



FSMA 204 – from its roots to its fruit

EXPLORING THE RULE'S ORIGIN, GROWTH, PURPOSE, COMPLIANCE
AND HOW WE CAN HELP

White paper



Fast-forward from FDA fact finding to FSMA 204

Following several high-profile food safety cases that impacted trust, the US Food and Drug Administration (FDA) released the Food Safety Modernization Act (FSMA). President Barack Obama signed FSMA into law on January 4, 2011, and it was published in the Federal Register on January 16, 2011.

Now, the FDA's FSMA 204(d) final rule on food traceability outlines additional recordkeeping requirements for certain foods and requires organizations, big and small, to update their food safety management system(s).

Defining "food traceability"

Food traceability: an organization's ability to track the movement of food materials throughout the supply chain until they become end products.

What is FSMA 204?

FSMA 204, also known as the Food Traceability Rule, aims to enhance food safety by improving supply chain traceability. It targets high-risk foods on the Food Traceability List (FTL) and mandates detailed recordkeeping, traceability plans and rapid data sharing.

These measures support the swift identification and removal of contaminated food from the market, reducing risks and strengthening consumer trust.

It applies to US and non-US organizations supplying food for consumption in the US. They must now keep additional traceability records if they hold, process, pack or manufacture foods on the FTL. Additional recordkeeping requirements include maintaining Key Data Elements (KDEs) and Critical Tracking Events (CTEs) and sending these records to the FDA, preferably within 24 hours.

FSMA 204 came into effect on January 20, 2023, with a compliance date of January 20, 2026, which the FDA could extend to July 2028. Either way, many retailers are pushing suppliers for earlier adoption.

The [FDA website](#) states: "We generally note that, while we aren't initiating routine inspections until 2027, we may do inspections for compliance with the Food Traceability Rule on a for-cause basis, such as during an outbreak investigation, once the compliance date of January 20, 2026, is reached."

Why did FSMA 204 become law?

The section was written into law for numerous reasons, including minimizing and mitigating food safety hazards, such as salmonella and E. coli.

The additional recordkeeping requirements aim to identify and remove potentially contaminated food from the market faster, minimizing foodborne illnesses and, worse, deaths.

FSMA 204 is also known as
**Requirements for Additional Traceability
Records for Certain Foods**

Traversing the terminology

FOOD TRACEABILITY LIST (FTL)

The FTL classifies specific food items that require enhanced recordkeeping under FSMA 204.

CRITICAL TRACKING EVENTS (CTEs)

A fundamental point in the supply chain, where capturing and documenting critical information is essential. There are seven CTEs that help decrease the chance of contamination and risk of foodborne diseases:

1. Harvesting: activities at farms to remove and prepare raw agricultural commodities (RACs) for food use, such as growing and raising processes
2. Cooling (before initial packing): reducing the temperature of RACs. Methods include hydro-cooling, icing (excluding seafood), forced air and vacuum cooling
3. Initial packing (RACs): the first packing of RACs, excluding seafood from fishing vessels, into containers for additional handling or transportation
4. First land-based receiver (seafood): the first organization on land to receive food from a fishing vessel
5. Shipping: arranging food for transportation, including intracompany shipments to different addresses, but not direct sales or donations to consumers
6. Receiving: accepting food shipments at a new location, including intracompany transfers, but not direct consumer deliveries
7. Transformation: significantly altering the food through processes, such as manufacturing, commingling, repacking or relabeling, specifically when the result is an FTL food

KEY DATA ELEMENTS (KDEs)

Crucial data for each CTE that organizations must maintain and disclose to supply chain partners and the FDA. These details should answer the “who” (parties involved), “what” (activities involving the food item), “when” (event date) and where (location).

Common KDEs include:

- The food’s location description: where it was harvested, cooled, packed, shipped, etc. (other than a transporter)
- Commodity (and food variety, if relevant)
- Food quantity and unit of measurement
- Location description: where the organization shipped the food
- Traceability Lot Code (TLC) the organization assigned or TLC Source
- Date of harvesting, cooling, initial packing, landing, shipping, receiving and transformation completion
- Reference document type and number

The FDA has the exact details and wording concerning which KDEs are needed for each CTE.

RAW AGRICULTURAL COMMODITY (RAC)

This is usually unprocessed fruits and vegetables.

RETAIL FOOD ESTABLISHMENTS

The places, e.g. supermarkets, stores and restaurants, where food is sold to the public.

TRACEABILITY LOT CODE (TLC)

A unique code, typically alphanumeric, assigned to a specific food batch to enable its traceability throughout the supply chain, particularly during recalls. An organization must assign a TLC to a food on the FTL when it:

- Initially packs a RAC, excluding foods from fishing vessels
- Performs the first land-based receiving of food from a fishing vessel
- Transforms a food

TLC SOURCE

The first location or facility where a food batch is assigned its TLC.

GLANCE AT THE FSMA 204 MENU

Menu

FSMA 204

Food traceability list

Standardized food
traceability system

Enhanced recordkeeping
requirement

Food traceability plan

What is FSMA 204's traceability rule?

FOOD TRACEABILITY LIST (FTL):

defines foods requiring enhanced recordkeeping. This applies to listed foods and those containing listed ingredients, provided they maintain the form in the list, e.g. fresh.

STANDARDIZED FOOD TRACEABILITY SYSTEM:

uses the FTL and KDEs to aid consistent and accurate monitoring of specific foods throughout the supply chain.

ENHANCED RECORDKEEPING REQUIREMENTS:

mandates thorough documentation of CTEs for the regulated foods. This guarantees a detailed audit trail.

FOOD TRACEABILITY PLAN:

your organization must create and follow a traceability plan detailing the procedures for new recordkeeping rules. This includes assigning and documenting TLCs and other identifiers to trace supply chain shipments.

What products are on the FTL?

The idea of a high-risk foods list dates back to 2014 when FSMA first required the FDA to request comments, scientific data and information to help implement a list.

The current FTL was established following detailed analyses of outbreak investigations and recalls. The number and frequency of outbreaks and recalls helped determine which foods to include.

The FDA will review the list every five years. As the list was updated in 2022, we anticipate a revised list in 2027.



THE CURRENT FTL

FTL item	Description
Cheese (made from pasteurized milk), fresh-soft or soft-unripened	<ul style="list-style-type: none"> • Soft-unripened/fresh-soft cheeses • Does not include frozen or previously frozen, shelf-stable at ambient temperature, or aseptically processed and packaged cheeses
Cheese (made from pasteurized milk), soft-ripened or semi-soft	<ul style="list-style-type: none"> • Soft-ripened/semi-soft cheeses • Does not include frozen or previously frozen, shelf-stable at ambient temperature, or aseptically processed and packaged cheeses
Cheese (made from unpasteurized milk), other than hard cheese	<ul style="list-style-type: none"> • All cheeses made with unpasteurized milk, other than hard cheeses • Does not include frozen or previously frozen, shelf-stable at ambient temperature, or aseptically processed and packaged cheeses
Shell eggs	<ul style="list-style-type: none"> • The eggs of domesticated chickens
Nut butters	<ul style="list-style-type: none"> • All types of tree nut and peanut butters • All forms of nut butters, including shelf-stable, refrigerated, frozen and previously frozen products • Does not include soy or seed butters
Fresh cucumbers	<ul style="list-style-type: none"> • All varieties of fresh cucumbers
Fresh herbs	<ul style="list-style-type: none"> • All types of fresh herbs • Herbs listed in 21 CFR 112.2(a)(1) are exempt
Fresh leafy greens	<ul style="list-style-type: none"> • All types of fresh leafy greens • Does not include whole-head cabbages, such as green, red or savoy cabbages • Does not include banana or grape leaves, and those grown on trees • Leafy greens listed in § 112.2(a)(1) are exempt

FTL item	Description
Fresh-cut leafy greens	<ul style="list-style-type: none"> All types of fresh-cut leafy greens, including single and mixed greens
Fresh melons	<ul style="list-style-type: none"> All types of fresh melons
Fresh peppers	<ul style="list-style-type: none"> All varieties of fresh peppers
Fresh sprouts	<ul style="list-style-type: none"> All varieties of fresh sprouts, regardless of seed source, including single and mixed sprouts
Fresh tomatoes	<ul style="list-style-type: none"> All varieties of fresh tomatoes
Fresh tropical tree fruits	<ul style="list-style-type: none"> All types of fresh tropical tree fruit Does not include non-tree fruits, tree nuts, pit fruits or citrus Tropical tree fruits listed in § 112.2(a)(1) are exempt
Fresh-cut fruits	<ul style="list-style-type: none"> All types of fresh-cut fruits Fruits listed in § 112.2(a)(1) are exempt
Fresh-cut vegetables, other than leafy greens	<ul style="list-style-type: none"> All types of fresh-cut vegetables, other than leafy greens Vegetables listed in § 112.2(a)(1) are exempt
Finfish, histamine-producing species (fresh, frozen and previously frozen)	<ul style="list-style-type: none"> All histamine-producing finfish species
Finfish, species potentially contaminated with ciguatoxin (fresh, frozen and previously frozen)	<ul style="list-style-type: none"> All finfish species potentially contaminated with ciguatoxin
Finfish, species not associated with histamine or ciguatoxin (fresh, frozen and previously frozen)	<ul style="list-style-type: none"> All finfish species not associated with histamine or ciguatoxin Siluriformes fish are not included

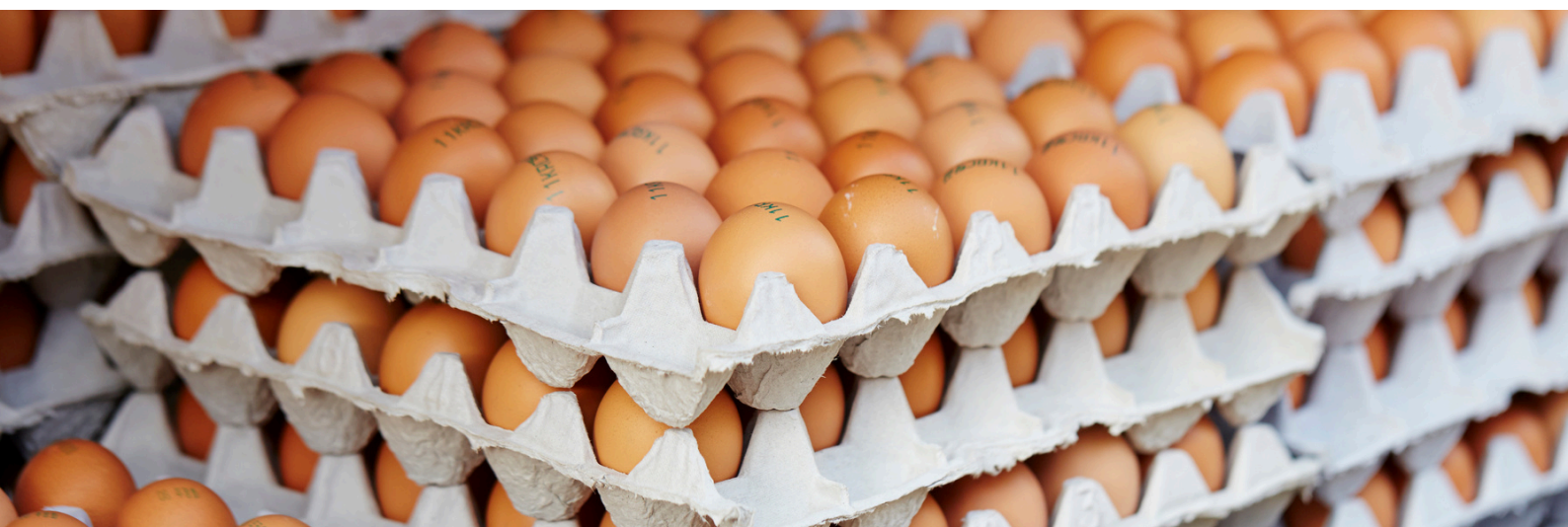
FTL item	Description
Smoked finfish (refrigerated, frozen and previously frozen)	<ul style="list-style-type: none"> All types of smoked finfish, including cold-smoked finfish and hot-smoked finfish
Crustaceans (fresh, frozen and previously frozen)	<ul style="list-style-type: none"> All crustacean species
Molluscan shellfish, bivalves (fresh, frozen and previously frozen)	<ul style="list-style-type: none"> All bivalve mollusk species Does not include scallop adductor muscle Raw bivalve molluscan shellfish that are (1) covered by National Shellfish Sanitation Program requirements; (2) subject to 21 CFR Part 123, Subpart C and 21 CFR 1240.60 requirements; or (3) covered by an FDA final equivalence determination for raw bivalve molluscan shellfish are exempt
Refrigerated, ready-to-eat deli salads	<ul style="list-style-type: none"> All types of refrigerated, ready-to-eat deli salads, including those frozen at some point in the supply chain before retail Does not include meat salads

Digital preferred

FSMA 204 does not mandate you to satisfy the new requirements with electronic records, but this is easier and more reliable than paper records.

Food traceability system requirements

For FSMA 204 compliance, you must ensure that your food traceability system(s) supports KDEs and CTEs, lot codes, a traceability plan and providing data to the FDA within 24 hours.



WHICH RECORDS MUST BE KEPT WHEN RECEIVING FTL FOOD?

Attribute	Details
1: TLC	Consensus on using a Global Trade Item Number (GTIN) alongside a lot code.
2: Quantity and unit of measure	Examples include 1 case, 10 reusable containers, 100 storage tanks, 1,000 pounds.
3: Product description	Details, such as the product name, brand, commodity type, variety and packaging specifics, like size or style, and seafood types.
4: Location description for receiver	Details, such as the organization's name, contact number and full address, including city, state, zip and country.
5: Location description for source	Includes the organization's name, contact information and full address with city, state, zip and country.
6: Date	Records the date the food was either shipped or received.
7: TLC Source	Where a food item received its TLC, noting the organization's address, city, state, zip and contact.
TLC Source Reference	Another way of detailing the location for the TLC Source, potentially including a web address, FFRN, DUNS or GLN, with FDA-mandated accessibility.
8: Reference documents	Include any business document or record containing KDEs for an event, such as BOL, PO, ASN, work orders, invoices, receipts, etc.
§ 1.1340: Shippers must provide (via electronic, paper or another written method) all details in this section to the next direct recipient (excluding transporters) of any shipped traceability lot.	



Which organizations are exempt from FSMA 204?

Some organizations are fully, partially or fully and partially exempt from the food traceability rule. The [Code of Federal Regulations](#) Section 1.1305 includes “what foods and persons are exempt from this subpart.”

Here are some examples of organizations that fall under the exemption categories:

Full exemptions

- Certain small-scale producers
- Direct-to-consumer farms selling or donating food directly to consumers
- Low-risk produce, typically not consumed raw
- Raw bivalve molluscan shellfish
- Entities that manufacture, process, pack or hold foods regulated by the US Department of Agriculture (USDA)
- Transport entities that move food
- Nonprofit food service establishments
- Individuals who handle food for personal consumption
- Food allocated for research or educational purposes

Partial exemptions

- Commingled raw agricultural commodities
- Small retail food outlets and eateries
- Restaurants buying directly from farms
- Retail food entities buying from other retail locations
- Educational programs, such as Farm to School and other institutional programs
- Individuals or entities managing fishing operations

Exemptions are not always straightforward. For example, an organization might not need to keep certain records for some foods but must keep them for others. An organization might also be exempt from some rules at a particular stage but require compliance at later stages. Finally, there are exemptions for foods subject to kill-step. Requirements apply until the kill-step is applied.

Organizations can check if they are exempt via the FDA’s [Exemptions to the Food Traceability Rule interactive flow chart](#).

Compliance steps

Your organization must follow these steps to ensure FSMA 204 compliance:

1. Establish a FSMA 204 compliance team
2. Familiarize yourself with the requirements
3. Map your entire supply chain
4. Determine the implementation scope
5. Assess your operation’s traceability and data compatibility
6. Conduct internal gap and risk assessments
7. Execute your compliance plan
8. Assign traceability duties and start tracking
9. Prioritize continuous improvement

Your team should comprise key staff who understand your food operations. A variety of roles will help cover the entire compliance process. A Preventive Controls Qualified Individual (PCQI), with crucial FSMA knowledge, would be a good candidate to lead the team.

Consider your scope and specific compliance needs when creating the team. Each role should be clearly outlined. A typical food business might adopt:

Role	Responsibilities
PCQI	Leads the team, including development, implementation and reviewing the food safety plan. Trains the team concerning compliance tasks.
Operations Manager	Manages traceability system(s) integration and ensures that all processes are FSMA 204 compliant.
Quality Assurance Specialist	Creates and maintains preventive controls, conducts hazard analyses and ensures the food safety plan meets correct standards.
IT Staff	Implements and maintains the technology to support traceability and recordkeeping.

You must thoroughly assess where changes are needed, from updating labeling requirements and enhancing your IT systems to addressing interoperability between supply chain partners.

The importance of FSMA 204 food traceability software

Many organizations are digitizing their food safety system(s), but choosing the right software will help your team:

- Meet and maintain compliance with your chosen standards
- Complete monitoring and traceability logs with less human error
- Safely and securely store and instantly access your food safety records





Fresh FSMA 204 Food Traceability Solutions

Meeting FSMA 204's requirements can be complicated but, with our integrated **FSMA 204 traceability solutions**, you can confidently navigate compliance while enhancing your food safety management system(s).

FSMA 204 audits: be prepared and confident

Our **FSMA 204 audits** help you meet the FDA's new traceability requirements while improving your supply chain resilience. Preparing for these audits is essential for compliance and helps safeguard public health by ensuring your rapid response to contamination events.

Our audits focus on verifying the accuracy, completeness and timeliness of your KDEs and CTEs. We assess if your traceability system(s) can quickly and accurately track food items through the supply chain to improve food safety and minimize risks. Our auditors identify gaps in compliance, recommend tailored solutions to enhance operational efficiency and regulatory compliance, and validate your recordkeeping system(s). They are also a great tool to help your suppliers comply and ensure that the traceability data you receive from them is accurate and adequate.

FSMA 204 training: stay ahead of compliance with expert-led training

Ensure your team is fully prepared to meet FSMA 204 requirements with our **expert-led training courses**. Available online and face-to-face, our courses provide in-depth guidance on FSMA 204 traceability rules, KDEs and CTEs. Through interactive sessions, case studies and practical exercises, you gain the knowledge and skills to implement a robust traceability plan and confidently navigate FDA inspections.

Introducing the TRAKKEY digital traceability platform

TRAKKEY, an enterprise-grade, digital platform, automates food traceability and enhances your FSMA 204 compliance journey with greater efficiency and data accuracy.

TRAKKEY is a powerful and scalable digital solution for real-time, supply chain-wide visibility that has been validated by billions of annual transactions in complex supply chains. TRAKKEY is multilingual and effortlessly integrates with your pre-existing IT systems and workflows, empowering you to enhance outbreak investigations, reduce recalls, improve product information and streamline data sharing.

Why choose SGS?

We are a leading provider of audit and compliance services for the global food industry, with extensive knowledge of FSMA requirements. By combining our expertise with the cutting-edge TRAKKEY digital traceability platform, we enable you to comply with FSMA 204 efficiently and confidently while delivering transformative value to food supply chains.

Discover our FSMA 204 food traceability solutions today



For more information:
FSMA 204 Food Traceability Solutions
section on www.sgs.com
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When you need to be sure

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