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The Global Language of Business

The What

Understanding the Basics of FSMA Rule 204

FMI THE FOOD INDUSTRY ASSOCIATION

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Speaker Introductions

Hilary Thesmar
Chief Science Officer
FMI

Marshall Keener
Government Engagement Director
GS1 US

FDA’s Recent Food Focus and How GS1 & FMI Support Industry

FDA's Path to Advancing Food Safety

1 New Era for Smarter Food Safety

- ❑ 1st Public Meeting Sept. 2019
- ❑ New Era Blueprint announced July 2020
- ❑ 10-year strategic blueprint
- ❑ 4 core elements

Policy

2 FSMA 204

- ❑ FDA heal public meeting Nov. 2020
- ❑ Public comment period ended February 2021
- ❑ Final Rule published Nov 2022
- ❑ Developed a Food Traceability List (FTL) and additional record keeping requirements

Regulation

3 IT Modernization

- ❑ FDA started an agency-wide data modernization and enhanced tech initiative in 2021
- ❑ FDA Technology Modernization Action Plan (TMAP) Sept 2021
- ❑ FDA Data Modernization Action Plan (DMAP) March 2021
- ❑ FDA Enterprise Modernization Action Plan (EMAP) May 2022

Agency Wide Initiative

4 Human Food Program

- ❑ Program designed to ensure the most strategic use of resources
- ❑ Recommendations came from the expert panel of the Reagan-Udall Foundation
- ❑ Restructure will impact the Office of Regulatory Affairs (ORA)

Restructuring

"Today, every business process is directly or indirectly dependent on the use of technology. Data is foundational to everything we do as a science-based agency and is also a necessary ingredient for most good business decisions."

Vid Desai
Chief Information Officer, FDA

GS1 – The Global Language Of Business

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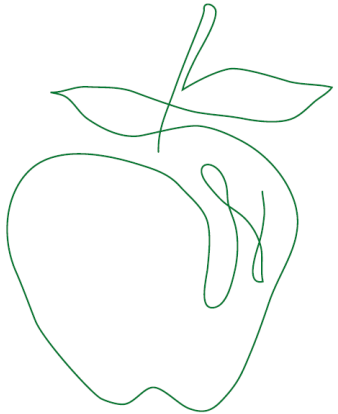
Global and local

Inclusive and collaborative

FMI – The Food Industry Association

As the **food industry association**, FMI works with and on behalf of the entire industry to advance a **safer**, **healthier** and **more efficient** consumer food supply.

FMI brings together a wide range of members across the value chain — from **retailers** who sell to **consumers**, to **producers** who supply the food, as well as the wide-variety of companies providing critical services — to **amplify** the collective work of the industry.



www.fmi.org

What is FSMA Final Rule Section 204?

FSMA 204 Final Rule Basics

What is it and Who is Impacted?	FSMA Final Rule on Requirements for Additional Traceability Records for high-risk products outlined in the **Food Traceability List. Includes foreign and domestic entities. Full and partial exemptions may apply.**
What is Required?	Must keep records on foods from Farm to Store/Restaurant by **production LOT**. Supply chain partners need to share records. Provide **CTEs-KDEs to FDA within 24 hours**. Must keep a documented **Traceability Plan**
When?	FINAL Rule Effective: January 2023 Compliance date: January 2026 Records should be maintained for 2 years

Requirements for Additional Traceability Records for Certain Foods

- *Federal Register,* Docket No. FDA-2014-N-0053
- November 21, 2022
  - Preamble pgs 70910-12076
  - Regulatory Language pgs 71077-71088
- Compliance date is January 20, 2026

70910 Federal Register / Vol. 87, No. 223 / Monday, November 21, 2022 / Rules and Regulations

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1

[Docket No. FDA–2014–N–0053]

RIN 0910–AI44

Requirements for Additional Traceability Records for Certain Foods

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is issuing a final rule establishing additional recordkeeping requirements for persons who manufacture, process, pack, or hold foods the Agency has designated for inclusion on the Food Traceability List (FTL). The final rule adopts provisions requiring these entities to maintain records containing information on critical tracking events in the supply chain for these designated foods, such as initially packing, shipping, receiving, and transforming these foods. The requirements established in the final rule will help the Agency rapidly and effectively identify recipients of foods to prevent or mitigate foodborne illness outbreaks and address credible threats of serious adverse health consequences or death resulting from foods being adulterated or misbranded. We are issuing this regulation in accordance with the FDA Food Safety Modernization Act (FSMA).

DATES: This rule is effective January 20, 2023. For the applicable compliance dates, see section VI ''Effective and Compliance Dates'' in the SUPPLEMENTARY INFORMATION section of this document.

ADDRESSES: For access to the docket to read background documents or comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this final rule, into the ''Search'' box and follow the prompts, and/or go to the Dockets Management Staff (HFA–305), 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT:

With regard to the final rule: Katherine Vierk, Office of Analytics and Outreach, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–2122, *Katherine.Vierk@fda.hhs.gov.*

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SUPPLEMENTARY INFORMATION:

Table of Contents

I. Executive Summary

A. Purpose and Coverage of the Rule

This final rule, which is part of FDA's implementation of FSMA (Pub. L. 111–353), establishes additional traceability recordkeeping requirements for persons who manufacture, process, pack, or hold foods for which the Agency has determined these additional requirements are appropriate and necessary to protect the public health in accordance with FSMA. These traceability recordkeeping requirements will help FDA rapidly and effectively identify recipients of such foods to prevent or mitigate a foodborne illness outbreak and address threats of serious adverse health consequences or death as a result of such foods being adulterated or misbranded (with respect to allergen labeling) under the Federal Food, Drug, and Cosmetic Act (FD&C Act). The requirements will reduce the harm to public health caused by foodborne illness outbreaks and limit adverse impacts on industry sectors affected by these outbreaks by improving the ability to quickly and efficiently trace the movement through the supply chain of foods identified as causing illness, identify and remove contaminated foods from the marketplace, and develop mitigation strategies to prevent future contamination.

We are issuing this rule because Congress directed us, in FSMA, to establish recordkeeping requirements for foods we designate that would be additional to the existing traceability recordkeeping requirements in the FD&C Act and FDA regulations. The existing regulations are designed to enable FDA to identify the immediate previous sources and immediate subsequent recipients of foods to address credible threats of serious adverse health consequences or death to humans or animals. This final rule adopts additional recordkeeping requirements for foods we have designated as high-risk foods in accordance with factors specified by Congress in FSMA. We are listing these foods on an FTL, which is included as a reference for the final rule. In accordance with FSMA, we also are publishing the FTL on our website concurrently with the issuance of the final rule. (See section V.B of this document for more information on the FTL.)

B. Summary of the Major Provisions of the Final Rule

The requirements of the final rule are focused on having persons who manufacture, process, pack, or hold FTL foods maintain and provide to their supply chain partners specific information (key data elements) for certain critical tracking events (CTEs) in the handling of the food, consistent with the developing industry consensus approach to food 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

Why do we have this rule and who is impacted?

How did we get here?

- Spinach outbreak 2006
  - 199 people ill with *E. coli* O157:H7
- Pepper outbreak 2008
  - 1400+ people ill with *Salmonella* Saintpaul
- Peanut Corporation of America 2008-2009
  - 700+ people ill with *Salmonella* Typhimurium

Food Safety Modernization Act 2011

Traceability Activities for GS1 US and FMI

- **2010:** Produce Traceability Initiative
- **2010:** Active engagement with Congress on the language in FSMA
- **2011-2012:** Pilot Projects for Improving Product Tracing, IFT
- **2013:** IFT Global Food Traceability Center established
- **2014:** Comments on draft methodology for high-risk foods
- **2020:** Proposed rule published (September 2020)
- **2020:** GS1US Section 204 Workgroup began
- **2020:** Leafy Greens Traceability Pilots Report (PMA, United Fresh, GS1US, IFT, IFDA, FMI)
- **2021:** Comments submitted on Food Traceability Proposed Rule
- **2021:** Traceability Workshops, FBIA
- **2022:** FDA Final Rule Published – work began

Who is subject to the rule?

Applies to **persons** who manufacture, process, pack, or hold foods (as foods or ingredients) that appear on the Food Traceability List (FTL)

This includes distributors, retail food establishments, convenience stores, restaurants, online food retailers, and meal-kit delivery companies.

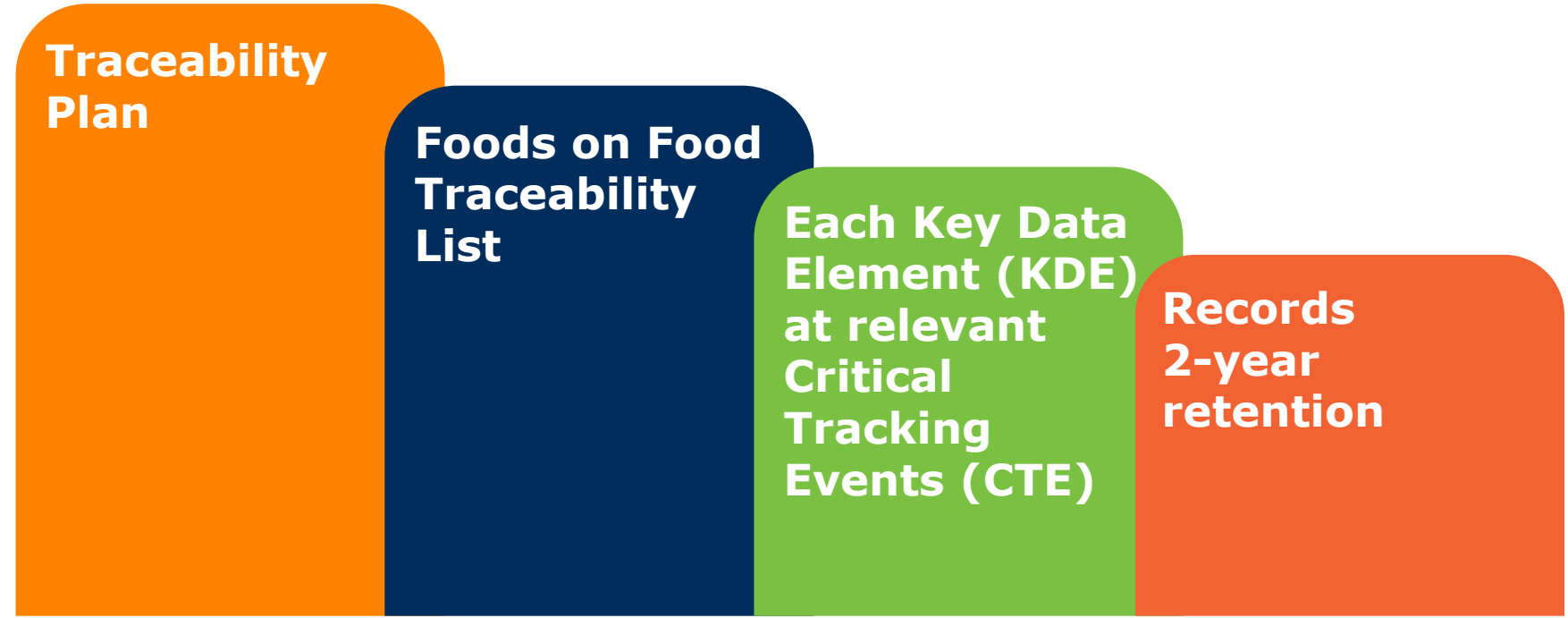
What Does the Rule Require?

Two Parts to Rule

Section 204(d) of the FDA Food Safety Modernization Act (FSMA) requires FDA to:

1. Create a list of designated "high-risk" foods
   - List is referred to in regulatory language but is not codified

2. Establish recordkeeping requirements for facilities that manufacture, process, pack, or hold those foods



Food Traceability List

Cheeses
(other than hard cheeses)

Crustaceans
(fresh and frozen)

Cucumbers
(fresh)

Finfish
(fresh and frozen)

Fruit
(fresh cut)

Herbs
(fresh)

Leafy Greens
(fresh)

Leafy Greens
(fresh cut)

Melons
(fresh)

Molluscan Shellfish, Bivalves
(fresh and frozen)

Nut Butters

Peppers
(fresh)

Ready-to-Eat Deli Salads
(refrigerated)

Sprouts
(fresh)

Shell Eggs

Smoked Finfish
(refrigerated and frozen)

Tomatoes
(fresh)

Tropical Tree Fruit
(fresh)

Vegetables Other Than Leafy Greens
(fresh cut)

Foods on the FTL

- All items on the FTL used as **ingredients** are included in rule:

- Foods in the form specified on the FTL
  - fresh
  - frozen
  - all forms
- Other forms not included for most FTL Foods (Documentation is needed)
  - dried
  - thermal or non- thermal processed

Examples of Foods

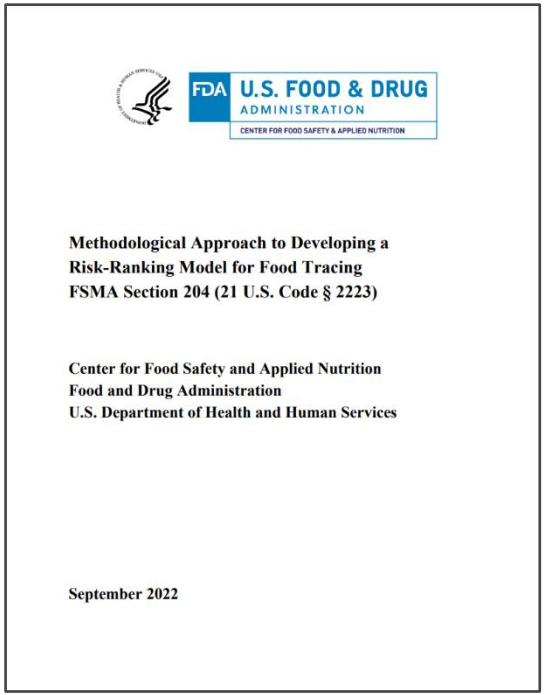
FTL Foods under the rule

- Peanut butter crackers
- Ice cream with peanut butter as ingredient
- Salad with fresh vegetables
- Sandwich with lettuce and tomatoes
- Fresh and frozen seafood (most types)
- Deli salads under FDA jurisdiction

Not Covered

- Frozen pizza
- Frozen fruits
- Frozen veggies
- Nuts
- Canned foods
- Pasteurized foods
- Pasteurized eggs

How did FDA come up with the FTL?

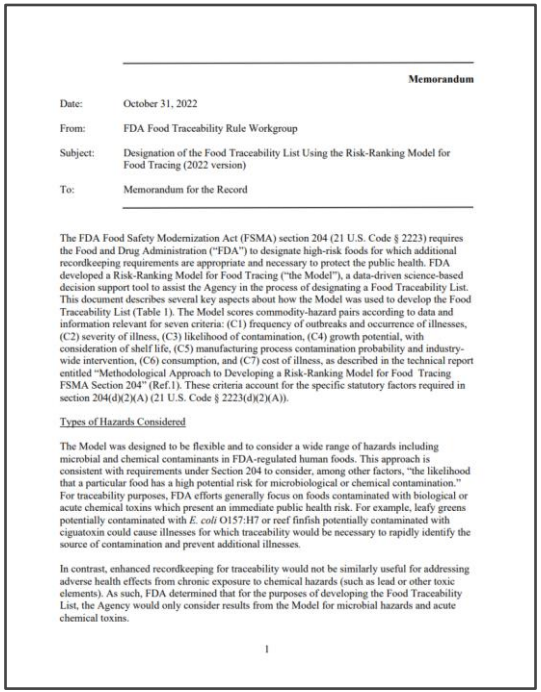


U.S. FOOD & DRUG ADMINISTRATION
CENTER FOR FOOD SAFETY & APPLIED NUTRITION

Methodological Approach to Developing a Risk-Ranking Model for Food Tracing FSMA Section 204 (21 U.S. Code § 2223)

Center for Food Safety and Applied Nutrition
Food and Drug Administration
U.S. Department of Health and Human Services

September 2022



Memorandum

Date: October 31, 2022

From: FDA Food Traceability Rule Workgroup

Subject: Designation of the Food Traceability List Using the Risk-Ranking Model for Food Tracing (2022 version)

To: Memorandum for the Record

The FDA Food Safety Modernization Act (FSMA) section 204 (21 U.S. Code § 2223) requires the Food and Drug Administration ("FDA") to designate high-risk foods for which additional recordkeeping requirements are appropriate and necessary to protect the public health. FDA developed a Risk-Ranking Model for Food Tracing ("the Model"), a data-driven science-based decision support tool to assist the Agency in the process of designating a Food Traceability List. This document describes several key aspects about how the Model was used to develop the Food Traceability List (Table 1). The Model scores commodity-hazard pairs according to data and information relevant for seven criteria: (C1) frequency of outbreaks and occurrence of illnesses, (C2) severity of illness, (C3) likelihood of contamination, (C4) growth potential, with consideration of shelf life, (C5) manufacturing process contamination probability and industry-wide intervention, (C6) consumption, and (C7) cost of illness, as described in the technical report entitled "Methodological Approach to Developing a Risk-Ranking Model for Food Tracing FSMA Section 204" (Ref.1). These criteria account for the specific statutory factors required in section 204(d)(2)(A) (21 U.S. Code § 2223(d)(2)(A)).

Types of Hazards Considered

The Model was designed to be flexible and to consider a wide range of hazards including microbial and chemical contaminants in FDA-regulated human foods. This approach is consistent with requirements under Section 204 to consider, among other factors, "the likelihood that a particular food has a high potential risk for microbiological or chemical contamination." For traceability purposes, FDA efforts generally focus on foods contaminated with biological or acute chemical toxins which present an immediate public health risk. For example, leafy greens potentially contaminated with *E. coli* O157:H7 or reef finfish potentially contaminated with ciguatoxin could cause illnesses for which traceability would be necessary to rapidly identify the source of contamination and prevent additional illnesses.

In contrast, enhanced recordkeeping for traceability would not be similarly useful for addressing adverse health effects from chronic exposure to chemical hazards (such as lead or other toxic elements). As such, FDA determined that for the purposes of developing the Food Traceability List, the Agency would only consider results from the Model for microbial hazards and acute chemical toxins.

1

What is required for foods on the FTL?

- Maintain records containing **Key Data Elements (KDEs)** associated with specific **Critical Tracking Events (CTEs)**

- Provide information to the FDA within 24 hours or within some reasonable time to which the FDA has agreed

What are CTE's and KDE's

Critical Tracking Events (CTE)

- Data elements required to be captured as records
- For example – location, lot code, date

Key Data Elements (KDE)

- Points in the supply chain where product is moved or sold
- For example – receiving, shipping, transforming

Critical Tracking Events for Foods on FTL

- Harvest or cool a raw agricultural commodity (RAC)
- Initial packing of a RAC
- First land-based receiver of a food obtained from a fishing vessel
- Shipping
- Receiving
- Transformation

Key Data Elements (KDE)

General categories, see rule for details

- Traceability Lot Code KDEs
- Location KDEs
- Description of product
- Quantity and Unit of measure of product(s)
- Harvest KDEs
- Harvest Aquaculture KDEs
- Date(s)
- Reference Documents
- Sprouts – specific requirements apply

Food Traceability Final Rule - CTEs and KDEs								Possible GS1 Standards application/use
Critical Tracking Events requiring records	Harvest RAC on FTL (ADDED)	Cooling RAC on FTL (ADDED)	Initial Packing of RAC (ADDED)	First Land Based Receiver of a food on FTL obtained from a fishing vessel (ADDED)	Ship a food on the FTL	Receive a food on the FTL	Transforming a food	Standardized data model for capturng and sharing physical event data (CTEs) - **Electronic Product Code Information Services (EPCIS)** standard
Section	§1.1325(a)	§1.1325(b)	§1.1330	§1.1335	§1.1340	§1.1345	§1.1350	
	Business name phone number for each KDE below	Business name phone number for each KDE below	Business name and phone number for the harvester of the food		Provide all information below to the to the immediate subsequent recipient of each traceability lot shipped			Entity identification - **GS1 Global Location Number / GS1 Company Prefix**
Traceabililty Lot Code KDEs			Traceability lot code assigned by the Packer of the RAC	Traceability lot code you assigned	Traceability lot code for the food	Traceability lot code for the food	Traceability lot code for the food used;	**Data structure for lot code** defined by standards - 10 alphanumeric characters
							The new traceability lot code for the food (after transformation)	
Location KDEs	Location description for immediate subsequent recipient;	Location description for the immediate subsequent recipient;	Location description for the farm where the food was harvested;	Location description for the first land based receiver (traceability lot code source) and if applicable the traceability lot code source reference	Location description for the immediate subsequent recipient of the food;	Location description for the immediate previous source;	Location description for where you transformed the food (traceability lot code source) and if applicable the traceability lot code source reference	Locations can be supported by **GS1 Global Location Numbers (at any desired level of use) and entered/shared/managed in Global Location Number registry (free to GS1 US members)** - enables assignment, management and standardized attribution about the entity and location
	Location description for the farm where food was harvested	Location description for cooling the food	Location description for where the food was packed (traceability lot code source) and if applicable the traceability lot code source reference		Location description for the location from which you shipped 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	Location description for the traceability lot code source, or the traceability lot code source reference		
Description			Product description of the packed food	Species and/or acceptable market name for unpackaged food or the product description for packaged food	Product description of the food	Product description of the food	Product description of the food received;	Standards for **product identifiers and data attributes** - example how we define ' product description' and data structure; standards for data product classification
							Product description of the food after transformed	
	Commodity and variety of food	Commodity and variety of food	Commodity and variety of food received					
Quantity and Unit of Measure	Quantity and unit of measure of food	Quantity and unit of measure of the food	Quantity and unit of measure of the food received;	Quantity and unit of measure of the food	Quantity and unit of measure of the food	Quantity and unit of measure of the food	For each traceability lot used, the quantity and unit of measure of the food used from that lot	**Data structure** defined for unit of measure
			Quantity and unit of measure of the packed food					
Harvest KDEs	*For produce,* name of field or other growing area (must correspond to the name used by the grower), or other harvest location as least as precise as the field or other growing area name		For produce, the name of the field or other growing area from which the food was harvested (which must correspond to the name used by the grower) or other information identifying the harvest location at lease as precisely as the field or other growing area name	The harvest date range and locations (as defined by NMFSOGC and UN FAO Fishing Area list) for the trip during which the fish was caught			For RACs received and transformed that were not packed, you must maintain the records in §1.1330	**GS1 Global Location Numbers and standardized attribution** such as GEO coordinates; date data structure defined as well as definition of harvest date

KDE's at Select CTE

Receiving	Transformation	Shipping
Traceability Lot Code for food on FTL	Traceability Lot Code for food on FTL New traceability lot code for transformed food	Traceability Lot Code for food on FTL
Quantity and unit of measure	Quantity and unit of measure of food used from that lot Quantity and unit of measure of transformed food	Quantity and unit of measure
Product description for food	Product description for the food to which lot code applies Product description for new food	Product description for food
Location description for immediate previous source	Location description for where you transformed food	Location description for immediate subsequent recipient
Location description for receiving	Reference document type and number for transformed food	Location description for location food was shipped
Date received	Date transformation completed	Date shipped
Location description for the traceability lot code source, or the lot code source reference	Location description for traceability lot code source reference	Location description for the traceability lot code source, or the lot code source reference

Summary of Regulatory Language

What Does the Rule Require?

- Expands the entities required to keep records (including restaurants and retail)
- Standardizes information collected throughout the supply chain
- Mandates linking certain information for incoming and outgoing products
- Requires covered entities to explain their traceability systems and records; and
- Encourages a transition from paper-based to electronic records

Subpart S – Additional Traceability Records for Certain Foods

- 1.1300 Who is subject to subpart S?
- 1.1305 Exemptions
- 1.1310 Definitions
- 1.1315 Traceability Plan
- 1.1320 Assignment of traceability Lot Codes
- 1.1325 Harvesting or Cooling a RAC on the FTL
- 1.1330 Packing RAC on FTL
- 1.1335 First Land Based Receiver of a food on FTL from a fishing vessel
- 1.1340 Shipping KDE
- 1.1345 Receiving KDE
- 1.1350 Transforming KDE
- 1.1360 – 1.1450 Modified requirements, exemptions, waivers
- 1.1455 Records
- 1.1460 Consequences for failure to comply

Traceability Plan

Must contain:

- Description of the procedures to maintain records including format and location
- Description of the procedures used to identify foods you manufacture, process, pack, or hold on the FTL
- Description of how traceability lot codes are assigned
- Statement identifying a point of contact for questions regarding traceability plan and records
- For harvesting, a farm map showing the areas with foods on the FTL
- each field with geographic coordinates
- For aquaculture, farm map must show the location and name of each container (pond, pool, tank, cage) including geographic coordinates
- Update traceability plan as needed – retain plan for 2 years after update

Records

Records are required at each applicable Critical Tracking Event

All Key Data Elements required must be kept as records

- Records may be established and maintained by another entity
- Records must be available in 24 hours
- Offsite storage is permitted if records can be onsite within 24 hours
- FDA has broad authority to request records for lot codes of interest
- Information must be provided in an electronic sortable spreadsheet within 24 hours unless you meet certain conditions
- Record retention – 2 years
- Multiple records are acceptable (flexibility to use existing records)

Sharing records with FDA

Within 24 hours

- "you must provide such information in an **electronic sortable spreadsheet**, along with any other information needed to understand the information in the spreadsheet"

Exceptions

- small farm <$250,000 per year
- small retailer or other company <$1,000,000 per year
- religious reasons

Exemptions

Exemptions and partial exemptions:

- Produce farms not subject to the Produce Safety Rule
- Shell egg producers with fewer than 3000 laying hens
- Small "originators of food" under $25,000 per year
- Direct to consumer farms
- Foods that receive commercial processing
- Produce rarely consumed raw (as defined by FDA Produce Safety Rule)
- Transporters of food
- Non-profit establishments (Donations are exempt)
- Ad hoc purchases – e.g. restaurants purchasing food from store not known to the store

What is not covered?

- Donations – no traceability records required
- Ad hoc purchases – not planned

Definitions

Lot Code Definitions

- Traceability Lot
- Traceability Lot Code
- Traceability Lot Code Source
- Traceability Lot Code Source of Reference

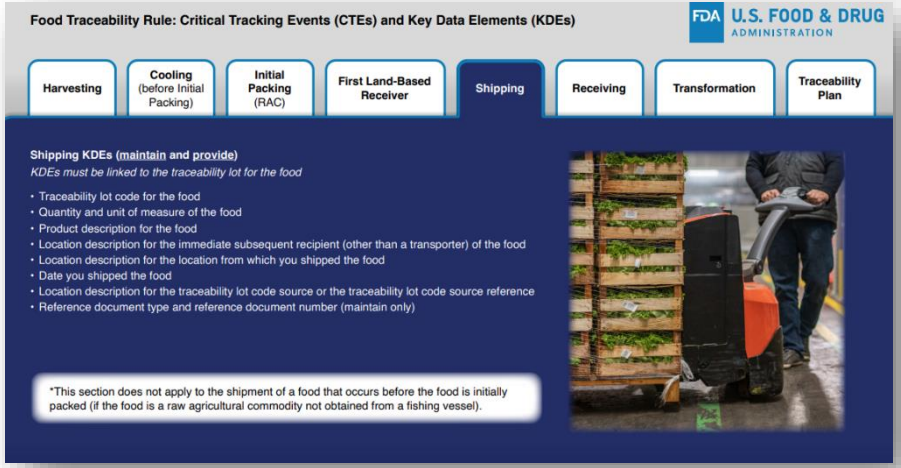
Lot code format is flexible, is assigned at specific times and cannot be changed at certain times

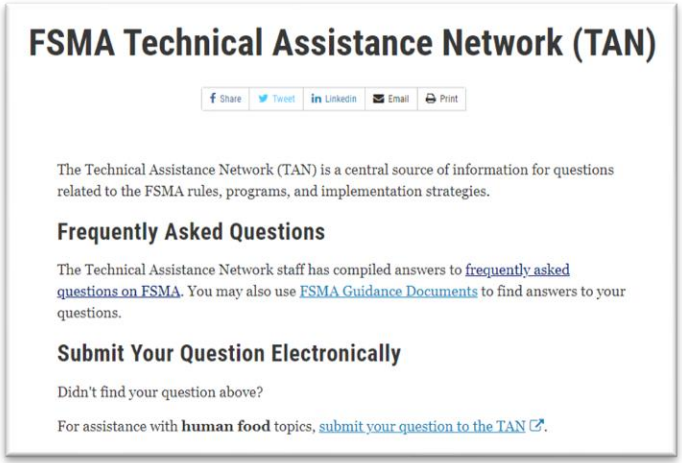
Notable definitions – please review

- Critical Tracking Events (CTE)
- Key Data Elements (KDE)
- Transformation
- Receiving
- Shipping
- Kill Step

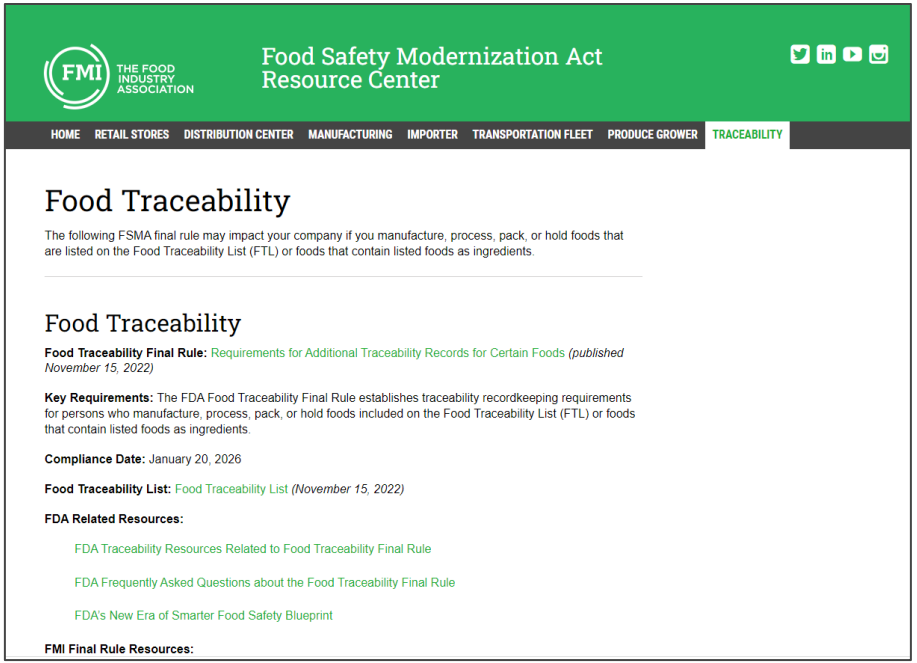
Resources

FDA Food Traceability Tools and Resources





FMI Resources



THE FOOD INDUSTRY ASSOCIATION

Food Safety Modernization Act Resource Center

HOME | RETAIL STORES | DISTRIBUTION CENTER | MANUFACTURING | IMPORTER | TRANSPORTATION FLEET | PRODUCE GROWER | TRACEABILITY

Food Traceability

The following FSMA final rule may impact your company if you manufacture, process, pack, or hold foods that are listed on the Food Traceability List (FTL) or foods that contain listed foods as ingredients.

Food Traceability

Food Traceability Final Rule: Requirements for Additional Traceability Records for Certain Foods *(published November 15, 2022)*

Key Requirements: The FDA Food Traceability Final Rule establishes traceability recordkeeping requirements for persons who manufacture, process, pack, or hold foods included on the Food Traceability List (FTL) or foods that contain listed foods as ingredients.

Compliance Date: January 20, 2026

Food Traceability List: Food Traceability List *(November 15, 2022)*

FDA Related Resources:

- FDA Traceability Resources Related to Food Traceability Final Rule
- FDA Frequently Asked Questions about the Food Traceability Final Rule
- FDA's New Era of Smarter Food Safety Blueprint

FMI Final Rule Resources:

GS1 US Resources

Next Steps

How to get started

Up next in series

- **August 9:** The How: Industry Defined Guidance to Help Meet FSMA 204 Record Keeping Requirements
- **August 16:** The Why: Driving Business Value Beyond FSMA 204 Regulatory Compliance
- **August 23:** The What's Next: Preparing to Meet FSMA 204 Requirements - Tools and Resources

Questions

EMAIL:

- foodsafety@gs1us.org

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