Exemptions Eligibility Tool

- <https://collaboration.fda.gov/tefcv13/>

Critical Tracking Event (CTE) and Key Data Elements (KDE) Slides

- <https://www.fda.gov/media/163132/download>

Supply Chain Examples

- <https://www.fda.gov/media/169511/download?attachment>

Small Entity Compliance Guide

- <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/small-entity-compliance-guide-requirements-additional-traceability-records-certain-foods-what-you>

FAQ

- <https://www.fda.gov/food/food-safety-modernization-act-fsma/frequently-asked-questions-fsma-food-traceability-rule>

FSMA Technical Assistance Network (TAN)

- <https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-technical-assistance-network-tan>