

FDA Food Traceability Final Rule

What do Retailers, Wholesalers and Manufacturers need to know about the FDA Food Traceability Final Rule?

In November 2022, the FDA published one of the last required regulations under the Food Safety Modernization Act (FSMA). The FDA was instructed to develop regulations to require additional traceability records to be maintained for high-risk foods as defined by the FDA. The FDA did not publish a list of high-risk foods, but instead developed a risk ranking model for foods and then published a more expansive [Food Traceability List \(FTL\)](#). The FTL identifies the categories of foods, but not the individual foods for which additional traceability records are required. FDA hopes that the recordkeeping requirements in the final rule will result in faster identification and rapid removal of potentially contaminated food from the market, resulting in fewer foodborne illnesses and/or deaths, but it does not have a prevention focus.

What is the timeline for compliance?

The current compliance date for all covered entities outlined in the rule is January 20, 2026.

Who does the rule impact?

The rule covers the entire food supply chain (domestic and foreign) and applies to persons who manufacture, process, pack, or hold foods on the Food Traceability List (FTL) or foods that contain a listed food as an ingredient, unless an exemption applies. The final rule provides a number of complete and partial exemptions for certain entities and foods from the requirements of the rule (§ 1.1305).

What foods are on the Food Traceability List and will require the additional traceability recordkeeping?

The Food Traceability List (FTL) is based on commodity categories and identifies foods for which additional traceability records are required. Additional traceability records are required for all foods listed on the FTL and all foods containing listed foods as ingredients (provided the listed food remains in the same form (e.g., fresh)). The foods listed on the [Food Traceability List](#) include:

- Cheeses, other than hard cheeses, specifically:
 - Cheese (made from pasteurized milk), fresh soft or soft un-ripened
 - Cheese (made from pasteurized milk), soft ripened or semi-soft
 - Cheese (made from unpasteurized milk), other than hard cheese
- Shell eggs
- Nut butter
- 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)

What traceability records are required?

Persons who manufacture, process, pack or hold foods on the Food Traceability List (FTL) must maintain and/or provide to supply chain partners, specific information (i.e., **Key Data Elements or KDEs**) associated with different events in the food supply chain (i.e., **Critical Tracking Events or CTEs**) and link that information to a traceability lot code. The rule identifies the following events in the food supply chain as the Critical Tracking Events (CTEs) for which traceability records containing Key Data Elements (KDEs) are required to be maintained and provided:

- Harvesting (§1.1325(a))
- Cooling (before initial packing) (§1.1325(b))
- Initial packing of a RAC (other than a food obtained from a fishing vessel) (§1.1330)
- First land-based receiving (of a food obtained from a fishing vessel) (§1.1335)
- Shipping (§1.1340)
- Receiving (§1.1345)
- Transformation of a food (§1.1350)

Traceability lot codes are central to the rule's operation and are used to identify food(s) as they move through the supply chain and maintain other records relating to their activities. At each Critical Tracking Event, required records must include the traceability lot code and Key Data Elements that are linked to the relevant traceability lot

In addition to records of certain CTEs, entities subject to the rule must establish and maintain a traceability plan. The **traceability plan** contains information related to an entities' traceability procedures and traceability operations and is intended to help regulators understand the records they review. The traceability plan must include:

- A description of the procedures used to maintain the required records;
- A description of the procedures used to identify foods on the FTL that an entity manufactures, processes, packs, or holds. For farms, this includes any foods on the FTL that the farm grows.
- A description of how traceability lot codes are assigned (if applicable);
- A point of contact for questions regarding your traceability plan and records; and
- *For farms that grow or raise food on the FTL*, a farm map showing the areas where the food is grown or raised. Farm map must show location and name of each field (or other growing area) where food on the FTL is grown, including geographic coordinates and any other information needed to identify the location of each field or growing area.
 - *For aquaculture farms*, the farm map instead must show the location and name of each container (e.g., pond, pool, tank, cage) in which the seafood on the FTL is raised, including geographic coordinates and any other information needed to identify the location of each container.

How often does the Food Traceability Plan need to be updated (§ 1.1315(b))?

The traceability plan must be updated as needed to ensure that the information provided reflects the current practices and to ensure compliance with the requirements. Previous traceability plans must be retained for 2 years after the plan has been updated.

Is a separate traceability plan needed for each food on the FTL that a covered entity handles?

An entity can have a single plan that covers all the FTL foods that they handle, provided that the plan describes, among other things, the procedures used to maintain the records required to be kept for all such foods.

How do the records need to be maintained and made available (§ 1.455)?

The final rule requires records be kept as original paper records, electronic records, or true copies. Records must be made available to FDA, upon request, within 24 hours (or within some reasonable time to which FDA has agreed) after the request is made along with any information needed to understand these records, such as internal or external coding systems, glossaries, abbreviations, and a description of how the records you provide correspond to the information required.

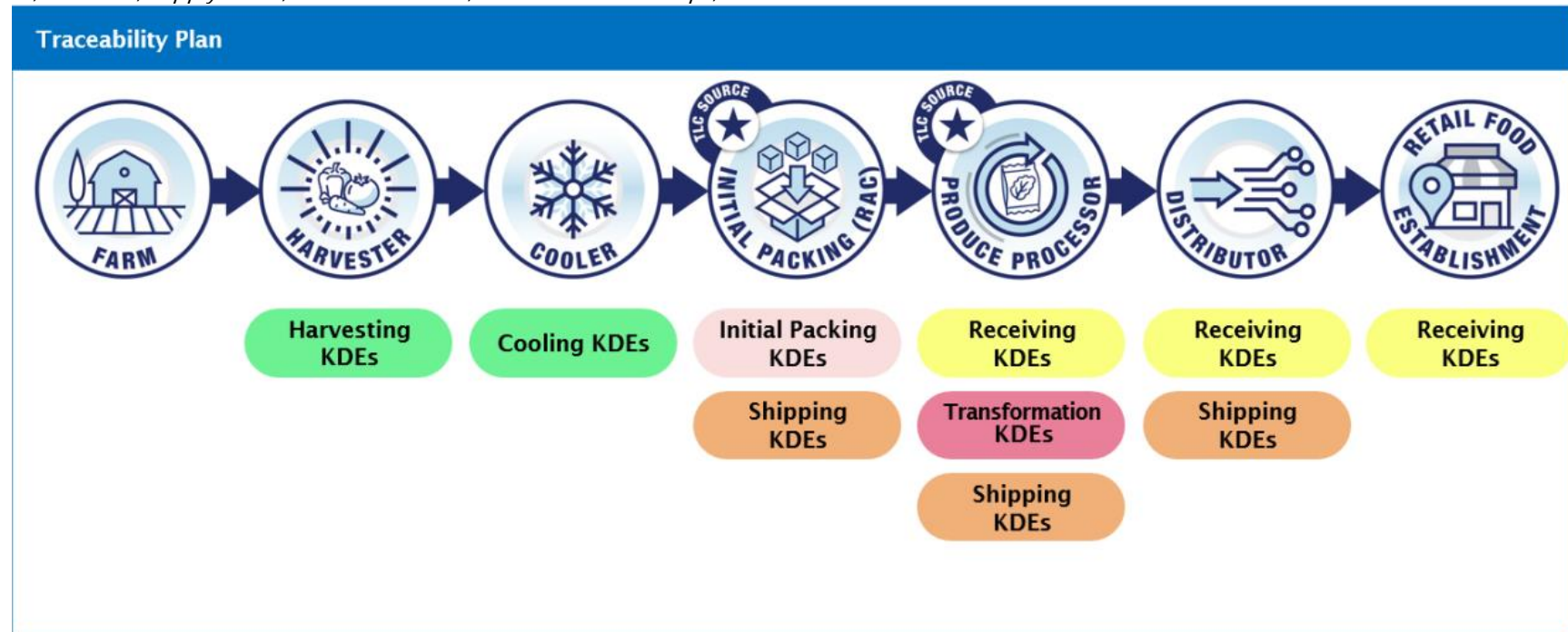
When information is requested that FDA feels is necessary to help prevent/mitigate a foodborne illness outbreak or assist with a recall or address other threats to public health, unless exempt, an electronic sortable spreadsheet containing relevant traceability information must be provided to FDA within 24 hours of a request.

How long do the records need to be kept?

In most cases, records containing the information required under the final rule must be maintained for 2 years from the date the records were created or obtained. Records maintained by a retail food establishment or restaurant for food purchased directly from a farm must be maintained for 180 days. A previous traceability plan must be retained for 2 years after the plan has been updated.

Example of CTEs and KDEs in a Fresh Cucumber Supply Chain

The graphic below provides an example of what Critical Tracking Events (CTEs) and Key Data Elements (KDEs) would be required for various entities in a fresh cucumber supply chain. *Note this is one example provided by FDA and requirements will vary depending on a number of factors, such as, the food, supply chain, entities involved, business relationships, etc.*



Additional Information and Resources

FMI FSMA Resource Center

<https://www.fmi.org/food-safety-modernization-act-resource-center/traceability>

FDA Food Traceability Webpage

<https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-final-rule-requirements-additional-traceability-records-certain-foods>

January 10, 2023