

Food Traceability Final Rule: Requirements for Additional Traceability Records for Certain Foods (FSMA Section 204)

DATE, 2023

MEETING/CONFERENCE NAME

NAME OF PRESENTER



Exemptions to the Food Traceability Rule

You are subject to the Food Traceability final rule, unless an exemption applies. To determine whether you may be exempt, please click on any of the following categories that may apply to you:

Farms	Certain types of processing
Commingled raw agricultural commodities (RAC)	Personal consumption, holding, food for specific consumers
Foreign vessels, public health threats	Other
Food food establishments (FFEL), restaurants	



What will the Food Traceability Rule require?



- Persons who manufacture, process, pack, or hold foods on the Food Traceability List
- Covers the entire food supply chain
- Includes both foreign and domestic entities
- Full and partial exemptions may apply

Exemptions

Farms

- Certain small produce farms
- Certain small shell egg producers
- Certain other small RAC producers
- Certain food produced + packaged on farm
- Farms selling food directly to consumers

Commingled raw agricultural commodities (RACs)

- Certain commingled RACs (not fruits & vegetables)
- Certain RACs that will be commingled

Fishing vessels, molluscan shellfish

- Owner/operator/agent in charge of a fishing vessel
- Raw bivalve molluscan shellfish

Retail food establishments (RFEs), restaurants

- Certain small RFEs + restaurants
- RFEs or restaurants purchasing food directly from a farm
- RFEs or restaurants purchasing food from another RFE or restaurant on ad hoc basis

Certain types of processing

- Produce and shell eggs that receive certain processing
- Exemptions related to a kill step
- Exemptions related to changing a food to a form not on the list

Personal consumption, holding food for individual consumers

- Personal consumption
- Holding food for individual consumers

Other

- Produce listed as “rarely consumed raw”
- Farm-to-school/farm-to-institution programs
- Foods regulated by USDA
- Transporters of food
- Non-profit food establishments
- Food for research or evaluation

Exemptions Tool

Exemptions to the Food Traceability Rule

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Personal consumption, holding food for specific consumers

Fishing vessels, molluscan shellfish

Other

Retail food establishments (RFEs), restaurants



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 and frozen)
Cucumbers (fresh)	Finfish (species potentially contaminated with ciguatoxin) (fresh and frozen)
Herbs (fresh)	Finfish, species not associated with histamine or ciguatoxin (fresh and frozen)
Leafy greens (fresh)	Smoked finfish (refrigerated and frozen)
Leafy greens (fresh-cut)	Crustaceans (fresh and frozen)
Melons (fresh)	Molluscan shellfish, bivalves (fresh and frozen)
Peppers (fresh)	Ready-to-eat deli salads (refrigerated)
Sprouts (fresh)	



Food Traceability List

- Foods specified as “fresh” on the FTL
- Fresh FTL foods used in multi-ingredient foods
- Changing the form of the food
- Foods not specified as “fresh” used in multi-ingredient foods
- Applying a kill step to the food

CTE and KDE Framework

The role of the entity in the supply chain defines the data it must keep and share

Critical Tracking Events

Harvesting, Cooling, Initial Packing, First Land-based Receiving, Shipping, Receiving, and Transforming are Critical Tracking Events (CTEs) for which records would be required.

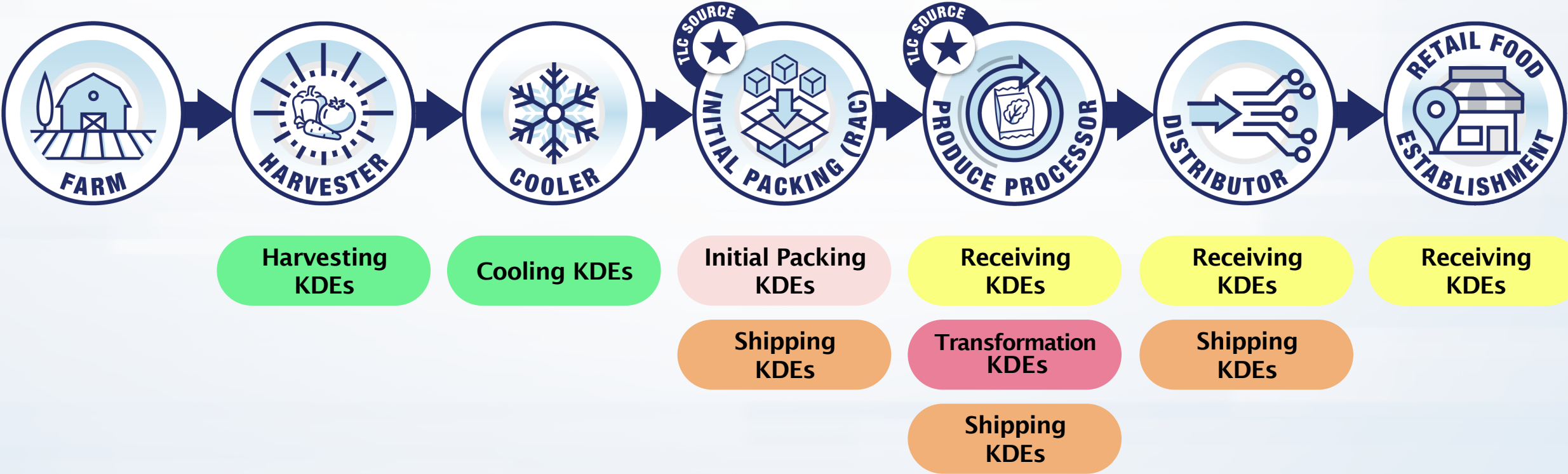
Key Data Elements

Required records would need to contain specific Key Data Elements (KDEs). The KDEs would depend on the CTE being performed.

The KDEs required would vary depending on the CTE that is being performed.

The records required at each CTE would need to contain and link the KDEs to the traceability lot.

Supply Chain Example: Fresh Produce



Initial Packer Example



KDEs for Incoming

- For each incoming RAC, the following KDEs should be linked to each traceability lot that gets packed:
- What you received*
- How much you received*
- Date you received it
- Where it came from*
- Information about harvesting and/or cooling*
- Reference document information



Packing KDEs

- For each traceability lot of a RAC that you pack, the following KDEs should be linked to the traceability lot:
- TLC you assigned
- Date you packed it
- What you packed
- How much you packed
- When you packed it
- Where you packed it
- Reference document information



Shipping KDEs

- For each traceability lot of a RAC that you ship after packing, the following KDEs should be linked to the traceability lot:
- TLC
- How much you shipped
- What you shipped
- Where you shipped it
- Where you shipped it from
- Date you shipped it
- Traceability lot code source information (i.e., where you packed it)
- Reference document information

* indicates KDEs you receive

Food Traceability Rule: Critical Tracking Events (CTEs) and Key Data Elements (KDEs)



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 (key data elements or 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 for FTL foods, as well as linking these lot codes to other information identifying the foods as they move through the supply chain.

Graphics on the subsequent pages provide readers with a list of KDEs required for each CTE performed.



Key Concepts of the Final Rule

- Framework of CTEs and KDEs
- Standard language
- Linking information by lot code
- Records provided to FDA within 24 hours
- Faster product identification and removal

Emphasis on...



Keeping and sharing KDEs



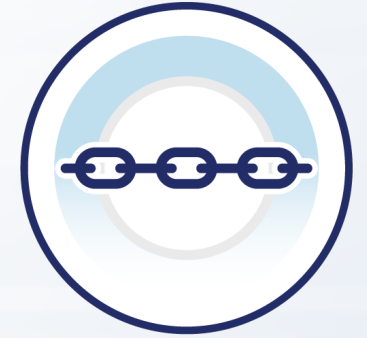
Traceability Lot Code (TLC)



Traceability Lot Code Source (TLC Source)



Traceability Plan



Working with supply chain partners

Records Maintenance and Availability



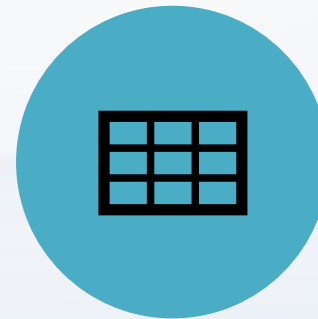
Legible **original paper, electronic**, or true copies. Stored to prevent deterioration or loss. May **include electronic links**.



Records must be **kept for 2 years**.



Available **within 24 hours (or reasonable time if FDA agrees)**. May be stored **offsite or by another entity**.



During an outbreak - **electronic sortable spreadsheet** within 24 hours of a request (including a **phone request**).

Compliance date

January 20, 2026

- Applies to all firms
- Provides 3 years for covered entities to work with supply chain
- We will educate before and while we regulate

More to come

- Outreach, education, technical assistance
- Additional communications materials to be posted
- Development of an internal FDA system to facilitate analysis of traceability information
- Development of system for sending required information to FDA



Implementation



- Currently considering best approach for conducting inspections under this rule
- Developing enforcement strategy and plan to work with State, Local, Tribal, Territorial and other regulatory partners to enforce rule
- Working with FSPCA to develop industry training

What can industry do to get started?

1. Do you manufacture, process, pack or hold a food on the [Food Traceability List](#)?
2. Do [any exemptions 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 final rule?
5. Develop a [traceability plan](#).
6. Talk with your supply chain partners.
 - Understand the record keeping practices in your supply chains
 - Determine how best to communicate required information
 - Discuss potential solutions
7. More resources available [here](#).



Available Resources

- **Food Traceability Final Rule ([Federal Register](#))**
 - Link directly to codified (Bookmark this!): <https://www.federalregister.gov/d/2022-24417/p-amd-1>
 - CTRL + F
- **Food Traceability Final Rule [webpage](#)**
 - NEW translations!
- **Frequently Asked Questions ([FAQs](#))**
 - NEW search feature!
- **Food Traceability Final Rule [Webinar](#)**
- **Critical Tracking Events and Key Data Elements [document](#)**
- **Exemptions [tool](#)**
- **Food Traceability List [webpage](#)**
- **Risk Ranking Model Results [tool](#)**

Available Resources (cont.)

- **Supply Chain Examples:**

- Produce Supply Chain Example
 - [Video Presentation](#)
 - [Transcript](#)
 - [Slides](#)
- Seafood Supply Chain Example
 - [Video Presentation](#)
 - [Transcript](#)
 - [Slides](#)
- Cheese Supply Chain Example
 - [Video Presentation](#)
 - [Transcript](#)
 - [Slides](#)
- Additional Supply Chain Examples
 - [Slides](#)

Retail Food Establishments and Restaurants

- Retail Food Establishments (RFEs) and Restaurants: [What Records Do I Need to Keep for the Food Traceability Rule?](#)
- Retail Food Establishments (RFEs) and Restaurants: [What You Need to Know About the Food Traceability Rule](#)
- Retail Food Establishments (RFEs) and Restaurants: [What You Need to Know About Establishing and Maintaining a Traceability Plan for the Food Traceability Rule](#)

Questions?

- FSMA Technical Assistance Network (TAN): <https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-technical-assistance-network-tan>

Thank you!

