

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

December 7, 2022



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
Domestic raw agricultural commodities (DRAC)	Personal consumption, taking food for specific consumers
Fishing vessels, public health risks	Other
Food food establishments (FFEL), restaurants	

What will the Food Traceability Rule require?



The rule requires covered persons to maintain records for foods on the Food Traceability List (FTL) to support more efficient and accurate traceability of potentially contaminated food

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

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 (RACs)

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

Key Concepts of the Final Rule

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

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.

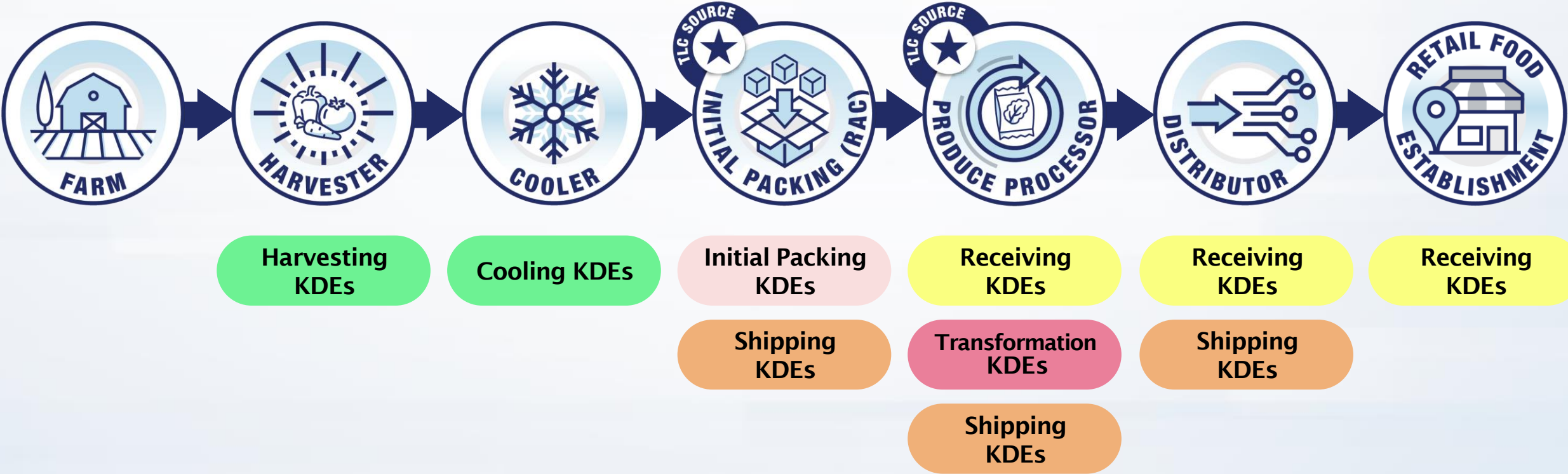
Key Data Elements

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



Emphasis on...



Keeping and sharing KDEs



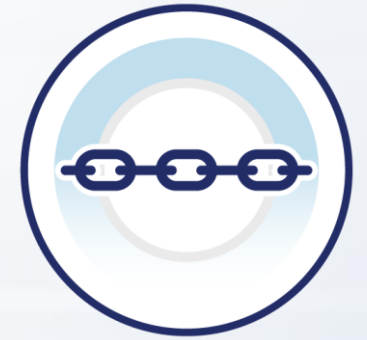
Traceability Lot Code (TLC)



Traceability Lot Code Source (TLC Source)



Traceability Plan



Working with supply chain partners



§1.1320: Establishing and Assigning Traceability Lot Codes



- Traceability Lot Code (TLC) is a descriptor, often alphanumeric, used to uniquely identify a traceability lot within the records of the traceability lot code source
- Traceability Plan must include a description of how you assign TLCs
- All KDEs must be linked to the traceability lot for the food
- Final rule offers flexibility on how TLCs are created and assigned



§1.1320: Establishing and Assigning Traceability Lot Codes



- TLC Source is the place where a food was assigned a TLC
 - This KDE helps FDA to more quickly identify this location and prioritize where we need to collect tracing data
- TLC Source Reference is an alternative method to provide TLC source information, examples include:
 - FDA Food Facility Registration Number for the traceability lot code source or
 - A web address that provides FDA with the location description for the traceability lot code source

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.





§1.1315: Traceability Plan

- A description of internal procedures used to maintain records under the rule
- Intended to help FDA more quickly review and understand the traceability information provided by a firm involving a food on the FTL
- Traceability plan must be updated as needed to reflect your current practices and ensure compliance with the final rule
 - The previous traceability plan must be maintained for 2 years after any update



§1.1315: Traceability Plan (Cont.)



- To understand the traceability records we review, firms must provide information on how they conduct their required traceability operations including:
 - Description of the procedures you use to maintain the records
 - Description of the procedures you use to identify foods on the FTL that you manufacture, process, pack, or hold
 - Description of how you assign traceability lot codes
 - A point of contact for questions regarding your traceability plan and records
 - If you grow or raise a food on the FTL (other than eggs), a farm map that shows the location and name of each field (or other growing area) in which you grow a food on the FTL



§1.1315: Farm Maps

For farms growing RACs (other than eggs), the farm map must show

- Farm map must show the location and name of each field (or other growing area) in which you grow a food on the FTL, including geographic coordinates
- Any other information needed to identify the location of each field or growing area

For aquaculture farms, the farm map must show

- The location and name of each container (e.g., pond, pool, tank, or cage) in which you raise seafood on the FTL, including geographic coordinates
- Any other information needed to identify the location of each container



§1.1315: Farm Maps (Cont.)



Appendix: Lizzie's Lettuce Field Map

Lizzie's Farm

Address: 113 Farm St, Farms, CA 11311

Field Name	Field Geographic Coordinates
Field A-08	-24.500145, -11.107417
Field D-03	-24.500144, -11.107418
Field C-02	-24.500146, -11.107419
Field B-09	-24.500147, -11.107416





§1.1325: Harvesting and Cooling a Raw Agricultural Commodity (RAC)



- This CTE pertains to RACs not obtained from a fishing vessel
- Farms that harvest or cool FTL food(s) prior to initial packing are required to keep KDEs and provide KDEs to the initial packer
 - Can be provided in electronic, paper, or other written form
 - Can be provided through the supply chain or directly to the initial packer
- Farms performing these activities are not required to maintain shipping or receiving KDEs for any FTL food before it is initially packed



§1.1330: Initial Packing of a RAC

- Initial packing KDEs including information about the incoming food and information about the packed food
- Farms that perform initial packing of FTL food(s) are not required to keep receiving KDEs, but they are required to keep and provide shipping KDEs relating to shipment after the food is initially packed
- Traceability lot codes are required to be assigned once a covered food is initially packed

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

§ 1.1455: Records Maintenance and Availability



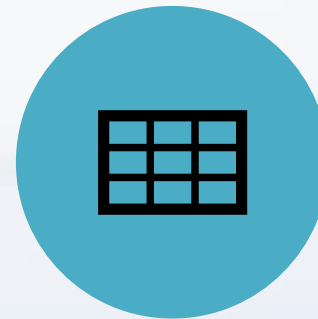
Legible **original paper, electronic**, or true copies. Stored to prevent deterioration or loss. May **include electronic links**.



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**).

§ 1.1455(c)(3)(ii): Electronic Sortable Spreadsheet

- Upon request by FDA, firms must provide an electronic sortable spreadsheet containing the information you are required to maintain:
 - When necessary to help prevent or mitigate a foodborne illness outbreak;
 - Assist in the implementation of a recall;
 - Or otherwise address a threat to public health
- Must be made available to FDA within 24 hours or within a reasonable, agreed upon time
- The electronic sortable spreadsheet will assist FDA in analyzing traceability information quickly

Electronic Sortable Spreadsheet Example

This represents an electronic sortable spreadsheet generated by a distribution center when FDA requested records for all FTL foods received from 9/18/2020 through 9/23/2020.

TLC	Quantity and UOM	Product Description	Immediate Previous Source Location Description*	Receiving Location Description*	Receive Date	TLC Source Location Description*/TLC Source Reference	Reference Document Type and Number
UPC:456456456403.BIUB:12OCT2020	50 CASES	CHARLES CHEESE CO. BRAND FETA CHEESE 10 x 32 OZ CONTAINERS	Charles' Cheese Co.	Distro Foodservice DC #45	9/23/2020	FFRN:456456	PO 111101
(01)11411411411404(10)FPP16-092220	100 CASES	FRESH PROCESSOR BRAND, CUT MANGOS, 12x1 LB BAGS	Fresh Processor Plant #16	Distro Foodservice DC #45	9/18/2020	11231 TLC Source, TLCville , MN, 55441	PO 456213
(01)11411411411402(10)FPP16-092420	50 CASES	FRESH PROCESSOR BRAND, CUT CANTALOUPE, 12x1 LB BAGS	Fresh Processor Plant #16	Distro Foodservice DC #45	9/21/2020	https://id.gs1.org/01/11411411411402/10/FPP16-092420	BOL 11401
(01)11411411411401(10)FPP16-092120	100 CASES	FRESH PROCESSOR BRAND, GARDEN SALAD KIT, 10x12 OZ BAGS	Fresh Processor Plant #16	Distro Foodservice DC #45	9/20/2020	https://id.gs1.org/01/11411411411401/10/FPP16-092120	BOL 11401
(01)22322322322302(10)FFI2020-09-20	140 CASES	FreshFish BRAND, FROZEN YELLOWFIN TUNA STEAKS, 25 LB CASE	FreshFish Importer Inc.	Distro Foodservice DC #45	9/22/2020	https://id.gs1.org/01/22322322322302/10/FFI2020-09-20	BOL 22302

*See Master Data Spreadsheet for full location descriptions

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
- Implementation planning has begun at FDA

Implementation and Enforcement



- Currently considering best approach for conducting inspections under this rule
- Developing compliance strategy and plan to work with State, Local, Tribal, Territorial and other regulatory partners to enforce rule
- Educate before and while we regulate

More to come

- Outreach, education, technical assistance
- Updates on FDA development of implementation approach
- Additional communications materials to be posted
- Development of system for sending required information to FDA



Thank you!

