FoodDocs

How to Get Compliant with FSMA 204 in 8 Steps

With a Quick Overview of the Food Traceability Rule

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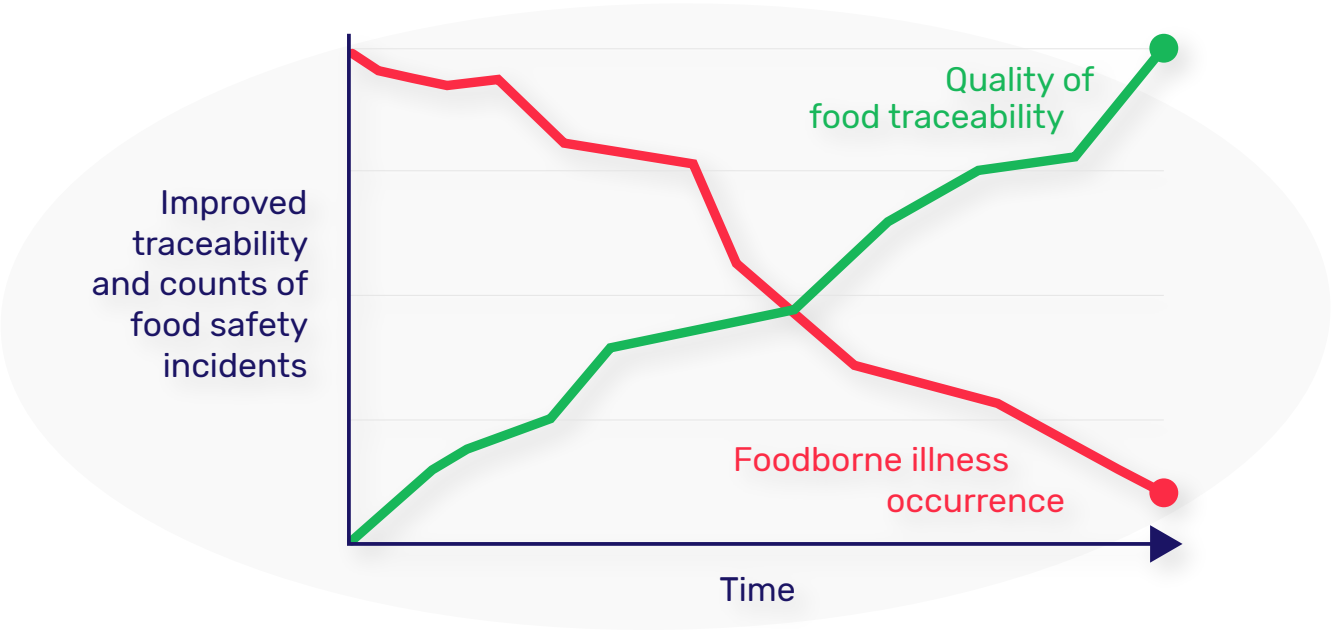
What is FSMA 204?

> *FSMA 204, also known as the Food Traceability Rule, is Section 204 of the Food Safety Modernization Act, which requires the FDA to identify foods that require additional recordkeeping to protect public health.*

Why was FSMA 204 written into law?

FSMA 204 was written into law for a number of reasons, one of the primary ones being to more effectively minimize and mitigate food safety hazards *(e.g., E. coli and Salmonella).*

In particular, these **additional recordkeeping requirements are intended to identify and remove potentially contaminated food from the market even faster**, resulting in fewer foodborne illnesses and worse, deaths.



What key will terms help to standardize our understanding of FSMA 204?

Food Traceability List (FTL)
A catalog of specific food items that require enhanced record-keeping as stipulated by FSMA 204.

Critical Tracking Events (CTE)
A pivotal point within the food supply chain where capturing and documenting key information is essential.

Key Data Elements (KDEs)
Essential data associated with each CTE that businesses must maintain and disclose to partners in the supply chain and the FDA.

Raw Agricultural Commodity
Typically refers to unprocessed fruits or vegetables.

Retail Food Establishment
Locations such as stores or restaurants where food is sold directly to the public.

Traceability Lot Code (TLC)
A distinctive code allocated to a specific batch of food to facilitate its traceability throughout the supply chain, especially during recalls.

TLC Source
The initial location or facility where a food batch is assigned its traceability lot code.

When is the FSMA 204 compliance date?

The FSMA 204 compliance date will be in July 2028.

Jan 4, 2011

FSMA Becomes Law

Nov 21, 2022

Final Rule on Food Traceability Published

July, 2028

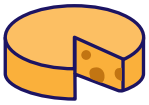
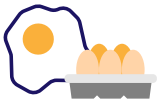
Compliance Deadline

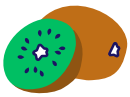
Note: On March 20, 2025, the FDA announced that it intends to extend the Food Traceability Rule compliance date by 30 months.

Who does FSMA 204 apply to?

FSMA 204 applies to businesses that need to keep additional traceability records if they hold, process, pack, or manufacture foods that are specifically on the Food Traceability List.

What's on the FSMA 204 food traceability list?

FTL	Description	
 Cheese	(made from pasteurized milk), fresh soft or soft unripened	Includes soft unripened/fresh soft cheeses. Doesn't include cheeses that are frozen or previously frozen, shelf stable at ambient temperature, or aseptically processed and packaged.
	(made from pasteurized milk), soft ripened or semi-soft	Includes soft ripened/semi-soft cheeses. Doesn't include cheeses that are frozen or previously frozen, shelf stable at ambient temperature, or aseptically processed and packaged.
	(made from unpasteurized milk), other than hard cheese	Includes all cheeses made with unpasteurized milk, other than hard cheeses. Doesn't include cheeses that are frozen or previously frozen, shelf stable at ambient temperature, or aseptically processed and packaged.
 Shell eggs	Shell egg means the egg of the domesticated chicken.	
 Nut butters	Includes all types of tree nut and peanut butters. Includes all forms of nut butters, including shelf stable, refrigerated, frozen, and previously frozen products. Doesn't include soy or seed butters.	
 Fresh cucumbers	Includes all varieties of fresh cucumbers.	
 Fresh herbs	Includes all types of fresh herbs. Herbs listed in 21 CFR 112.2(a)(1) are exempt.	
 Fresh Leafy greens	Regular	Includes all types of fresh leafy greens. Doesn't include whole head cabbages such as green cabbage, red cabbage, or savoy cabbage. Doesn't include banana leaf, grape leaf, and leaves that are grown on trees. Leafy greens listed in § 112.2(a)(1) are exempt.
	Fresh	Includes all types of fresh-cut leafy greens, including single and mixed greens.

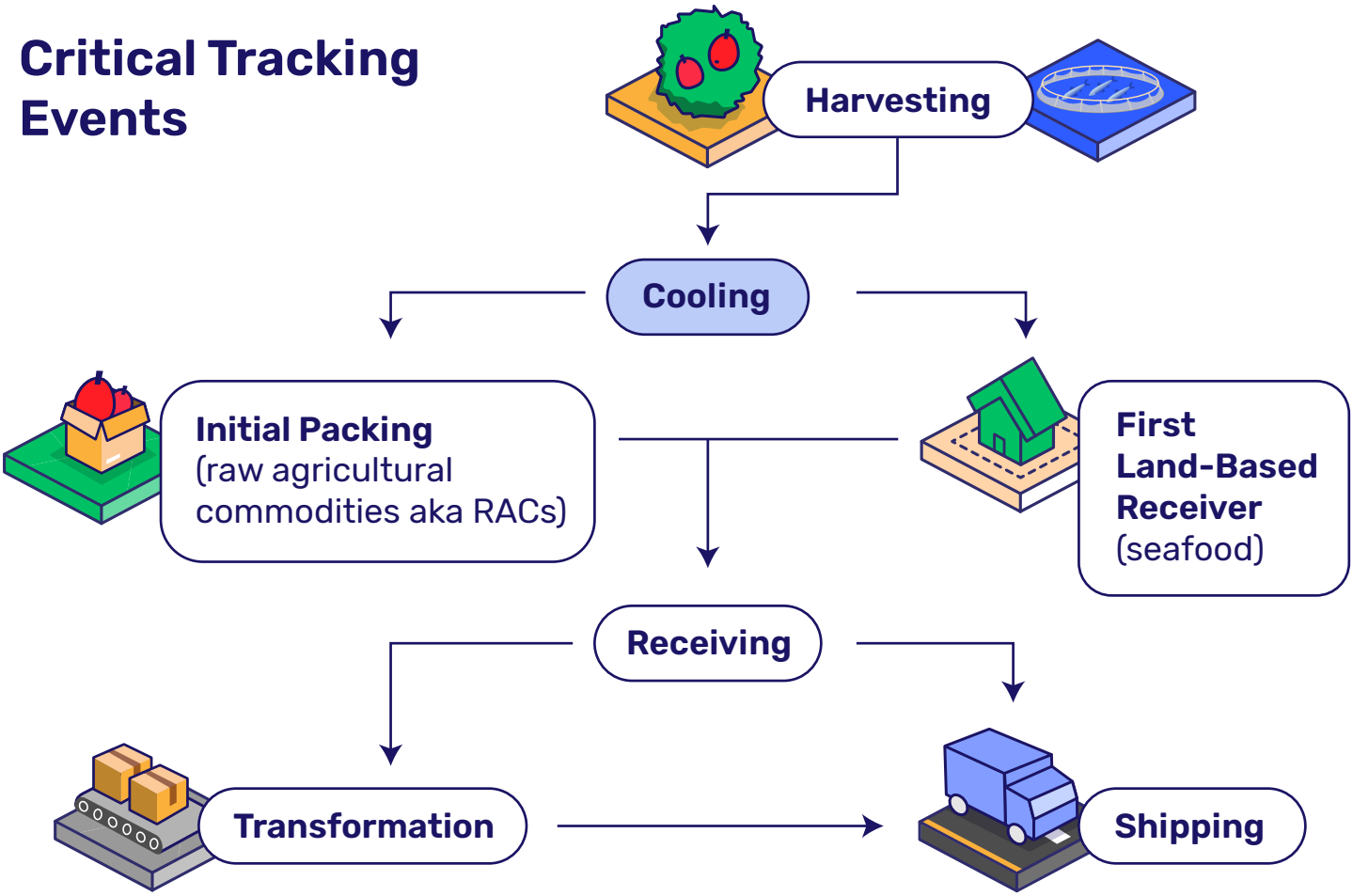
	FTL	Description
	Fresh melons	Includes all types of fresh melons.
	Fresh peppers	Includes all varieties of fresh peppers.
	Fresh sprouts	Includes all varieties of fresh sprouts (irrespective of seed source), including single and mixed sprouts.
	Fresh tomatoes	Includes all varieties of fresh tomatoes.
	Fresh fruits from tropical trees	Includes all types of fresh tropical tree fruit. Doesn't include non-tree fruits, tree nuts, pit fruits, nor citrus.
	Fresh-cut fruits	Includes all types of fresh-cut fruits. Fruits listed in § 112.2(a)(1) are exempt.
	Fresh-cut vegetables other than leafy greens	Includes all types of fresh-cut vegetables other than leafy greens. Vegetables listed in § 112.2(a)(1) are exempt.

FTL		Description	
	Finfish (fresh, frozen, and previously frozen)	Histamine-producing species	Includes all histamine-producing species of finfish.
		Species potentially contaminated with ciguatoxin	Includes all finfish species potentially contaminated with ciguatoxin.
		Species not associated with histamine or ciguatoxin	Includes all species of finfish not associated with histamine or ciguatoxin. Siluriformes fish are not included.
	Smoked finfish (refrigerated, frozen, and previously frozen)	Includes all types of smoked finfish, including cold smoked finfish and hot smoked finfish.	
	Crustaceans (refrigerated, frozen, and previously frozen)	Includes all crustacean species.	
	Molluscan shell-fish, bivalves (refrigerated, frozen, and previously frozen)	Includes all species of bivalve mollusks. Doesn't include scallop adductor muscle. Raw bivalve molluscan shellfish that are (1) covered by the requirements of the National Shellfish Sanitation Program; (2) subject to the requirements of 21 CFR part 123, subpart C, and 21 CFR 1240.60; or (3) covered by a final equivalence determination by FDA for raw bivalve molluscan shellfish are exempt.	
	Refrigerated ready-to-eat deli salads	Includes all types of refrigerated ready-to-eat deli salads, including ready-to-eat deli salads that are frozen at some point in the supply chain prior to retail. Doesn't include meat salads.	

What are Critical Tracking Events?

> *Critical Tracking Events are important aspects of a food item's journey that help to decrease likelihood of contamination and reduce risk of foodborne diseases.*

Critical Tracking Events



There are **7 critical tracking events** which include:

Harvesting

Activities performed at farms to remove and prepare raw agricultural commodities for food use, including both growing and raising processes.

Cooling (before Initial Packing)

The process of actively reducing the temperature of a raw agricultural commodity using methods such as hydro-cooling, icing (excluding seafood), forced air, or vacuum cooling.

Initial Packing (raw agricultural commodities aka RACs)

The first packing of a raw agricultural commodity, excluding seafood from fishing vessels, into containers for further handling or transport.

First Land-Based Receiver

The first business entity on land to take possession of food directly from a fishing vessel.

Shipping

The act of arranging food for transport from one location to another, which includes intracompany shipments to different addresses but not direct sales or donations to consumers.

Receiving

The act of accepting food shipments at a new location, including intracompany transfers, but not direct consumer deliveries.

Transformation

Involves significantly altering the food through processes like manufacturing, commingling, repacking, or relabeling.

What are Key Data Elements?

Key Data Elements are different pieces of data that are determined by the specific CTEs which businesses have to keep track of.

Common KDEs include:

- **Location description of the food for where it was either harvested, cooled, packed, shipped, etc.** (other than a transporter)
- **Commodity** (and variety of food, if relevant)
- **Food quantity and unit of measurement**
- **Location description for the location from which you shipped the food**
- **Traceability lot code you assigned or traceability lot code source**
- **Date of harvesting/cooling/initial packing/landing/shipping/receiving/transformation completion**
- **Reference document type and number**

What are Traceability Lot Codes?

Traceability Lot Codes or TLCs are unique identifiers (usually alphanumeric) assigned to items on the food traceability list in order to increase supply chain transparency You must assign a TLC to a food on the Food Traceability List (FTL) when you:

- **Initially pack a RAC** (excluding foods obtained from fishing vessels)
- **Perform the first land-based receiving** of food obtained from a fishing vessel
- **Transform** a food

Examples of traceability lot codes

(01)045621357851 33
(17)140704 (10) DE-456

GS1-128 Example

1147M2023213

1. 2. 3.

1. Product code
2. Facility
3. Julian date

475123C

6-digit code + letter to represent grower/manufacturing location

134AD5607

Randomized alphanumeric code generated by firm's traceability system

BFCA179A152023213

1. 2. 3. 4. 5.

1. Company name
2. Production location
3. Product
4. Grower
5. Julian date

8 Steps to get compliant with FSMA 204

1. Create an FSMA 204 compliance team

This group should be composed of key personnel who understand the complexities of your food operations.

It's beneficial to **include a mix of roles, such as:**

Role	Responsibilities
Operations Manager	Manages the integration of traceability systems and ensures all processes comply with FSMA 204 requirements.
Quality Assurance Specialist	Develops and maintains preventive controls, conducts hazard analyses, and ensures the food safety plan meets regulatory standards.
IT Staff	Implements and maintains technology solutions to support traceability and record-keeping required by FSMA 204.
PCQI (Preventive Controls Qualified Individual)	Leads the development, implementation, and review of the food safety plan; trains team members on compliance-related tasks.

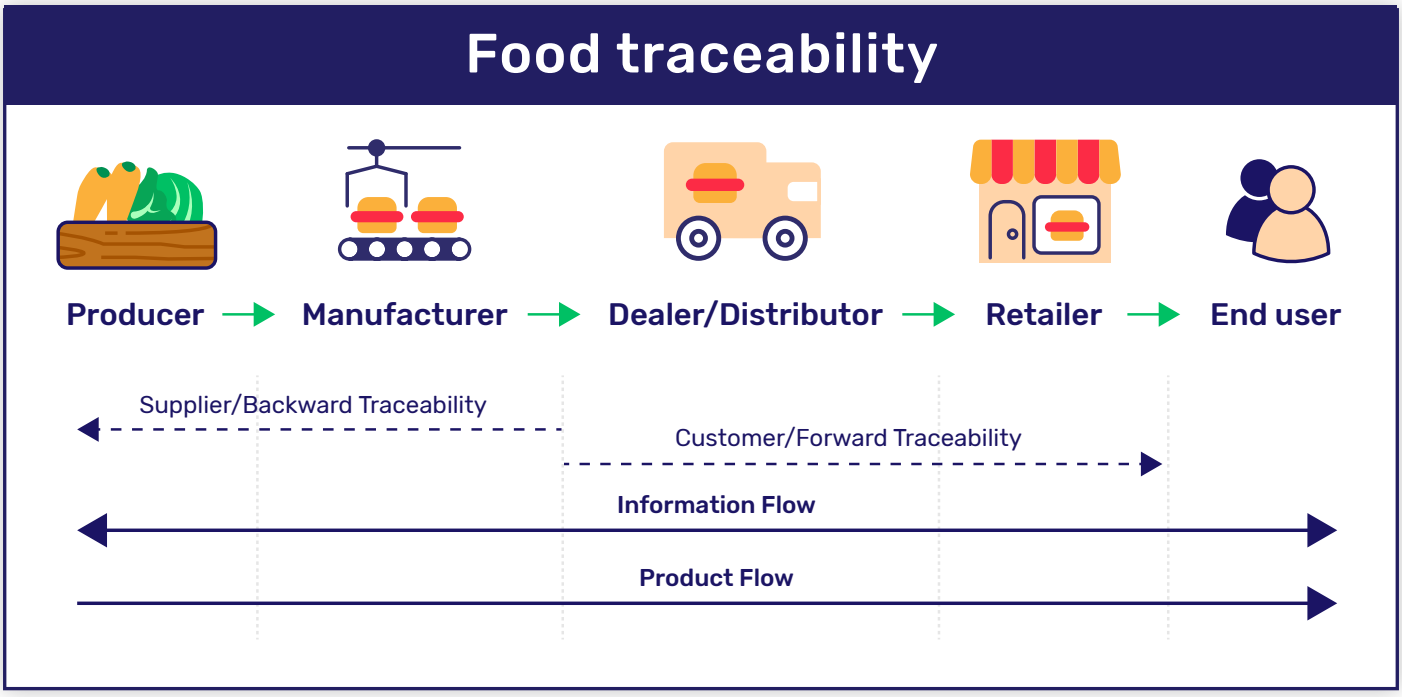
Example of who could be on an FSMA 204 compliance team

2. Get familiar with FSMA 204 requirements

Start by reviewing the official final rule and lean on resources like the one you're reading now. Build a comprehensive resource list that includes eBooks, webinars, and presentations from the FDA and other experts to deepen your understanding.

Here's a starter list:

- FSMA Final Rule on Requirements for Additional Traceability Records for Certain Foods
- Food Traceability Rule Resources Walkthrough on FDA.gov
- The FSMA Final Rule on Requirements for Additional Traceability Records for Certain Foods
- FSMA 204 Food Traceability List poster

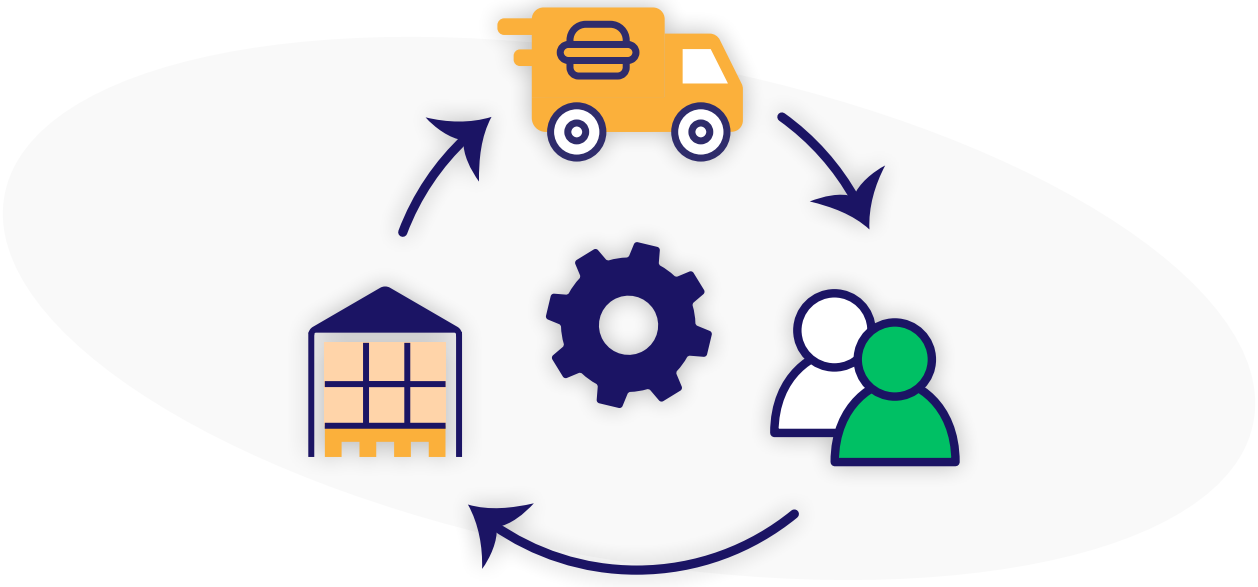


3. Establish the scope of implementation

Take these steps to help determine the scope of FSMA 204 compliance:

- Begin by reviewing the Food Traceability List **to identify which of your products or ingredients are affected.**
- **Document your current traceability processes** to determine how you manage and track these FTL items.
- Next, **develop or refine your strategy for capturing the necessary data,** such as lot or batch numbers, dates, and quantities.

Essentially, assess your existing food traceability program to ensure it meets the transparency and safety requirements throughout your supply chain.



4. Assess your operation's traceability and data compatibility

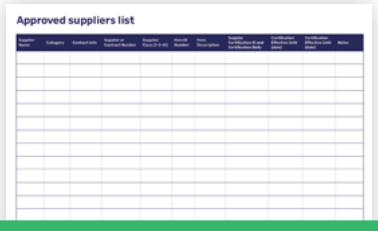
> *Do you hold, process, pack, or manufacture foods?*

Start by pinpointing your company's role in the supply chain to understand your specific responsibilities under FSMA 204.

Examine your current systems for tracking and managing traceability data to see how well they align with FSMA requirements. Check how you currently receive, or plan to receive, traceability data from your suppliers.

Evaluate whether your trading partners are prepared for FSMA compliance, ensuring that all links in your supply chain are ready to meet these regulatory requirements.

Start with your approved suppliers list and based on their FSMA compliance (or lack thereof), you can decide whether you'll need to source new ones.



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5. Conduct internal gap and risk assessments

Common gaps might include inadequate data capture capabilities or insufficient traceability measures for items on the Food Traceability List.

Review the impact of these gaps on your:

- **Systems:** Non-compliant systems may lead to inefficient tracking and reporting, potentially causing delays in identifying and addressing food safety issues.
- **Hardware:** Inadequate hardware could fail to support new software requirements for data logging and real-time tracking, limiting your ability to maintain continuous oversight.
- **Operational procedures:** Gaps might result in flawed procedures that do not ensure all key data elements are captured, leading to incomplete records that could jeopardize both compliance and responses to food safety incidents.

You should also assess potential risks in your traceability system, such as the vulnerabilities of a paper-based system versus the benefits of adopting food traceability software.

Searching through piles of paper for specific food safety monitoring records when the FDA gives you just 24 hours to provide the recall data becomes a lot more stressful and difficult. With digital traceability logs, you can share the information with the FDA in seconds.

6. Implement the FSMA 204 compliance plan

To effectively implement your FSMA 204 compliance plan:

- **Start by identifying the Critical Tracking Events** that pertain to your operations.
- **Establish a system for consistently collecting and managing Key Data Elements** associated with these CTEs.
- **Standardize your Traceability Lot Code system** to ensure uniformity across all products and processes.
- **Develop FSMA 204-specific Standard Operating Procedures (SOPs)** to guide your team's daily activities.
- **Provide comprehensive training for your team,** which could include in-person sessions, video courses, or step-by-step instructions integrated within your software applications.

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7. Assign traceability tasks and start tracking

For effective traceability management, assign role-based traceability tasks using your chosen system — paper-based or digital. Here's a list of typical traceability monitoring tasks in a food business:

- **Logging incoming raw materials** with batch numbers and source details.
- **Tracking processing and packaging activities** with time or temperature stamps.
- **Recording storage conditions** and durations.
- **Documenting shipments** with destination and carrier information.

8. Prioritize continuous improvement

Regularly monitor and review your food traceability program and FSMA 204 compliance, establishing a review cadence that aligns with your business operations.

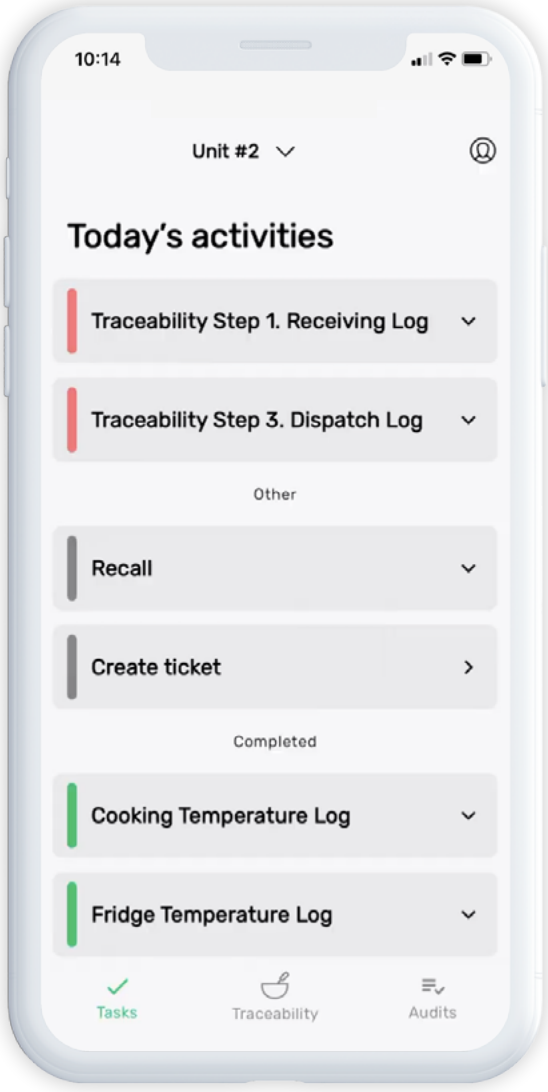
> ***Incorporate training sessions and mock audits as part of this ongoing process to keep your team sharp and prepared.*** *You can use the FSMA compliance checklist and place a particular focus on the final Recall section.*

Be prepared to re-assess your compliance strategies, particularly when significant operational changes occur or when new regulations are introduced, such as the FDA's updates to the Food Traceability List every five years.

How FoodDocs helps you manage FSMA 204 compliance

Would you like to make traceability logging and recall management easier? FoodDocs' software is built so you can log your traceability within seconds, saving time on repetitive activities and making the whole traceability process easy to trace in case of a recall.

- **Intuitive and simple:** FoodDocs' traceability system is easy to use and applies to all traceability needs.
- **Quick and efficient logging:** Create traceability logs within seconds to save time and effort on repetitive activities.
- **Easy recall management:** Instantly access detailed recall information about products and ingredients to ensure quick and effective responses.



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Why choose FoodDocs?

One platform for everything – Smart, Simple, Safe

+2h daily

Saved on supervision

Save 10 hours weekly on routine tasks and monitor food safety procedures with a real-time dashboard.

15-minute

Implementation time

Your workspace is created based on your company profile. Adjust checklists and logs to meet your food safety standards.

4.9/5 rating

Recommended by customers

Users consistently praise our user-friendly interface, smart features, and exceptional customer support.

Save time with all-in-one Traceability System

Trace and manage your products with ease

START A FREE TRIAL

GetApp ★★★★★ Capterra ★★★★★ Software Advice ★★★★★

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