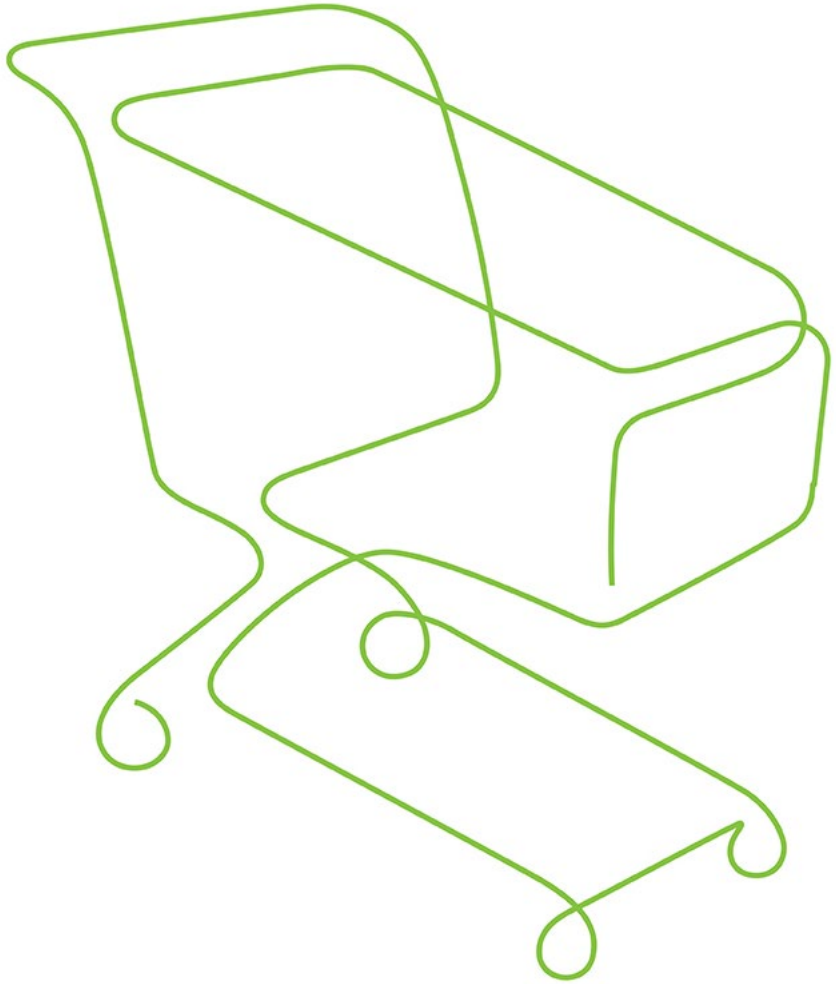
THE FOOD INDUSTRY ASSOCIATION

FDA TRACEABILITY RULE: FSMA SECTION 204



December 14, 2022

Antitrust Policy

FMI believes strongly in competition. Our antitrust laws are the rules under which our competitive system operates. It is FMI's policy to comply in all respects with the antitrust laws.

Association meetings or workshops by their very nature bring competitors or potential competitors together. It is expected that all member representatives involved in FMI activities, as well as FMI consultants and other participants, will be sensitive to the legal issues and act in compliance with applicable antitrust and competition laws both at FMI meetings and FMI-sponsored events.

Accordingly, it is necessary to avoid discussions of sensitive topics that can create antitrust concerns. Agreements to fix prices, to allocate markets, to engage in product boycotts, to refuse to deal with third parties, and to fix employee wages or to agree not hire one another's employees can be illegal under the antitrust laws. At any association meeting, discussions of prices (including elements of prices such as allowances and credit terms), employee compensation, quality ratings of suppliers, and discussions that may cause a competitor to cease purchasing from a particular supplier, selling to a particular customer, or competing to hire employees should be avoided. Also, there should be no discussion that might be interpreted as a dividing up of territories.

An antitrust violation does not require proof of a formal agreement. Discussion of a sensitive topic, such as price, followed by action by those involved or present at the discussion, may be enough to show a price fixing conspiracy. As a result, those attending an association-sponsored meeting should remember the importance of avoiding not only unlawful activities, but even the appearance of unlawful activity.

Allegations of wrongdoing can pose financial and reputational risk, and violations of the antitrust laws can have serious consequences, for FMI, individual companies, and their employees. Antitrust investigations and litigation are lengthy, complex, and disruptive. The Sherman Act is a criminal statute and may even result in penalties punishable by steep fines and imprisonment. The Justice Department, the Federal Trade Commission, state attorneys general and any person or company injured by a violation of the antitrust laws may bring an action for three times the amount of the damages, plus in some cases, attorney's fees.

September 2022

FMI

Who we are and what we do-

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.

Disclaimer - We are not the FDA and did not write this rule

Housekeeping

Please use the Q&A to submit questions

Slides and resources will be available through SQFI

Background

FSMA – Enhancing Tracking and Tracing of Food and Recordkeeping

2011

FSMA Statute – Section 204

2014

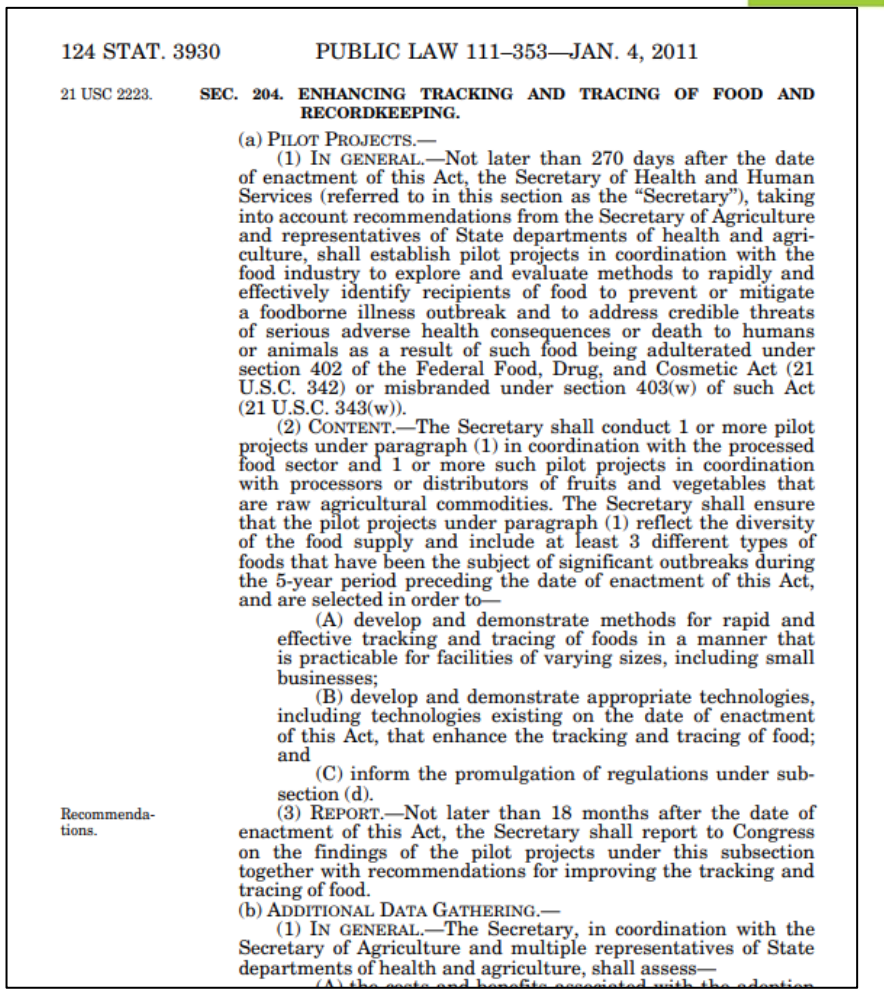
Docket No. FDA–2014–N–0053

Designation of High-Risk Foods for Tracing; Request for Comments and for Scientific Data and Information

September 2020

Docket No. FDA–2014–N–0053

RIN 0910–AI44 "Requirements for Additional Traceability Records for Certain Foods"



124 STAT. 3930 PUBLIC LAW 111–353—JAN. 4, 2011

21 USC 2223.

SEC. 204. ENHANCING TRACKING AND TRACING OF FOOD AND RECORDKEEPING.

(a) PILOT PROJECTS.—

(1) IN GENERAL.—Not later than 270 days after the date of enactment of this Act, the Secretary of Health and Human Services (referred to in this section as the "Secretary"), taking into account recommendations from the Secretary of Agriculture and representatives of State departments of health and agriculture, shall establish pilot projects in coordination with the food industry to explore and evaluate methods to rapidly and effectively identify recipients of food to prevent or mitigate a foodborne illness outbreak and to address credible threats of serious adverse health consequences or death to humans or animals as a result of such food being adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342) or misbranded under section 403(w) of such Act (21 U.S.C. 343(w)).

(2) CONTENT.—The Secretary shall conduct 1 or more pilot projects under paragraph (1) in coordination with the processed food sector and 1 or more such pilot projects in coordination with processors or distributors of fruits and vegetables that are raw agricultural commodities. The Secretary shall ensure that the pilot projects under paragraph (1) reflect the diversity of the food supply and include at least 3 different types of foods that have been the subject of significant outbreaks during the 5-year period preceding the date of enactment of this Act, and are selected in order to—

(A) develop and demonstrate methods for rapid and effective tracking and tracing of foods in a manner that is practicable for facilities of varying sizes, including small businesses;

(B) develop and demonstrate appropriate technologies, including technologies existing on the date of enactment of this Act, that enhance the tracking and tracing of food; and

(C) inform the promulgation of regulations under subsection (d).

Recommendations.

(3) REPORT.—Not later than 18 months after the date of enactment of this Act, the Secretary shall report to Congress on the findings of the pilot projects under this subsection together with recommendations for improving the tracking and tracing of food.

(b) ADDITIONAL DATA GATHERING.—

(1) IN GENERAL.—The Secretary, in coordination with the Secretary of Agriculture and multiple representatives of State departments of health and agriculture, shall assess—

FMI Activities

2010	Active engagement with Congress on the language in FSMA including section 204
2011-2012	Pilot Projects for Improving Product Tracing along the Food Supply System- Final Report, IFT
2014	Comments submitted on draft methodology for high-risk foods
2020	Leafy Greens Traceability Pilots Report PMA, United Fresh, GS1-US, IFT, IFDA, FMI
2021	Comments submitted on Food Traceability Proposed Rule
2021	Traceability Workshops Food and Beverage Issues Alliance (FBIA)
2022	Met with the Office of Management and Budget (OMB)

Where can I find the Final Rule and Resources?

Food Traceability Final Rule

Designation of High-Risk Foods for Tracing; Request for Comments and for Scientific Data and Information

Federal Register Vol. 87, No. 223 /Monday, November 21, 2022

Pages 70910 – 71088

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

Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

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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

FDA Resources

U.S. FOOD & DRUG ADMINISTRATION

Search | Menu

Home / Food / Guidance & Regulation (Food and Dietary Supplements) / Food Safety Modernization Act (FSMA) / FSMA Final Rule: Requirements for Additional Traceability Records for Certain Foods

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

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Food Safety Modernization Act (FSMA)

- Frequently Asked Questions on FSMA
- FSMA Rules & Guidance for Industry
- What's New in FSMA
- FSMA Training
- FSMA Technical Assistance Network (TAN)

Content current as of:
11/17/2022

Regulated Product(s)
Food & Beverages

When do I need to comply?

Publication date: November 21, 2022

+ 60 days

+ 3 years

= **January 20, 2026**

Components of the rule – 2 Parts

Food Traceability List (published on FDA.gov, Nov 2022)

- Not codified
- Updated approximately every 5 years by FDA
- Foods that require additional recordkeeping for traceability

Requirements for Additional Traceability Records for Certain Foods

- Final rule in the Code of Federal Regulations

Food Traceability List

Food Traceability List

- Cheeses, other than hard cheeses, specifically:
  - Cheese (made from pasteurized milk), fresh soft or soft unripened
  - Cheese (made from pasteurized milk), soft ripened or semi-soft
  - Cheese (made from unpasteurized milk), other than hard cheese
- Shell eggs
- Nut butters
- Cucumbers (fresh)
- Herbs (fresh)
- Leafy greens (fresh)
- Leafy greens (fresh-cut)
- Melons (fresh)
- Peppers (fresh)
- Sprouts (fresh)
- Tomatoes (fresh)
- Tropical tree fruits (fresh)
- Fruits (fresh-cut)
- Vegetables other than leafy greens (fresh-cut)
- Finfish (fresh and frozen), specifically:
  - Finfish, histamine-producing species
  - Finfish, species potentially contaminated with ciguatoxin
  - Finfish, species not associated with histamine or ciguatoxin
  - Smoked finfish (refrigerated and frozen)
- Crustaceans (fresh and frozen)
- Molluscan shellfish, bivalves (fresh and frozen)
- Ready-to-eat deli salads (refrigerated)

Examples of foods

FTL Foods under the rule

Peanut butter crackers

Salad with fresh vegetables

Sandwich with lettuce and tomatoes

Ice cream with peanut butter as ingredient

Not covered

Frozen pizza

Frozen fruits

Frozen veggies

Nuts

Canned foods

Pasteurized foods

Pasteurized eggs

Foods on the FTL

All items on the FTL used as Ingredients are included in rule

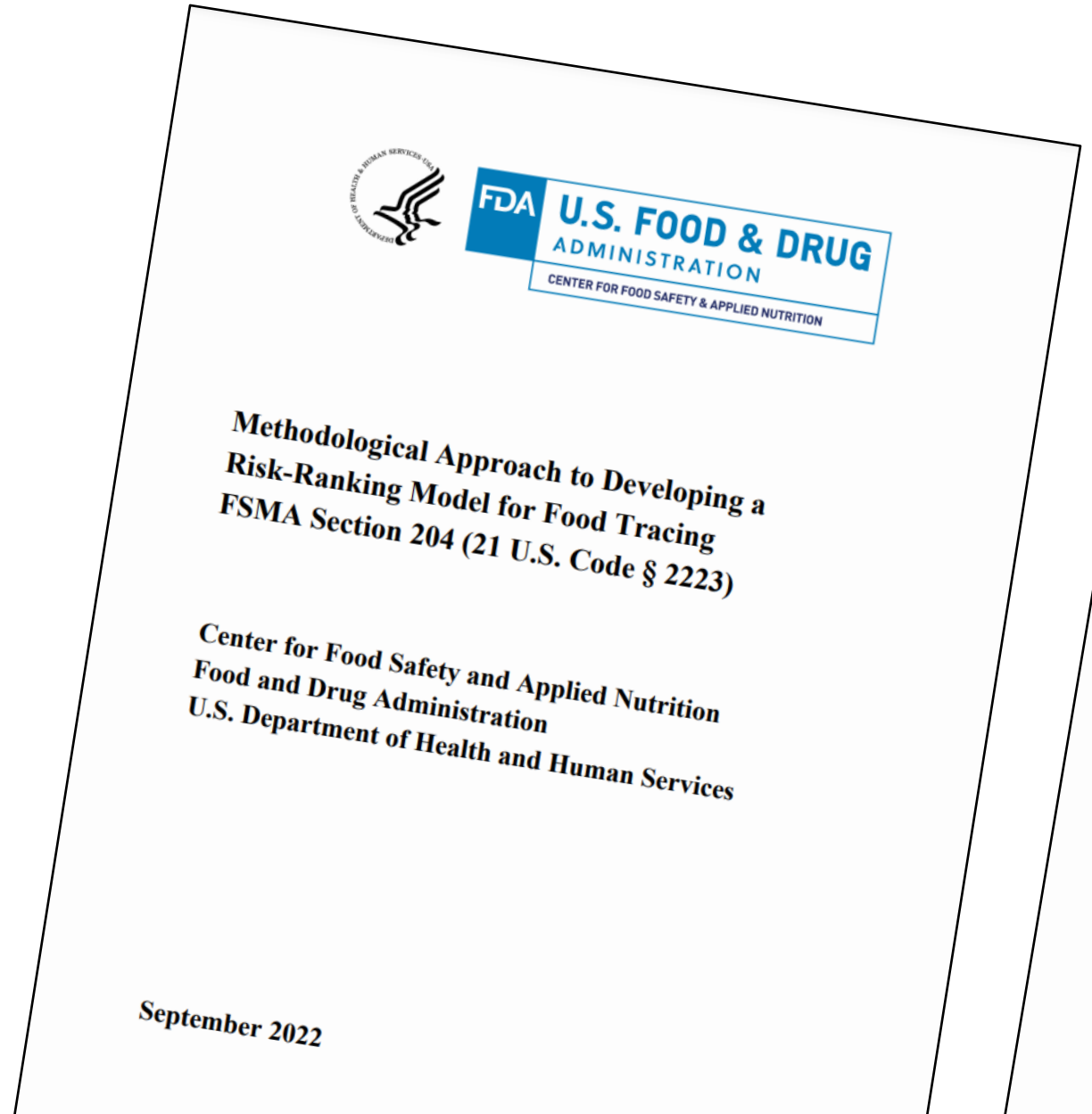
Foods in the form specified on the FTL

- fresh
- frozen
- all forms

Other forms not included for most FTL Foods (Documentation is needed)

- dried
- thermal or non- thermal processed

How did FDA come up with the FTL?

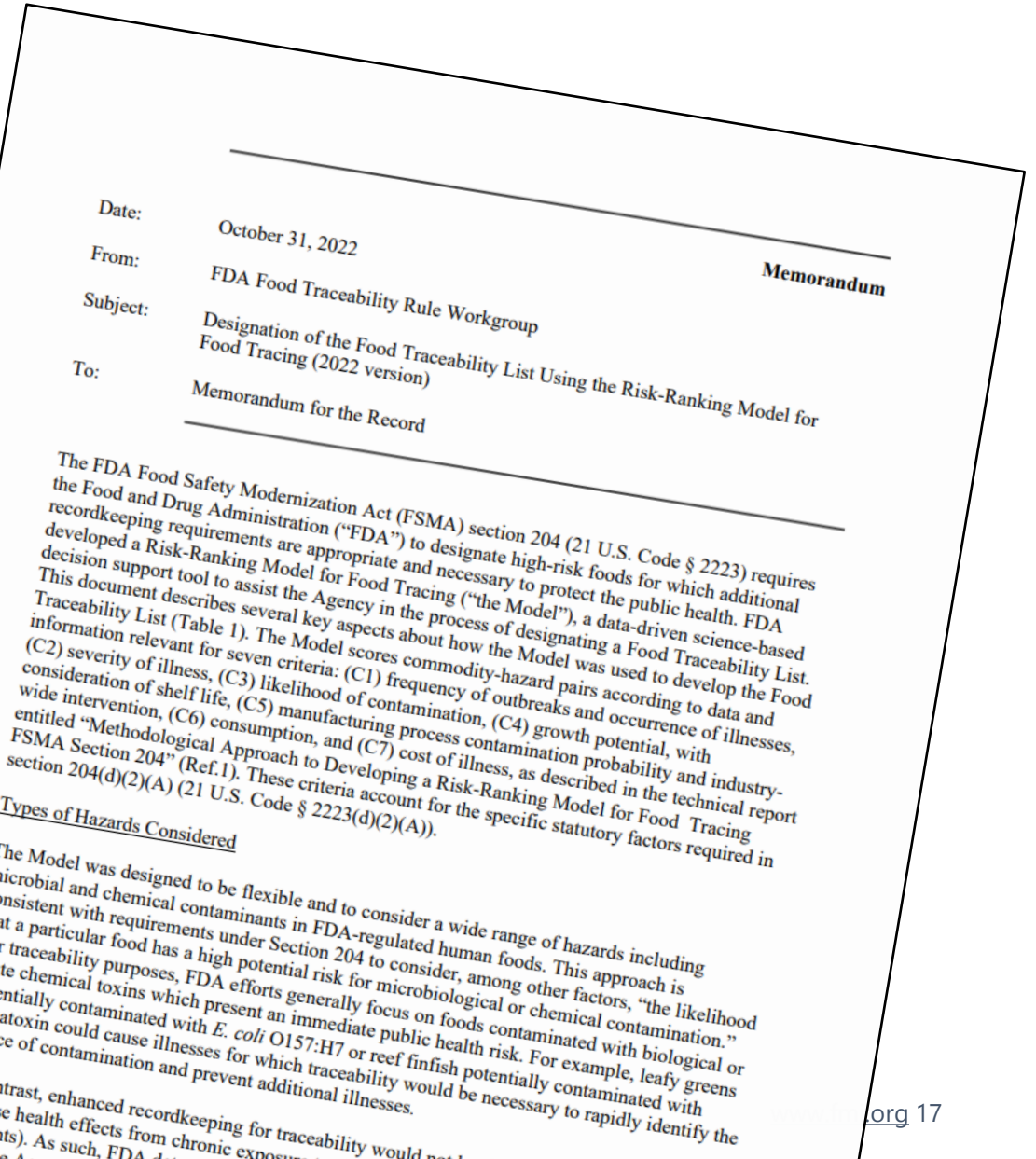


U.S. FOOD & DRUG ADMINISTRATION
CENTER FOR FOOD SAFETY & APPLIED NUTRITION

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
adverse health effects from chronic exposu
elements). As such, FDA d
List, the A

Scope of the Traceability Final Rule

What does the rule require?

The rule “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”

Who must comply?

"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."

Definitions in Final Rule § 1.1310

Lot Code Definitions

Traceability Lot means a batch or lot of food that has been initially packed (RAC), received by the first land-based receiver (from fishing vessel), or transformed.

Traceability Lot Code means a descriptor, often alphanumeric, used to uniquely identify a traceability lot within the records of the traceability lot code source.

Traceability Lot Code Source means the place where a food was assigned a traceability lot code

Traceability Lot Code Source of Reference means an alternative method for providing FDA with access to the location description for the traceability lot code source as required under this subpart. Examples of a traceability lot code source reference include the 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.

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

Critical Tracking Event (CTE)

"Event in the supply chain of a food involving the harvesting, cooling (before initial pacing), initial packing of a raw agricultural commodity other than a food obtained from a fishing vessel, first land-based receiving of a food obtained from a fishing vessel, shipping, receiving, or transformation of the food"

Key Data Element (KDE)

"Information associated with a critical tracking event for which a record must be maintained and/or provided in accordance with this subpart."

Transformation

"Event in the food's supply chain that involves manufacturing/processing a food or changing a food (comminglingly, repacking, or relabeling) or its packaging or packing, when the output is a food on the Food Traceability List. Transformation does not include the initial packing of a food or activities preceding at event (harvesting, cooling)."

Receiving

"An event in a food's supply chain in which a food is received by someone other than a consumer after being transported (by truck or ship) from another location.

Receiving includes receipt of an intracompany shipment of food from one location at a particular street address of a firm to another location at a different street address of the firm."

Receiving

"An event in a food's supply chain in which a food is received by someone other than a consumer after being transported (by truck or ship) from another location.

Receiving includes receipt of an intracompany shipment of food from one location at a particular street address of a firm to another location at a different street address of the firm."

Shipping

"Event in a food's supply chain in which a food is arranged for transport (truck or ship) from one location to another location. Shipping does not include the sale or shipment directly to a consumer or the donation of surplus food. Shipping includes sending an intracompany shipment of food from one location at a particular street address of a firm to another location at a different street address of the firm."

Shipping

"Event in a food's supply chain in which a food is arranged for transport (truck or ship) from one location to another location.

Shipping does not include the sale or shipment directly to a consumer or the donation of surplus food.

Shipping includes sending an intracompany shipment of food from one location at a particular street address of a firm to another location at a different street address of the firm."

Kill Step

"Lethality processing that significantly minimizes pathogens in a food"

Notes:

Validation is not required in Subpart S for kill steps

Documentation that process was applied

Written assurances do apply

Example – incoming ingredient is fresh herb, facility applies a thermal process

Rule Requirements

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.

CTEs and KDEs

Critical Tracking Event (CTE)

Points in the supply chain where product is moved or sold

For example – receiving, shipping, transforming

Key Data Element (KDE)

Data elements required to be captured as records

For example – location, lot code, date

	A	B	C	D	E	F	G	H
1	Food Traceability Final Rule - CTEs and KDEs							
2	**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**
3	**Section**	§1.1325(a)	§1.1325(b)	§1.1330	§1.1335	§1.1340	§1.1345	§1.1350
4		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		
5	**Traceabilily 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;
6								The new traceability lot code for the food (after transformation)
7	**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
8		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;	
9						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	
10	**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;
11								Product description of the food after transformed
12		Commodity and variety of food	Commodity and variety of food	Commodity and variety of food received				
13	**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
14				Quantity and unit of measure of the packed food				
15	**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
16	**Harvest/Aquaculture KDE**	*For aquacultured food*, the name of the container (pond, pool, tank, cage) from which the food was harvested (which must correspond to the container name used by the aquaculture farmer (or other information identifying the harvest location at least as precisely as the container name		For aquacultured food, the name of the container (pond, pool, tank, cage) from which the food was harvested (which must correspond to the container name used by the aquaculture farmer (or other information identifying the harvest location at least as precisely as the container name				
17	**Date KDEs**	Date of harvesting	Date of cooling	Date food was received;	Date the food was landed	Date food was shipped	Date food was received	Date transformation completed
18				Date of harvesting;				
19				Date of initial packing;				
20				Date of Cooling;				
21	**Reference Documents**	Reference document type and reference document number	Reference document type and reference document number	Reference Document Type and Reference Document Number	Reference document type and reference document number	Reference document type and reference document number	Reference document type and reference document number	Reference document type and reference document number for the transformation event
22	**Notes**			Additional requirements for sprouts and if receiving products from a person not subject to the traceability rule – Please see §1.1330			Additional requirements for foods received from a person not subject to the traceability rule – Please see §1.1345	** does not apply to retail food establishments and restaurants when foods are sold directly to consumers

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
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

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)

Examples for Manufacturing/processing Facilities – foods or ingredients on FTL

Receiving

Transformation

Shipping

Examples for Production + Manufacturing/processing Facilities

Harvesting/Cooling a RAC

Packing a RAC

Shipping a RAC

Receiving

Transformation

Shipping

Example – Salad Kit Production from farm to processing facility

Example for Manufacturing to Retail KDEs required at each CTE

- **Receiving at Manufacturing**
- **Transformation**
- **Shipping from Manufacturing**
- **Receiving at DC**
- **Shipping at DC**
- **Receiving at Retail Store or Restaurant**

Example – Nut Butter Processing

Transformation

Shipping from Manufacturing

Receiving at DC

Shipping at DC

Receiving at Retail Store or Restaurant

Nuts are not on the FTL
Nut butters are on the FTL so KDE's start with Transformation from nuts to nut butter

Exemptions §1.1305

Exemptions

Size exemptions – volume or sales based

Comingled RACS – exemption only applies to shell eggs or seafood

Processing exemptions – Kill step or changing the form of food on the FTL (fresh vs frozen for certain items)

Transporters

Non-profit food establishments

FDA has online tool – "Exemptions to the Food Traceability Rule"

Other Items in Rule

Waivers – upon request

Important Dates

Compliance Date

Three years after the effective date – 60 days after date of publication

Compliance Date = January 20, 2026

What do I do now?

Tips and Tricks

Codified section is in the back of *Federal Register* notice

- Pages 71077 – 71088

Preamble

- Pages 70910 – 71077
- Use this as “current thinking” or “guidance”
- Ctrl + F is your friend

Read the definitions in §1.1310

What is next?

1. Evaluate current capabilities

2. Gap assessment with current systems

3. Develop plan with interdepartmental team

    Food safety, IT, Supply chain, Management

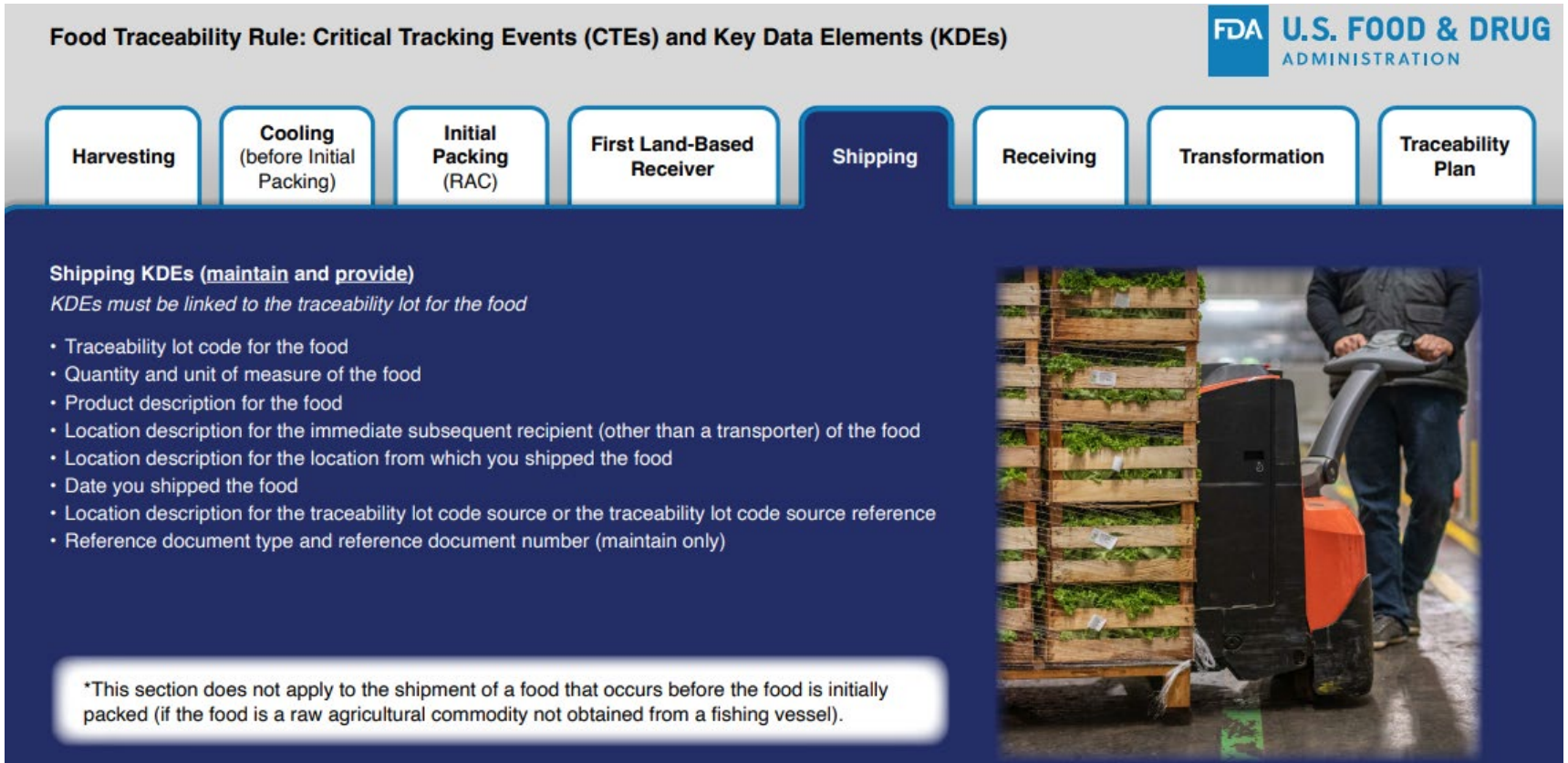
Next Steps

- **Review the Final Rule and resources**
- **Assess Current Operations** – Does your operation manufacture, process, pack or hold a food on the Food Traceability List or any food that contains a listed food as an ingredient? If yes, what role do you play?
- **Complete a Gap Analysis** – Review and evaluate your current traceability system.
- ***Questions to help evaluate your traceability system (Note this is not an exhaustive list)***
    - What KDEs do you currently capture?
    - How are the KDEs captured and in what format?
    - Where are the KDEs captured (i.e., source records, record storage location)?
    - How are records maintained?
    - How accessible are the KDEs/records containing KDEs (i.e., ease of access, time to access)?
    - Who has permission to access the KDEs/records containing KDEs?
    - How do you share information with supply chain partners?
    - How do supply chain partners share information with you?
    - What data/information do you share with supply chain partners?
    - What data/information do supply chain partners share with you?
- **Create a Traceability Plan** - If you are subject to the requirements of the final rule, you must establish and maintain a traceability plan.
- **Implement Traceability Plan**

Additional Resources

SQFI.com

FDA Food Traceability Tools and Resources



This is just the beginning…

Hilary Thesmar, PhD, RD, CFS
Chief Science Officer and SVP Food and Product Safety
hthesmar@fmi.org

How does this compare to SQF?

- Current requirements under Identification (2.6.1) and Traceability (2.6.2) do not align with the final rule.
- To be evaluated under 2.4.1.1- Food Legislation.
- Responsibilities and requirements would vary based on the FTL, CTE, or KDE.