

The FDA Food Traceability Rule At-A-Glance



Background

The Food Traceability Rule (FTR) establishes additional traceability recordkeeping requirements (beyond what is already required in existing regulations) for persons who manufacture, process, pack, or hold foods on the [Food Traceability List](#) (FTL).

The new requirements will allow for faster identification and removal of potentially contaminated food from the market, resulting in fewer foodborne illnesses and deaths.

The rule applies to domestic entities as well as foreign entities producing food for U.S. consumption. The FTR contains certain exemptions and partial exemptions. See FDA's [online exemptions tool](#) for more information.

Food Traceability List (FTL)

The recordkeeping requirements in the rule 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.



Food Traceability List

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

What are the requirements of the rule?

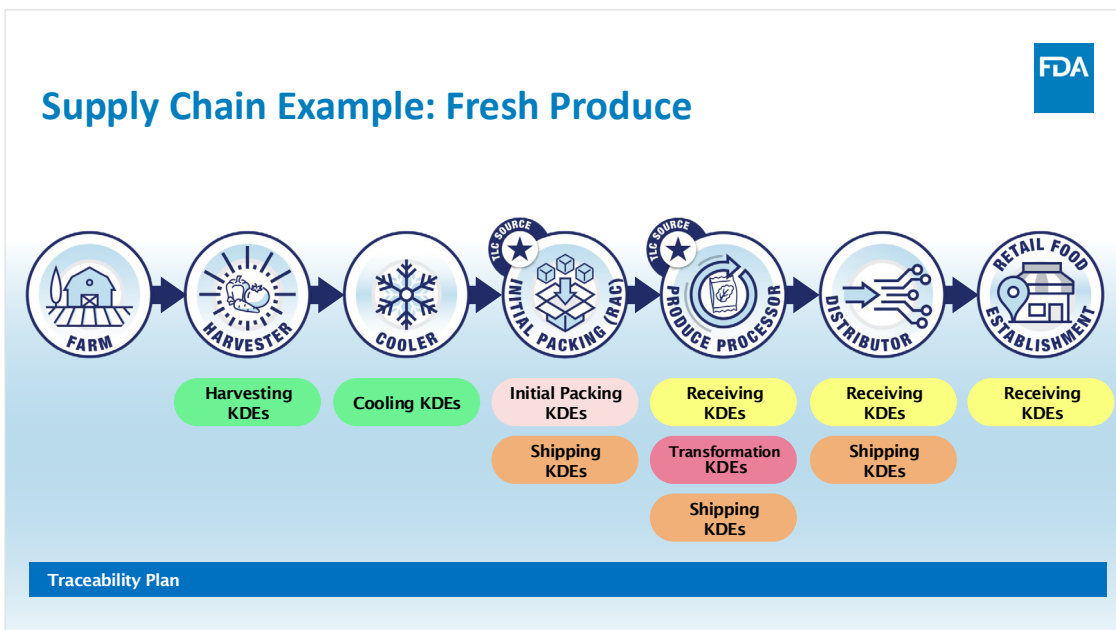
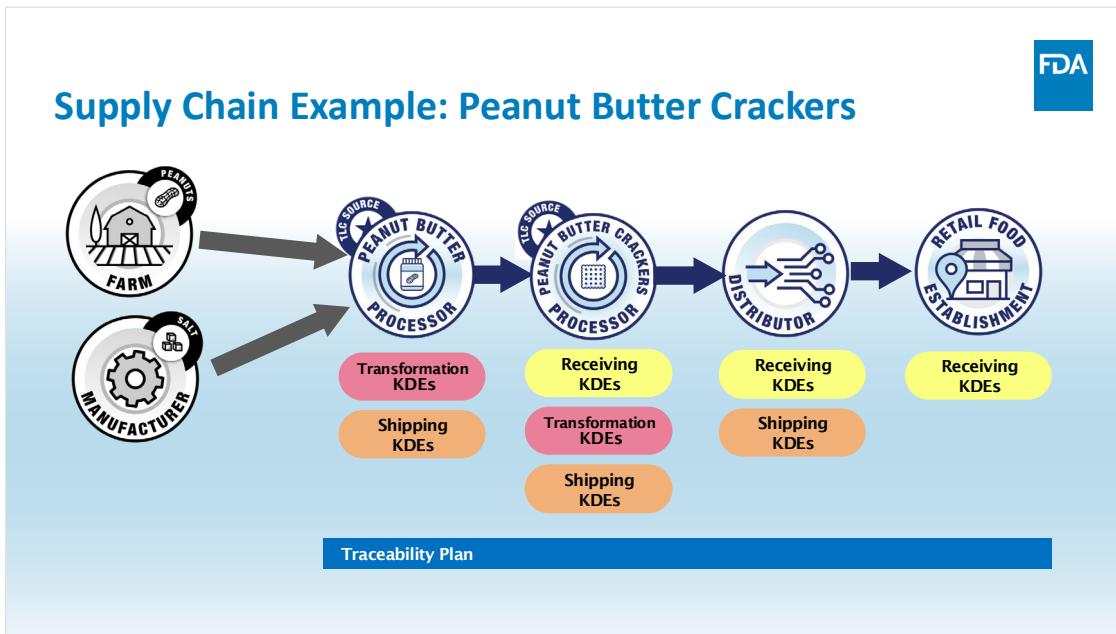
Critical Tracking Events and Key Data Elements

The rule identifies Critical Tracking Events (CTEs) along the supply chain where it is necessary to collect traceability information. These are:

Harvesting	Cooling (Before Initial Packing)	Initial Packing (RAC)	First Land-Based Receiver	Shipping	Receiving	Transformation
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For each CTE an entity conducts, the rule requires that **Key Data Elements (KDEs)** are maintained. The KDEs required will vary depending on the CTE that is being performed.

Below are two supply chain examples that demonstrate the CTEs at different points in the supply chain where KDEs must be maintained. Additional examples are available on [FDA's Food Traceability Rule webpage](#).



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 TLC to a food on the FTL when you do any of the following:

- Initial Packing
- First Land-Based Receiving
- Transformation
- Receiving an FTL food from someone who did not assign a TLC because they are exempt (not required if you are a Retail Food Establishment (RFE) or restaurant)

You cannot change the TLC in any other situation. It stays the same as the product moves through the supply chain. All of the KDEs, including the TLC, must be linked to the relevant traceability lot of the food.

How to get started

1. Do you manufacture, process, pack or hold a food on the [Food Traceability List](#)?
2. Do [any full or partial exemptions from the Food Traceability Rule](#) apply to your situation?
3. What [Critical Tracking Events \(CTEs\)](#) do you conduct?
4. What [Key Data Elements \(KDEs\)](#) do you already maintain? What additional KDEs do you need to maintain to be in compliance with the rule?
5. Develop a [traceability plan](#).
6. Talk with your supply chain partners. Understand the recordkeeping practices in your supply chains. Determine how best to communicate required information. Discuss potential solutions.

Traceability Plan

The traceability plan describes your traceability procedures and helps FDA understand how your firm is maintaining the required records. Examples of traceability plans are available on [FDA's Food Traceability Rule webpage](#), and the full requirements are outlined in [section 1.1315](#) of the FTR. You must establish and maintain a traceability plan containing:

1. Procedures you use to maintain the required records, including the format and location;
2. Procedures you use to identify foods on the FTL that you handle;
3. How you assign traceability lot codes to foods on the FTL, if applicable;
4. A point of contact for questions regarding your traceability plan and records; and
5. A farm map showing the areas in which you grow or raise foods on the FTL, if applicable.

Additional Requirements

Records must be maintained as original paper or electronic records, or true copies.

Records must be available within 24 hours after a request by FDA, unless FDA agrees to a longer timeline. You do not need to duplicate the records you already keep, and you do not need to keep all of the required information in a single set of records; you may supplement your existing records as necessary so that you have all of the required information.

During an outbreak, recall, or other threat to public health, the traceability information must be provided in an **electronic sortable spreadsheet** within 24 hours (or within some reasonable time to which FDA has agreed) of a request by FDA. An electronic sortable spreadsheet template is available on [FDA's Food Traceability Rule webpage](#).

Additional Resources:

- [FDA Food Traceability Final Rule webpage](#) (includes resources in Spanish, Chinese, French, Thai, Vietnamese, and Indonesian)
- [Food Traceability List webpage](#)
- [Frequently Asked Questions webpage](#)
- Questions related to the rule should be sent to the [FSMA Technical Assistance Network](#)
- Access to resources:
[FSMA Final Rule on Requirements for Additional Traceability Records for Certain Foods](#)

