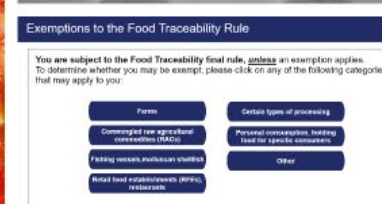
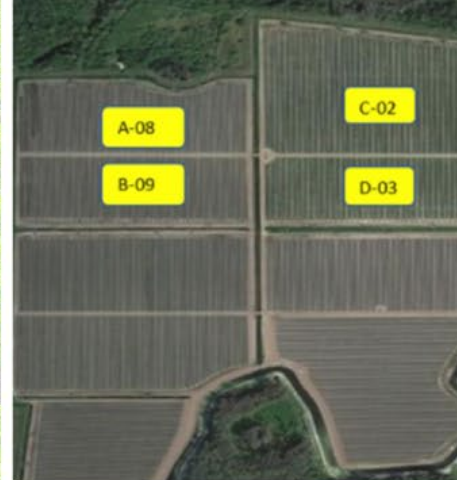


Food Traceability Final Rule: Requirements for Additional Traceability Records for Certain Foods (FSMA Section 204)

May 13, 2024

Michigan Department of Agriculture Food
Safety Alliance Meeting

Chris Waldrop, Senior Health Scientist,
CFSAN, FDA



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

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, 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)	



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

Updating the Food Traceability List

- We anticipate updating the list approximately every 5 years
- We will publish a notice in the *Federal Register* with the proposed changes, providing an opportunity for public comment
- A second *Federal Register* notice will state the final decision on any changes being made
- Additions to the list would become effective 2 years after this second *Federal Register* notice, unless otherwise stated
- Deletions from the list would be effective immediately

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.

Traceability Lot Code (TLC)



**Traceability Lot
Code (TLC)**

TLCs can only be assigned or changed when the following occurs:

- Initial packing of a RAC
- First land-based receiving of a food obtained from a fishing vessel
- Transformation of a food



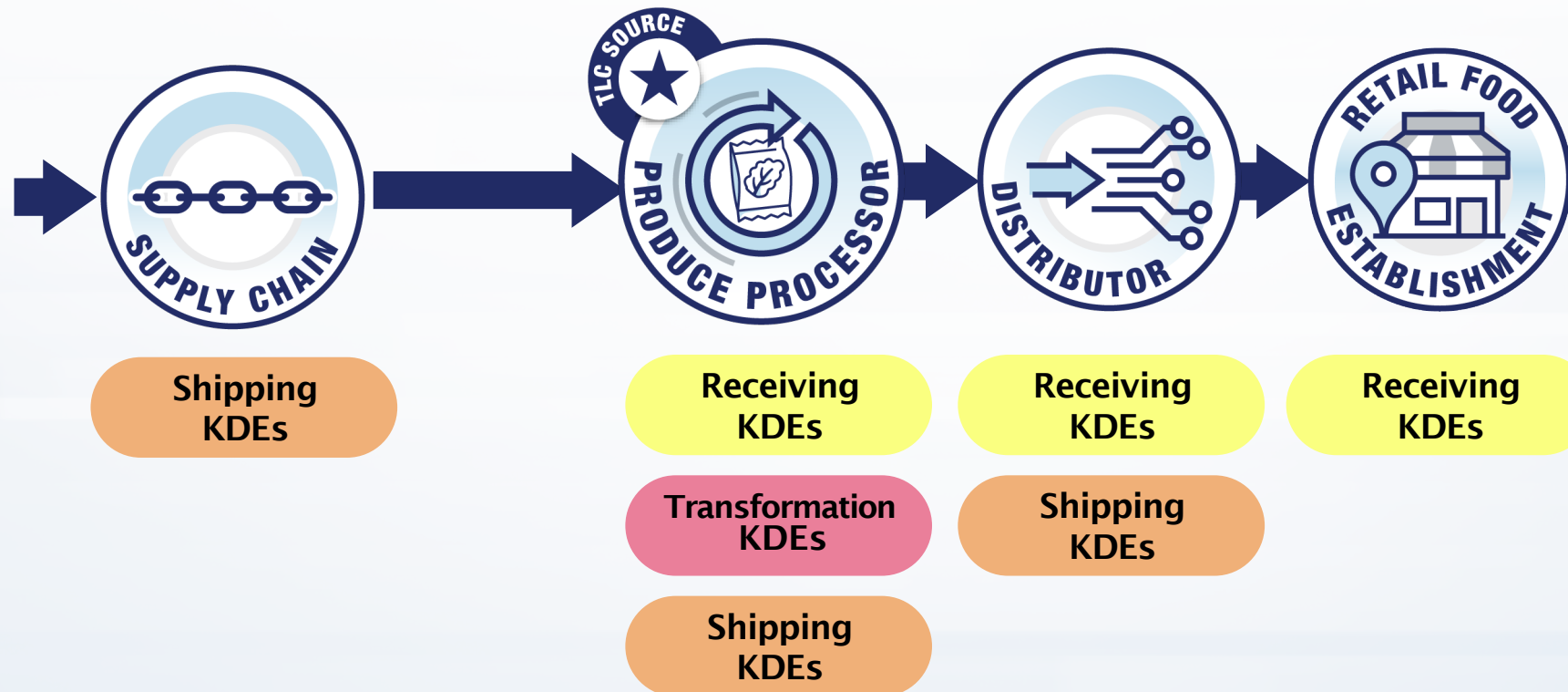
**Traceability Lot Code
Source (TLC Source)**

Once a TLC is assigned, the TLC must remain unchanged and passed thru the supply chain (unless a transformation even occurs)

Supply Chain Example: Fresh Produce



Partial Supply Chain Example



Traceability Plan

Manufacturer Example



Receiving KDEs

- For each traceability lot of FTL food received, the following KDEs should be linked to the traceability lot:
- TLC*
- How much you received*
- What you received*
- Where it came from*
- Where you received it*
- Date you received it*
- Traceability Lot Code Source information*
- Reference document information

* indicates KDEs you receive



Transformation KDEs

- For each traceability lot of FTL food used as an ingredient, the following KDEs should be linked to the new traceability lot:
 - Incoming TLC*
 - How much you used
 - What you used*
- For each new traceability lot of food produced:
 - New TLC
 - Where you transformed it (i.e., the TLC Source)
 - Date you made it
 - What you made
 - How much you made
 - Reference document information



Shipping KDEs

- For each traceability lot of FTL food you ship, 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
- Reference document information

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

Harvesting

Cooling
(before Initial
Packing)

Initial
Packing
(RAC)

First Land-Based
Receiver

Shipping

Receiving

Transformation

Traceability
Plan

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.





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 Example

The following is the Traceability Plan for Lizzie's Lettuce. **This is an example of a Traceability Plan. Please refer to §1.1315 of the Final Rule for the information that should be included in a Traceability Plan.*

Procedures to Maintain the Records

Digital records of all required KDEs are captured and stored in our commercial software solution.

Hard copies of Bills of Ladings are provided to subsequent recipients containing all KDEs except TLC/TLC Source Reference which is barcoded on product case labels. Some companies also receive digital advanced shipment notices containing all required KDEs.

Procedures to Identify FTL Foods

All products packed at this facility are on the FTL.

Assigning Traceability Lot Codes

Unique products/pack sizes are assigned a 14-digit case GS1 GTIN. Internal lot codes are assigned using date (MMDDYY) and packing line ("AAA" – "ZZZ"). Together the case GTIN and Internal Lot code represent our **traceability lot code**.

Point of Contact

Sarah Tree, Traceability Manager, 123-456-7899

Farm Map

See Appendix

Traceability Plan Updates

This plan is reviewed annually as part of our management review of our food safety system, as well as whenever something changes in our traceability procedure. Each previous traceability plan is kept in a [folder on SharePoint](#) for at least two years after it is updated.

Records Maintenance and Availability



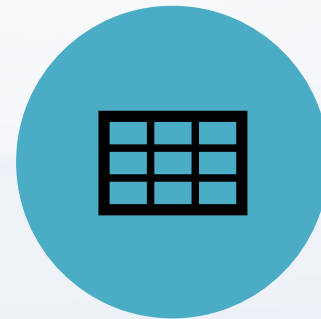
Legible **original paper, electronic**, or true copies. Stored to prevent deterioration or loss. May **include electronic links**.



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**).

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
- We will educate before and while we regulate
- Routine inspections will not begin until 2027

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

Available Resources

- Food Traceability Final Rule Preamble ([Federal Register](#))
 - Link directly to [codified](#)
- Food Traceability Final Rule [webpage](#)
- Translations
- Food Traceability List [webpage](#)
- Frequently Asked Questions ([FAQs](#))
- Food Traceability Final Rule [Webinar](#)
- Small Entities Compliance [Guide](#)
- Traceability Lot code [webpage](#)
- Critical Tracking Events and Key Data Elements [document](#)
- Exemptions [tool](#)
- Risk Ranking Model Results [tool](#)
- PSR/FTR exemptions [chart](#)
- Farms:
 - [What you need to know about the Food Traceability Rule: Coverage and Exemptions for Produce Farms](#)
 - [What you need to know about the Food Traceability Rule: Recordkeeping Information for Produce Farms](#)



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](#)
 - [Deli salads](#)

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!

