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Traceability Final Rule

IFPA Virtual Town Hall

December 14, 2022

Agenda

- Overview
- Scope: Who and What is Covered
- Traceability Lot Code and Traceability Lot Code Source
- Requirements by Critical Tracking Event
- Traceability Program Records
- Recordkeeping and Production Requirements
- Compliance Timeline

How did we get here?

- Section 204(d) of the FDA Food Safety Modernization Act (FSMA) requires FDA to:
 - Create a list of designated “high risk” foods; and
 - Establish recordkeeping requirements for facilities that manufacture, process, pack, or hold those foods
 - New recordkeeping would apply in addition to existing one up, one back records requirements under the Bioterrorism Act
- In February 2014, FDA issued a draft approach to identifying high-risk foods and soliciting comments
- In October 2018, two consumer groups sued FDA to compel the agency to implement Section 204(d)
- In a settlement, FDA committed to issue the final rule by November 7, 2022

Overview of the Final Rule

- Creates new recordkeeping requirements to facilitate tracing “high risk” foods in the event of a foodborne illness outbreak or recall
- The designated “Food Traceability List” identifies foods that are subject to additional traceability requirements
- Requires entities that perform certain events in the food supply chain (Critical Tracking Events) to establish and maintain records containing certain information (Key Data Elements) and link that information a traceability lot code
 - Critical Tracking Events = harvesting, cooling, initial packing of raw agricultural commodities, first land-based receiving, transforming, receiving, shipping
- Entities are also required to establish general traceability program records to describe their recordkeeping operations
- FDA requires most entities to provide the agency with an electronic, sortable spreadsheet within 24 hours of request by FDA in certain situations

Who and what is covered by the rule?

- Final Rule applies to persons who manufacture, process, pack, or hold foods that appear on the Food Traceability List **OR** foods that contain a listed food as an ingredient, unless an exemption applies
- The **Food Traceability List** includes:

Cheeses, other than hard cheeses	Shell eggs	Nut butter (does not include soy or seed butters)	Cucumbers (fresh)
Herbs (fresh)	Leafy greens (fresh), including fresh-cut leafy greens	Melons (fresh)	Peppers (fresh)
Sprouts (fresh)	Tomatoes (fresh)	Tropical tree fruits (fresh)	Fruits and vegetables (fresh-cut)
Finfish, including smoked fish (fresh and frozen)	Crustaceans (fresh and frozen)	Mollusks, bi-valves (fresh and frozen)	Ready-to-eat deli salads (refrigerated)

Key Exemptions

- FDA provides a complete exemption for the following entities:
 - Farms (or the farm activities of farm mixed-type facilities) with respect to the produce they grow, when the farm is not subject to the Produce Safety Rule or farms with no more than \$25,000 in average annual produce sales as calculated under 21 CFR 112.4(a)
 - Food produced on a farm, including food packaged on a farm, when the owner, operator, or agent in charge of the farm sells or donates the food directly to a consumer
- FDA provides a complete exemption for the following foods:
 - Food that is produced and packaged on a farm when the packaging remains in place until the food reaches the consumer and the packaging label indicates the contact information for the producing farm
 - Produce that receives commercial processing that adequately reduces the presence of microorganisms of public health significance, provided the conditions in Section 112.2(b) of the Produce Safety Rule are satisfied
 - Produce that is identified as rarely consumed raw in 21 C.F.R. § 112.2(a)(1)

Treatment of Foods Subject to Further Processing

- FTL foods that undergo a **kill step**
 - Entity performing the kill step must maintain records of the application of the kill step and EITHER:
 - Receiving records OR
 - A written agreement with the shipper of the food stating that the receiver will apply a kill step
- Foods that are **changed** such that they are no longer on the FTL (e.g., freezing fresh spinach)
 - Entity performing the change must maintain receiving records
- When it is known early in the supply chain that the food will be subject to a kill step or be changed by another entity (other than by a restaurant, retail food establishment, or consumer) such that the food is no longer on the FTL, the food is exempt from traceability requirements provided there is **a written agreement** between the shipper and receiver stating that that the receiver will apply a kill step or change the food such that it is no longer on the FTL
- Foods to which a kill step already has been applied or that have been changed such that they are no longer on the FTL are exempt from the rule

Traceability Lot Codes

- Traceability lot codes are central to the rule's operation
- A **traceability lot code** is a descriptor, often alphanumeric, used to identify a traceability lot
- A **traceability lot** means a batch or lot of food that has been initially packed (for RACs other than food obtained by a fishing vessel), received by the first land-based receiver (for food from a fishing vessel), or transformed.
 - **Traceability lot codes can only be assigned at these CTEs, and when a receiver is the first covered entity to handle an FTL food**
- The **traceability lot code source** is the place where a food was assigned a traceability lot code
- The **traceability lot code source reference** is an alternative method for providing FDA with access to the location description for the traceability lot code source
 - Examples include the FDA Food Facility Registration Number or a web address that provides FDA with the location description for the traceability lot code source
- **At each Critical Tracking Event, entities would be required to link the traceability lot code to Key Data Elements**

Critical Tracking Events

- The CTEs for which recordkeeping is required are:
 - Harvesting
 - Cooling
 - **Initial Packing of Raw Agricultural Commodities**
 - **First Land-Based Receiving**
 - **Transformation**
 - Shipping
 - Receiving

Harvesting

Harvesting means the activities that are traditionally performed on farms for the purpose of removing raw agricultural commodities from the place they were grown or raised and preparing them for use as food.

Recordkeeping requirements include:

- Location description for the immediate subsequent recipient (other than a transporter) of the food
- Commodity and, if applicable, variety of the food
- Quantity and unit of measure of the food
- Location description for the farm where the food was harvested
- Date of harvesting
- For Produce:
 - Name of the field or other growing area from which the food was harvested (must correspond to the name used by the grower)
 - Other information identifying the harvest location at least as precisely as field or growing area name
- Reference document type and reference document number

The listed KDEs, except the reference document type and number, must be provided to the initial packer along with the harvester's business name and phone number

Cooling (before initial packing)

Cooling means the active temperature reduction of a raw agricultural commodity.

Recordkeeping requirements include:

- Location description for the immediate subsequent recipient (other than a transporter) of the food
- Commodity and, if applicable, variety of the food
- Quantity and unit of measure of the food
- Location description for where the food was cooled
- Date of cooling
- Location description for the farm where the food was harvested
- Reference document type and reference document number

The listed KDEs, except the reference document type and number, must be provided to the initial packer.

Initial Packing (RAC)

Initial Packing of RACs means the packing of a raw agricultural commodity for the first time.

Recordkeeping requirements include:

- Commodity and, if applicable, variety of the food received
- Quantity and unit of measure of the food received and date of receipt
- Location description for the farm where the food was harvested and harvesting date
- For Produce:
 - Name of the field or other growing area from which the food was harvested (must correspond to the name used by the grower)
- Business name and phone number for the harvester of the food
- Location description for where the food was cooled and date of cooling (if applicable)
- Traceability lot code assigned by the initial packer
- Product description of the packed food
- Quantity and unit of measure of the packed food and date of initial packing
- Location description for where you initially packed the food (i.e., traceability lot code source), and (if applicable), the traceability lot code source reference
- Reference document type and reference document number

All of the listed KDEs must be linked to the traceability lot code assigned at this CTE.

Transformation

Transformation means an event in a food's supply chain that involves manufacturing/processing a food or changing a food or its packaging, when the output is on the Food Traceability List.

Recordkeeping requirements include:

For FTL foods used as ingredients-

- Traceability lot code for the food
- Product description for the food to which the traceability lot code applies
- For each traceability lot used, the quantity and unit of measure of the food used from that lot

For new FTL foods produced-

- New traceability lot code for the food
- Location description for where you transformed the food (i.e., the traceability lot code source), and (if

applicable) the traceability lot code source reference

- Date transformation was completed
- Product description for the food
- Quantity and unit of measure of the food
- Reference document type and reference document number

* For RACs and sprouts that are not initially packed before transformation, the transformer must maintain initial packer KDEs

All of the listed KDEs must be linked to the traceability lot code assigned at this CTE.

* Transformation does not apply to retail food establishments and restaurants with respect to foods they do not ship (foods they send or sell directly to consumers).

Shipping

Shipping refers to an event in a food's supply chain where it is transported from one physical address to another, including intercompany shipments.

Recordkeeping requirements include shippers maintain and provide:

- Traceability lot code for the food
- Quantity and unit of measure of the food
- Product description for the food
- Location description for the immediate subsequent recipient (other than a transporter) of the food
- Location description for the location from which the food was shipped
- Date the food was shipped
- Location description for the traceability lot code source or the traceability lot code source reference
- Reference document type and reference document number (maintain only)

All of the listed KDEs must be linked to the traceability lot code previously assigned.

Shipping KDEs do not apply to the shipment of food that occurs before the food is initially packed.

Receiving

Receiving refers to an event in a food's supply chain when food is received by someone other than a consumer after being transported from another physical location, including intracompany shipments.

Recordkeeping requirements include:

- Traceability lot code for the food
 - Quantity and unit of measure of the food
 - Date the food was received
 - Product description for the food
 - Location description for the immediate previous source (other than a transporter) for the food
 - Location description for where the food was received
 - Location description for the traceability lot code source or the traceability lot code source reference
 - Reference document type and reference document number
- * When food is received from a person who is exempt from the rule; the receiver must assign a traceability lot code if one has not been already been assigned (does not apply to RFEs or restaurants) and maintain the same receiving KDEs

All of the listed KDEs must be linked to the traceability lot code previously assigned.

Putting It All Together

Initial Packer Example

FDA



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

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Putting It All Together Continued...

Distributor Example

FDA



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

* Indicates KDEs you receive

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Putting It All Together Continued...

Manufacturer Example

FDA



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

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Traceability Plan

- A roadmap of your program and where things are located
- Your traceability plan must include:
 - Description of the procedures you use to maintain the required records, including the format and location of the records
 - Description of the procedures you use to identify foods on the FTL that you manufacture, process, pack, or hold and how you assign traceability lot codes to foods on the FTL, if applicable
 - Description of how you assign traceability lot codes
 - Statement identifying 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 showing the areas in which you grow or raise such foods, including the location and name of each field (or other growing area) in which you grow a food on the FTL, including geographic coordinates and any other information needed to identify the location of each field or growing area
- You must update your traceability plan as needed to ensure that the information reflects your current practices and to ensure you are compliant with the rule
- You must retain your previous traceability plan for 2 years after you update the plan

Farm Map Example

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



Recordkeeping Requirements

- Records required under the rule must be maintained for 2 years from the date they were created
- Offsite storage of the records is permissible, provided the records can be made available to an FDA representative no later than 24 hours after a request
 - Electronic records are considered onsite if they are accessible from an onsite location
- Electronic records may include electronic links
- Records also can be required to be provided in English within a reasonable time if they are maintained in a language other than English
- Covered entities may enter into agreements with individuals or firms to create and keep the records required by the rule on their behalf
- No need to create duplicate records; or maintain information in a single set

Record Availability and Format

- All records must be made available within 24 hours of a request (or a reasonable time to which FDA has agreed)
 - Can be made during routine inspection
 - May also need to provide coding, glossary, explain abbreviations, how information corresponds
- The final rule requires entities to provide records to FDA within 24 hours (or a reasonable time to which FDA has agreed) in an **electronic, sortable spreadsheet** for specified foods and date ranges when requested by FDA in certain situations
 - Providing information in this format is required when necessary to help FDA prevent or mitigate a foodborne illness outbreak; to assist in the implementation of a recall; to otherwise address a threat to the public health, including situations where FDA has a reasonable belief that a food presents a SAHCODHA hazard
 - Request may be made by phone, and in writing upon 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, TLCrylle , 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://fd.gs1.org/01/11411411411402/10/FPP16-092420	BOL 114401
(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://fd.gs1.org/01/11411411411401/10/FPP16-092120	BOL 114401
(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://fd.gs1.org/01/22322322322302/10/FFI2020-09-20	BOL 22302

*See Master Data Spreadsheet for full location descriptions

Exemptions to Electronic Spreadsheet Requirement

- Three types of entities are exempt from this requirement:
 - (1) farms with a three-year rolling sales average of no more than \$250,000,
 - (2) retail food establishments and restaurants with a three-year rolling sales average of no more than \$1 million, and
 - (3) persons other than a farm, retail food establishment, or restaurant whose three-year rolling sales average is no more \$1 million

Compliance Date

- FDA has determined that the compliance date for all covered entities will be 3 years after the effective date of the final regulations on **January 20, 2026**

Questions?



Contact Information



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