Navigating the FDA Food Traceability Rule: A Resource Guide for AFFI Members

AMERICAN FROZEN FOOD INSTITUTE

This document represents a high-level summary designed to assist members of the American Frozen Food Institute (AFFI) in familiarizing themselves with FDA's Final Rule: Requirements for Additional Traceability Records for Certain Foods and 21 CFR Subpart J governing the establishment, maintenance, and availability of records under the Bioterrorism Act of 2002. Although this summary highlights certain current regulatory requirements, it is not intended to be and cannot serve as a substitute for careful review or application of the regulatory framework as it relates to each member's own products and operations, nor does adherence to the descriptions of regulatory requirements contained herein ensure compliance with applicable statutory and regulatory requirements. **THIS DOCUMENT IS FOR GENERAL INFORMATION ONLY AND IS NEITHER INTENDED AS NOR DOES IT CONSTITUTE LEGAL ADVICE OR CREATE AN ATTORNEY-CLIENT RELATIONSHIP WITH ANY PERSON OR ENTITY**. Competent legal counsel should be consulted regarding any member's compliance with FDA regulations, and the information herein should not be used or relied upon in regard to any particular facts or circumstances. AFFI does not guarantee the accuracy, adequacy, completeness, or availability of any information provided herein and is not responsible for (and disclaims all liability for) any errors or omissions or for any results obtained from the use of such information. AFFI makes no warranties, expressed or implied, guarantees, or assurances concerning the accuracy, application, or use of this information, and any responsibility for the use of this information is disclaimed. This document does not reflect any developments after the date on the first page.

Background:

In November 2022, FDA issued its final rule titled "Requirements for Additional Traceability Records for Certain Foods" or the "Food Traceability Rule." The rule requires any person who manufactures, processes, packs, or holds a food on the Food Traceability List (FTL) and participates in certain Critical Tracking Events (CTEs) to maintain and pass forward certain traceability information known as Key Data Elements (KDEs). The relevant CTEs include harvesting, cooling, initial packing, first land-based receiving of seafood, receiving, shipping, and transformation, and most of the required KDEs are likely already being tracked and maintained by the food supply chain. However, because the Food Traceability Rule requires entities to pass traceability information forward and be able to provide records to FDA in an electronic sortable spreadsheet within 24 hours, many companies are finding the rule challenging to implement.

Most frozen foods, with the exception of seafood and foods containing nut butters, are NOT included in the Food Traceability List (FTL) and therefore are not subject to the requirements of the FDA Food Traceability Final Rule. However, some retail customers have communicated their expectation that all suppliers meet these standards (or at least provide "traceability information" using the ASN 856). It is unclear at this time whether those retailers will be tracking all foods to the individual store location (as required by the rule for FTL foods).

Additionally, the one up/one back recordkeeping requirements that began in 2006 are still in effect and DO apply to most of the frozen food industry. FDA has not historically conducted inspections to verify compliance with the one up/one back requirements. Implementation of the Food Traceability Final Rule for companies that do not manufacture, process, pack, or hold food on the FTL would be voluntary and therefore not subject to FDA review. To limit confusion on the part of regulators, companies that choose to enhance their traceability programs for foods that are *not* on the FTL consistent with the Food Traceability Rule and beyond the one up/one back requirements should manage these as separate programs.

AFFI has prepared this list of resources to help members understand the rule and how to implement its requirements.

1. For frozen food manufacturers who voluntary align with the essence of the rule, AFFI recommends conducting a gap analysis that considers the availability of the relevant KDEs, current practices for providing data to customers, and certain logistical concerns. Questions A, B, C, and D address the availability of information, Question E assesses the ease of communicating with trading partners, and Question F relates to logistic concerns your customers may have:

a. Do you currently capture each of the Key Data Elements in your records? If so, what form are these data elements in and can they be organized into an electronic sortable spreadsheet?
b. How are ingredient lot numbers and related information currently linked to finished product lot numbers?
c. How are finished product lot numbers and other relevant information communicated to the immediate subsequent recipient location (e.g., not a broker who does not handle the product)?
    i. Are all or some of the Key Data Elements on product cases?
        1. If so, what is the data carrier? Human readable/text only vs barcode vs RFID tag?
    ii. Are all or some of the Key Data Elements communicated via Advance Ship Notices (e.g., ASN 856)?
    iii. Are all or some of the Key Data Elements communicated via Bills of Lading (BOLs)?
d. What systems are used to capture traceability information (especially lot numbers) during the receipt of ingredients/raw materials, production, and distribution?
e. Does the company use GS1 standards, and if so, in what ways?
    i. Does the company have a company prefix?
    ii. Are finished products identified by a Global Trade Item Number (GTIN)?
    iii. Is master data housed in and available to supply chain partners from a Global Data Synchronization Network (GDSN)?
    iv. Are finished product cases identified with a GS1 barcode (e.g., ITF 14, GS1-128, etc.)?
    v. Is information shared through the supply chain using GS1 standards for electronic communication (EDI) such as advance ship notices (ASNs)?
f. How often do pallets of finished product contain multiple lot numbers?

2. The Food Traceability Rule includes several requirements, summarized below:
    a. A traceability plan that includes the following:
        i. A description of the procedures used to maintain traceability records
        ii. An indication of how a company identifies the food it handles on the FLT
            1. *This is moot if no foods are on the FTL*
        iii. A description of how Traceability Lot Codes are developed (e.g., if there is an "encoding" that can be deciphered)
        iv. A point of contact for follow up
    b. The capture, maintenance, and sharing of specific Key Data Elements at certain Critical Tracking Events

        i. For the frozen food supply chain, the main CTEs of concern are receiving, transformation (e.g., production/ manufacturing), and shipping
        ii. Most Key Data Elements are available today (dates, locations, quantities, descriptions- many are repeats of the one up/one back requirements). The KDEs that are more challenging today are the traceability lot code, and traceability lot code source
            1. The Rule requires the TLC and TLC source to flow through the supply chain and be available at the point of sale/service (retail, restaurant, etc.) and only certain CTEs can assign a traceability lot code.
    c. The availability of an electronic sortable spreadsheet containing the traceability information specifically requested by FDA. Note: this does *not* mean that traceability information must be digital at all times (although this is a great goal)

3. FDA wrote the rule and is the ultimate "truth" for information. FDA should be the first stop when verifying a claim about the rule (e.g., made by a customer, supplier, technology provider, etc.). FDA's main traceability page has several easy-to-read resources.
    a. https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-final-rule-requirements-additional-traceability-records-certain-foods
    b. FDA's Frequently Asked Questions are a great place to start
        i. Frequently Asked Questions: FSMA Food Traceability Rule | FDA https://www.fda.gov/food/food-safety-modernization-act-fsma/frequently-asked-questions-fsma-food-traceability-rule

4. FMI developed an implementation guide
    a. https://www.fmi.org/docs/default-source/food-safety/fsma-microsite---traceability/fmi-traceability-implementation-guide.pdf?sfvrsn=2a006e5b_3
        i. While long, it serves as a "how to", focusing on retail distribution (with less information on transformations/processing)

5. GS1 (a not for profit standards setting organization; not a technology solution provider itself) has a suite of resources
    a. https://www.gs1us.org/supply-chain/standards-and-regulations/food-safety-modernization-act#FSMA204
        i. Most useful include:

1. Readiness checklist: GS1-US-FSMA-204-Readiness-Checklist.pdf (gs1us.org)
2. Retail and foodservice application of GS1 standards for FSMA 204: GS1-US-Application-of-GS1-System-of-Standards-to-Support-FSMA-204-Guideline.pdf (gs1us.org) (this is a long document but a good primer on GS1)

6. Although Institute of Food Technologists (IFT) has a Global Food Traceability Center, the vast majority of resources are only available to IFT members: https://www.ift.org/gftc/
    a. IFT also collaborated with CAST to provide a background paper on traceability. It mentions, but is not focused on, the FDA rule: https://cast-science.org/publication/food-traceability-current-status-and-future-opportunities/

7. The fresh produce industry's voluntary traceability standards are reasonably well aligned with FDA requirements, and many resources are available: https://producetraceability.org/resources/
    a. Pages 26-31 include data that digests/interprets the KDEs in the context of GS1 standards; pages 38-49 give tips and insight for those who transform, ship, and receive (as distributors).

Comparison:

One Up/One Back Rule vs. FDA Traceability Rule (FSMA 204)

Summary: The new rule builds on the pre-existing rule in a few main ways:

- Many more types of businesses are covered by the new rule, because the new rule applies to all persons that manufacture, process, pack, or hold foods on the food traceability list
    - Farms (including harvesting and cooling), first land-based receivers, restaurants, and retail food establishments (including convenience stores, grocery stores, etc.) ARE subject to the new rule
    - Transporters will continue to need to comply with the one up/one back requirements but ARE NOT subject to the new Food Traceability Rule
- For those entities subject to the new rule, more information must be maintained and passed forward in the supply chain, notably the traceability lot code and the traceability lot code source
- Although information can be shared and maintained in any form, if FDA requests records required under the Food Traceability Rule, these records must be provided within 24 hours and, in some cases, this information must be provided in an electronic sortable spreadsheet.

The table below compares the two rules. Please consult the rules (via the linked CFR references) for a complete understanding of each rule. Both have nuances and complexities that are difficult to capture in a simple table.

	One up/ down	Final traceability rule
CRF reference	21 CFR Chapter 1 subpart J "Establishment, Maintenance, and Availability of Records"	21 CFR Chapter 1 Subpart S "Additional Recordkeeping Requirements for Certain Foods"
Final rule date	Dec 9, 2004	Nov 21, 2022
Compliance date	Dec 9, 2005 (extra 6 and 12 months for small and very small businesses)	January 20, 2026 for all covered entities

Covered foods	Any food produced or handled by covered entities (excluding those regulated by USDA FSIS)	Those on the Food Traceability List
Covered entities	Persons who manufacture, process, pack, transport, distribute, receive, hold or import food into the US, whether in interstate commerce or nor. Farms, fishing vessels (depending on activity) and restaurants are specifically excluded	Persons who manufacture, process, pack or hold food on the FTL including farms, first land-based receivers of seafood, and restaurants. Transporters are excluded
Global scope	No: applies to entities in the US only (including importers)	Yes: applies to entities handling FTL foods that will be consumed in the US, even if the entity is outside the US
Receiving requirements	Contact info of the immediate source (domestic or foreign), description of food (including brand name/ variety), date received, quantity, contact info of the transporter, and for manufacturers, lot numbers if they exist	Specific Key Data Elements (KDEs) are required to be captured, including the traceability lot codes (TLCs) for FTL foods, Traceability Lot Code Sources (TLCS), quantity and unit of measure, product description, information on the immediate previous source, date of receipt, reference document type and number, and location description for place where received.
Shipping requirements	Contact info of the subsequent recipient, description of food (including brand/ variety), date released, quantity, contact info of the transporter, and for manufacturers, lot numbers	Specific KDEs are required to be shared, including the traceability lot codes (TLCs) for FTL foods, Traceability Lot Code Sources (TLCS), quantity and unit of measure, product description, location description for place where received, location description for the place where shipped, and date shipped.
Manufacturing/ transformation requirements	"your records must include information reasonably available to you to identify the specific source of each ingredient	Specific KDEs including linking the TLCs of ingredients on the FTL to the new FTL food TLC, location description for transformation location, date of transformation, product

	used to make every lot of finished product”	description (both ingredient and transformed product), date of transformation, quantity and unit of measure (ingredient and transformed product), and reference document type and number.
Transporter requirements	Names of sources and recipients, origin and destination, date received and released, # packages, description of the freight, route, transfer points	n/a
Timeframe to respond to FDA records request	24 hours	24 hours (unless otherwise negotiated)
Information to provide to FDA upon request	Information requested, in any form, including paper	Records maintained; if requested, data in an electronic sortable spreadsheet
Enforcement experience/ expectation	Not part of routine inspections; not enforced during investigations, with the exception of one 483 issued	TBD. Especially unclear how enforcement at retail food establishments (under state/ local authority) will occur. FDA says routine enforcement will not occur before 2027
Record retention	6 months for foods likely to spoil within 60 days; 1 year for foods likely to spoil between 60 days- 6 months; 1 year for animal food including pet food; 2 years for all other foods	2 years
Exemptions/modifications	Yes, based on activity	Yes, based on business size/ sales and certain processing activities
Other requirements	N/A	Written traceability plan