

**Webinar on the Food Traceability Final Rule
December 7, 2022
Presentation Slides**

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 |
| Commingled raw agricultural commodities (RAC) | Personal consumption, holding, food for specific consumers |
| Federal weapon, public-use facilities | Other |
| Retail food establishments (RFE), restaurants | |





Overview of the Final Rule

Katherine Vierk, Division Director, Division of Public Health Informatics & Analytics, Office of Analytics and Outreach (OAO), CFSAN

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



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) | |

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

Common questions on coverage

- Foreign entities?
- Farms?
- Importers?
- Aquaculture farms?
- Brokers?
- Wild-caught seafood?
- Distributors?
- Manufacturers?
- Restaurants?
- Repackers?
- Retail Food Establishments?
- Warehouses?
- Airline caterers?

If you manufacture, process, pack, or hold foods on the FTL, you are covered

***Full or partial exemptions may apply for your situation**

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.

Emphasis on...



Keeping and sharing KDEs



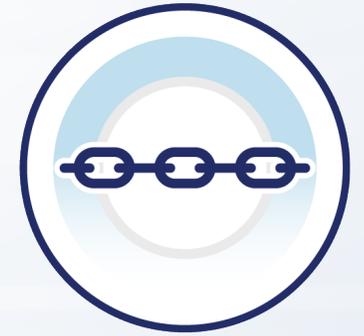
Traceability Lot Code (TLC)



Traceability Lot Code Source (TLC Source)



Traceability Plan



Working with your supply chain partners

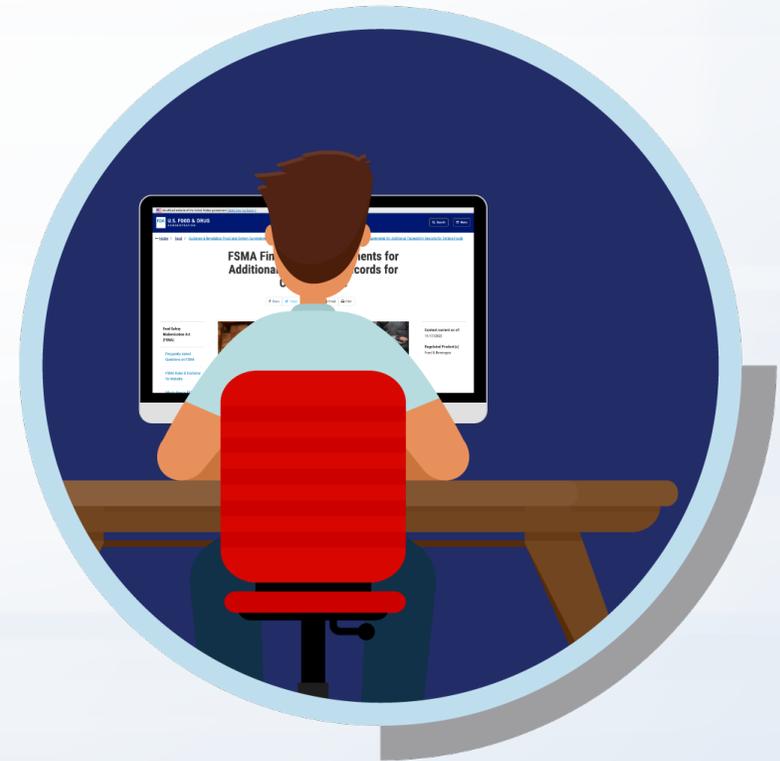
When do you have to comply?

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

What can you do to get started?

- **Review the materials on [fda.gov](https://www.fda.gov)**
 - Exemption tool
 - CTE and KDE clickable pdf
 - Videos of supply chain examples
 - FAQs
- **Begin talking to your supply chain partners**
 - Understand the record keeping practices in your supply chains
 - Determine how best to communicate required information
 - Discuss potential solutions



More to come

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

But we need to hear from you – what do you need?





FSMA Final Rule: Requirements for Additional Traceability Records for Certain Foods

Share Tweet LinkedIn Email Print

- Food Safety Modernization Act (FSMA)
- Frequently Asked Questions on FSMA
- FSMA Rules & Guidance for Industry
- What's New in FSMA
- FSMA Training



Content current as of: 11/17/2022
Regulated Product(s): Food & Beverages

- Full and Partial Exemptions
- Critical Tracking Events and Key Data Elements
- Supply Chain Examples
- Frequently Asked Questions about the Food Traceability Final Rule
- Stakeholder Calls, Webinars, and Meetings
- Contact Us**
- Additional Information

Additional questions, and requests for meetings and speaking engagements can be submitted via the links below. For meeting and speaker requests, please include a request form when you contact us.

[Inquiry/Information](#)

[Meeting Request](#) [Meeting Request Form](#)

[Speaker Request](#) [Speaker Request Form](#)

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

Contact Us – for questions and speaking requests

What you will hear today

Overview of the Final Regulatory Impact Analysis

Exemptions

Food Traceability List

Recordkeeping Requirements

Records Maintenance and Availability

Questions & Answers



Final Regulatory Impact Analysis Overview

Aliya Sassi, PhD, Senior Economist, Office of Economics and Analysis, Office of Policy, Legislation, and International Affairs, Office of the Commissioner, FDA

Economic Impact Summary

| Measure | Final rule |
|--|------------|
| Covered Firms | 323,872 |
| Covered Establishments | 484,124 |
| Benefits (millions \$*) | |
| - Public Health Benefits | \$780 |
| - Non-health Benefits from Avoiding Overly Broad Recalls | \$575 |
| Costs (millions \$*) | |
| - Costs to Domestic Entities | \$570 |
| - Costs to Foreign Entities | \$51 |
| Net Health Benefits (millions \$*) | \$210 |

*in \$2020, 7% discount rate, over 20 years. Non-quantified benefits and costs discussed in the RIA are not included in this table.

Benefits

- Public health benefits
 - The value of averted foodborne illnesses
 - The rule is likely to reduce the time that a contaminated food product is distributed in the market
- Benefits from avoiding costs of overly broad recalls
 - The value of implementing more precise food recalls and advisories due to improved tracing
- Other benefits discussed qualitatively

Other (Non-Health) Benefits

- Avoidance of costs due to unnecessary preventive actions by consumers
- Reduction in food waste
- Improvements in supply chain management and inventory control
- More expedient initiation and completion of recalls
- Cost savings to FDA and industry from outbreak investigation efficiencies
- Other supply system efficiencies due to standardized approach to traceability, including increase in transparency and trust

Types of Costs to Industry

- Firms that manufacture, process, pack or hold foods on the FTL would need to:
 - Read and understand the rule (one-time cost)
 - Establish a traceability plan and search inventory for covered products (one-time cost)
 - Invest in capital if needed (one-time and recurring costs)
 - Train personnel (one-time and recurring costs)
 - Maintain and provide the required records (recurring costs)

Thank you!





Exemptions

Rebecca Goldberg, Senior Counsel, Office of the Chief Counsel, Office of the Commissioner, FDA

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

Size-Based Exemptions

| Type of Entity | Exemption Cut-off |
|---------------------|-------------------|
| Produce Farms | Sales ≤ \$25,000 |
| Shell Egg Producers | < 3,000 layers |
| Other RAC Producers | Sales ≤ \$25,000 |
| RFEs & Restaurants | Sales ≤ \$250,000 |

Exemptions related to farms

- Food produced and packaged on the farm
 - Packaging must remain in place until the food reaches the consumer
 - Packaging must maintain integrity of the food and prevent subsequent contamination
 - Labeling that reaches the consumer must include farm name, address, and phone number
- Food sold directly to consumers by the farm

Exemptions related to commingled RACs

- RACs that are combined or mixed after harvesting but before processing
 - Only applies to RACs that are not fruits or vegetables
 - Combining or mixing must involve:
 - Food from different farms under different company management (e.g., eggs or aquacultured seafood); or
 - Food from different landing vessels after the vessels have landed
 - If required to register with FDA as a food facility, exempt entities must maintain records of immediate previous source and immediate subsequent recipient

Exemptions related to commingled RACs (Cont.)

- RACs that will be combined or mixed after harvesting but before processing
- Provided that you enter into a written agreement

Exemptions related to fishing vessels, molluscan shellfish

- Owner, operator, or agent in charge of a fishing vessel
 - If required to register with FDA as a food facility, then must maintain records of immediate previous source and immediate subsequent recipient
- Entities that handle food obtained from a fishing vessel that has not yet been sold by the owner, operator, or agent in charge of the fishing vessel
 - If required to register with FDA as a food facility, then must maintain records of immediate previous source and immediate subsequent recipient
- Raw bivalve molluscan shellfish
 - Covered by NSSP, or
 - Subject to the requirements of part 123, subpart C, and § 1240.60, or
 - Covered by final equivalence determination by FDA

Exemptions related to retail food establishments and restaurants

- Purchasing food directly from a farm
 - Food is produced on the farm
 - Food is sold and shipped directly to the RFE or restaurant, by the farm
 - Must keep a record (for 180 days) documenting the name and address of the farm
- Purchasing food from another RFE or restaurant on an ad hoc basis
 - Both entities are exempt, but purchaser must keep a record (e.g., sales receipt) documenting the food, date of purchase, and name and address of place of purchase

Certain types of processing

- Exemptions related to a kill step
- Exemptions related to changing a food to a form not on the list

Certain types of processing (Cont.)

- Produce that receives the Produce Safety Rule’s “commercial processing exemption”
 - Full exemption, even before the processing occurs
 - Produce Safety Rule conditions (21 CFR §112.2(b)) must be met
- Shell eggs that are exempt from certain provisions of the Egg Rule because all the eggs on the farm receive a treatment
 - Full exemption, even before the processing occurs
 - All of the eggs produced at the particular farm must receive a treatment as defined in the Egg Rule (21 CFR §118.3)

Other exemptions

- Personal consumption
- Holding food on behalf of individual consumers
- Produce listed as rarely consumed raw in the Produce Safety Regulation
- Farm-to-school/institution programs
 - School food authority or relevant procurement entity must keep record (for 180 days) of name and address of the farm
- Food during and after the time it is within the exclusive jurisdiction of USDA
- Transporters of food
- Nonprofit food establishments
- Food for research and evaluation

Sortable Spreadsheet Exemptions

| Type of Entity | Electronic Spreadsheet Exemption |
|---|----------------------------------|
| Farms | Sales ≤ \$250,000 |
| RFEs & Restaurants | Sales ≤ \$1M |
| Person other than a farm, RFE, or restaurant | Sales ≤ \$1M |

Thank you!





Food Traceability List

Christopher Waldrop, Senior Health Scientist, Division of Public Health Informatics & Analytics, Office of Analytics and Outreach (OAO), Center for Food Safety and Applied Nutrition (CFSAN), FDA

Designating the Food Traceability List

Risk-Ranking Model for Food Tracing

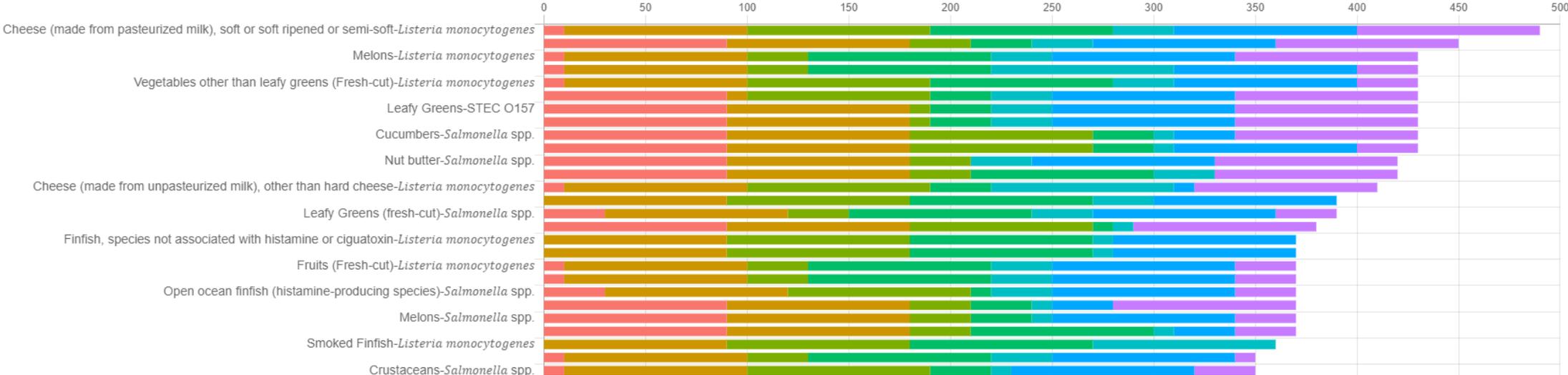
Introduction Methods and Criteria RRM-FT Results Table **RRM-FT Results Figure for Commodity-Hazard Pairs** RRM-FT Results Figure for Commodities

View the full graph by selecting "All" for Commodity and Hazard. View a sub-graph by selecting one Commodity or one Hazard. Users can select from the dropdown lists, and search for a Commodity or a Hazard of interest by typing some letters in the search box. For mobile devices, the full graph may not show, and the sub-graph view is the option to use. The x-axis of the graph shows risk score for the commodity-hazard pair.

Commodity

Hazard

■ C1: Outbreaks and illnesses
 ■ C2: Severity of illness
 ■ C3: Likelihood of contamination
 ■ C4: Growth potential
 ■ C5: Industry intervention
 ■ C6: Consumption
 ■ C7: Cost of illness (Note: All criteria are weighted)





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) |
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| Cucumbers (fresh) | Finfish (species potentially contaminated with ciguatoxin) (fresh and frozen) |
| Herbs (fresh) | Finfish, species not associated with histamine or ciguatoxin (fresh and frozen) |
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| 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) | |

Foods for which traceability records will be required

- Foods specifically listed on the FTL
- Foods that contain listed foods as ingredients
 - Provided that the listed food remains in the same form (e.g., fresh) in which it appears on the FTL



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



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



Foods specified as “fresh” on the FTL



Food specified as “fresh and frozen” on the FTL



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



Fresh FTL foods used in multi-ingredient foods



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



Changing the form of the food



Changing the form of the food



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



Foods not specified as “fresh” used in multi-ingredient foods



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**



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

Thank you!





Final Rule Record Keeping Requirements, Part 1

Angela Fields, Senior Consumer Safety Officer, Coordinated Outbreak Response and Evaluation Network (CORE), Center for Food Safety and Applied Nutrition (CFSAN), FDA

Covered Topics

- §1.1315: Traceability Plan
- §1.1320: Assigning Traceability Lot Codes
- §1.1325: Harvesting and Cooling a RAC
- §1.1330: Initial Packing of a RAC
- §1.1335: First Land-based Receiver
- §1.1340: Shipping KDEs
- §1.1345: Receiving KDEs
- §1.1350: Transformation KDEs
- § 1.1455(c)(3)(ii): Electronic Sortable Spreadsheet



§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: 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.



§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 |





§1.1320: 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.





§1.1325: 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



§1.1330: Initial Packing of a RAC (Sprouts)



- All KDE requirements for sprouts are outlined in §1.1330(b)
 - KDEs include information about growing, harvesting, conditioning/processing, packing of seeds and seed suppliers
- For sprouts, the final rule clarifies:
 - The requirements for sprouts do not apply to soil- or substrate-grown sprouts harvested without their roots
 - Creates consistency with the type of sprouts that are subject to subpart M (“Sprouts”) of the Produce Safety regulation

§1.1335: First Land-based Receiver of a food obtained from a fishing vessel



- “First land-based receiver” is the person taking possession of a food for the first time on land directly from a fishing vessel
- The first land-based receiver is required to assign a traceability lot code(s)
 - First land-based receiver would be considered the TLC source

Seafood Dealer Example



First Land-Based Receiver KDEs

- For each FTL food obtained from a fishing vessel, the following KDEs should be linked to each traceability lot:
 - TLC you assigned
 - How much you obtained
 - What you obtained
 - Location and date range of the trip during which it was caught
 - Date you obtained it
 - Traceability lot code source information (i.e., your location)
 - 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 (i.e., your location)
 - Reference document information



§1.1340: Shipping KDEs

- For each traceability lot shipped, firms must maintain and link the required KDEs
- Entities performing shipping are required to maintain and send specified KDEs to the recipient of the food
 - The proposed requirement for farms to send additional, farm-related information to the recipient has been removed
- Recordkeeping requirements for shipping do not apply to:
 - Farms (or other entities) that ship a RAC before it is initially packed



§1.1345: Receiving KDEs

- For each traceability lot received, firms must maintain and link the required KDEs
- Receiving requirements do not apply to the receipt of a food that occurs before initial packing (if not obtained from a fishing vessel) or to the receipt by the first land-based receiver (if obtained from a fishing vessel)
- Most receiving KDEs will be sent to the receiver by the shipper. Persons receiving FTL food(s) from an exempt entity are required to maintain reduced receiving KDEs (outlined in §1.1345(b))

Distributor 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



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



§1.1350: Transformation KDEs

- In the final rule, the Transformation CTE includes manufacturing/processing a food or changing a food (e.g., by commingling, repacking, or relabeling) or its packaging or packing, when the output is a food on the Food Traceability List
- Records need to be maintained for FTL foods used as ingredients in the transformation
- If a food used as an ingredient is not on the FTL, records do not need to be maintained for that ingredient
 - Records would only be required for the FTL food produced through transformation
- Transformation KDEs do not apply when a RAC (other than a food obtained from a fishing vessel) is transformed before it is initially packed
 - Only the initial packing KDEs will apply
- RFEs and restaurants are excluded from transformation requirements with respect to foods they do not ship

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



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

* indicates KDEs you receive

Electronic Sortable Spreadsheet

§ 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



Final Rule Record Keeping Requirements, Part 2

Jessica Kocian, Case Review Specialist, Division of Compliance and Enforcement, Office of Policy, Compliance, and Enforcement (OPCE), FDA

§ 1.1455: Records Maintenance and Availability



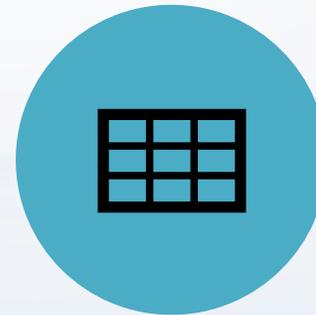
Legible **original paper, electronic**, or true copies. Stored to prevent deterioration or loss. May **include electronic links**.



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(a) General Requirements for Records



You must keep records as original paper or electronic records or true copies (such as photocopies, pictures, scanned copies, or other accurate reproductions of the original records).

Electronic records may include valid, working electronic links to the information required to be maintained under this subpart.

1.1455(b) Establishment and maintenance of records by another entity



You may have another entity establish and maintain records required under this subpart on your behalf, but you are responsible for ensuring that such records can be retrieved and provided onsite within 24 hours of request for official review.

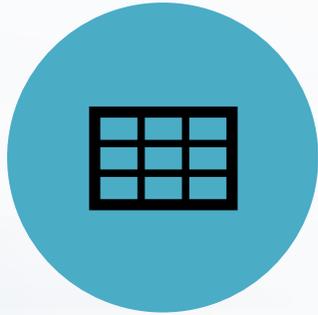
1.1455(c) Record availability



(1) You must make all records required under this subpart available to an authorized FDA representative, upon request, **within 24 hours (or within some reasonable time to which FDA has agreed)** after the request,

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 under this subpart.

1.1455(c) Record availability (Cont.)



(3) When necessary to help FDA prevent or mitigate a foodborne illness outbreak, or to assist in the implementation of a recall, or to otherwise address a threat to the public health...

you must make available, within 24 hours (or within some reasonable time to which FDA has agreed) **of a request made in-person or remotely (e.g., by phone)** by an authorized FDA representative, the information you are required to maintain under this subpart, for the foods and date ranges or traceability lot codes specified in the request.

(i) If FDA's request for the information specified in paragraph (c)(3) of this section is made by phone, we will also provide the request to you in writing upon your request; however, you must provide the requested information within 24 hours (or within some reasonable time to which FDA has agreed) of the phone request.

1.1455(d) Record Retention



Except as specified otherwise in this subpart, you must maintain records containing the information required by this subpart for **2 years from the date you created or obtained** the records.

1.1455(f) Use of existing records



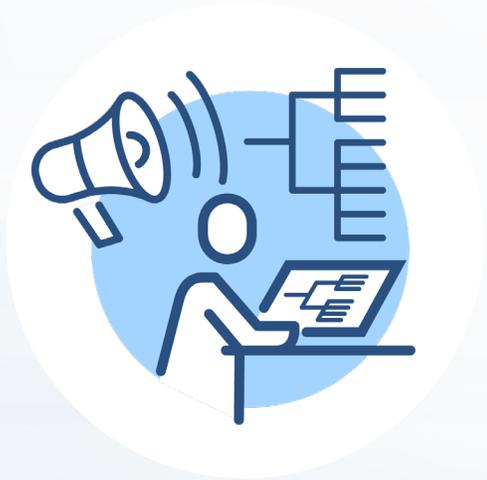
You do not need to duplicate existing records you have (e.g., records that you keep in the ordinary course of business or that you maintain to comply with other Federal, State, Tribal, territorial, or local regulations) if they contain the information required by this subpart. You may supplement any such existing records as necessary to include all of the information required by this subpart.

Compliance Dates



- Rule will become effective 60 days after published in the Federal Register [January 20, 2023]
- Compliance date is 3 years after the effective date of the final rule [January 20, 2026]

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

Thank you!

