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
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”
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?
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 foods.

Operations, Food and Drug Administration, Three White Flint North, 10A–124M, 11001 Landsgrove St., North Bethesda, MD 20852, 301–796–5733, PRASStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

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B. Summary of Comments on the Proposed Rule
C. General Overview of the Final Rule
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FDA Resources

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

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?
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).”
"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
<table>
<thead>
<tr>
<th>A</th>
<th>B</th>
<th>C</th>
<th>D</th>
<th>E</th>
<th>F</th>
<th>G</th>
<th>H</th>
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</thead>
<tbody>
<tr>
<td>Food Traceability Final Rule - CIEs and KIDEs</td>
<td>Critical Tracking Events requiring records</td>
<td>Initial Packing of RAC (ADDED)</td>
<td>Cooling RAC on FTLS (ADDED)</td>
<td>Harvest RAC on FTL (ADDED)</td>
<td>First Layer Based (Receiver of a food on FTL, obtained from a fishing vessel)</td>
<td>Stipulate date on the FTL (ADDED)</td>
<td>Receive a food on the FTL</td>
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<td>Harvest KIDEs</td>
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<td>Date of Harvesting</td>
<td>Date of cooling</td>
<td>Date food was received</td>
<td>Date food was shipped</td>
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<td>Additional requirements for foods received from a person not subject to the traceability rule. Please use 1.160</td>
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</table>
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

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.