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What is FSMA Section 204, the Food Traceability Rule?

The **Food Traceability Rule (FSMA Section 204)** is a federal food safety regulation that affects how certain foods must be tracked as they move through the supply chain. Many growers and processors are already familiar with other FSMA rules, such as the Produce Safety Rule or Preventive Controls for Human Food, but may be unsure how the Food Traceability Rule fits in.

This publication provides a plain-language overview of what the Food Traceability Rule is, why it was created, and how it differs from other FSMA requirements. It is intended to help growers and processors understand the rule, not to provide step-by-step compliance instructions.

The Food Traceability Rule was originally set to take effect on Jan. 20, 2026. The Food and Drug Administration (FDA) announced a delay in enforcement to allow additional time for industry readiness. Operations that may be affected should begin reviewing their recordkeeping systems and supply chain practices now.

Why This Matters for Your Operation

Even if your operation is small or exempt, traceability is becoming a standard expectation across the food supply chain. Buyers, distributors and retail partners may require traceability records as part of doing business. Understanding this rule can help you maintain market access and avoid disruptions.

Supply Chain Example: Fresh Produce



Figure 1. Example of how fresh produce moves through the supply chain from farm to retail. The Food Traceability Rule focuses on tracking food as it moves between these stages.

What is the Food Traceability Rule?

The **Food Traceability Rule (FTR)** was finalized by the FDA in 2022 under Section 204 of the Food Safety Modernization Act. The rule requires certain operations to keep records so food can be tracked rapidly through the supply chain if a foodborne illness outbreak or recall occurs.

The rule applies only to foods listed on the FDA's Food Traceability List (FTL), foods that have been frequently linked to foodborne illness outbreaks in the past. Examples include leafy greens, melons, tomatoes, cucumbers, peppers, fresh herbs and some processed foods.

The primary goal of the Food Traceability Rule is to ensure that the FDA and industry can identify:

- Where the food came from;
- Where the food was sent next; and
- How it moved through the supply chain within a short time period during an investigation.

Why did the FDA create the Food Traceability Rule?

In previous foodborne illness outbreaks, tracing contaminated food back to its source often took days or weeks. Inconsistent records, missing information and incompatible systems across the supply chain made investigations slow and incomplete.

The Food Traceability Rule was created to:

- Speed up traceback investigations during outbreaks;
- Improve the accuracy and effectiveness of recalls;
- Reduce the amount of food unnecessarily removed from the market; and
- Protect public health and maintain consumer confidence.

By requiring standardized traceability records for higher-risk foods, the rule helps regulators and food businesses respond more quickly when problems occur. For businesses, this means faster response during recalls and less disruption when accurate records are available.

How is the Food Traceability Rule different from other FSMA rules?

Many growers and processors already comply with other FSMA regulations. Although these rules are related, they serve different purposes.

Produce Safety Rule (PSR): Focuses on preventing contamination on produce farms through practices such as worker hygiene, agricultural water management, sanitation and soil amendments.



Preventive Controls for Human Food (PCHF): Applies primarily to food processing facilities and focuses on identifying and controlling food safety hazards through a written food safety plan.

Food Traceability Rule (FSMA 204): Focuses on tracking the movement of certain higher-risk foods through the supply chain by requiring specific records to be created and maintained.

In simple terms:

- PSR and PCHF focus on prevention.
- The Food Traceability Rule focuses on traceability and rapid response.

The Food Traceability Rule does not replace other FSMA rules. An operation may need to comply with more than one FSMA regulation, depending on its activities and coverage.

What the Food Traceability Rule does — and doesn't do

What does the rule do?

- Applies only to foods on the Food Traceability List.
- Requires certain records to be kept at key points as food moves through the supply chain.
- Allows FDA to request traceability records during an outbreak investigation, typically within 24 hours.
- Requires records to be maintained in an accessible format that can be provided to FDA when requested.

What does the rule not do?

- It does not apply to all foods.
- It does not require special software or technology.
- It does not replace existing food safety practices.
- It does not automatically apply to all farms or small businesses.

Whether the rule applies depends on the type of food handled, the sales channel, and the food's movement through the supply chain.

Who should be aware of the Food Traceability Rule?

You should pay attention to the Food Traceability Rule if your operation:

- Sells produce on the Food Traceability List (FTL) into wholesale markets.
- Packs, holds or processes foods on the Food Traceability List.
- Handles food that moves beyond direct-to-consumer sales.
- Supplies grocery stores, distributors or food hubs.

Many small and midsize operations, especially those selling directly to consumers, may be exempt. However, exemptions depend on how food is sold and handled, not just operation size.

Even if your operation qualifies for an exemption, buyers such as grocery stores, distributors or food hubs may still require traceability records from their suppliers. Checking with your customers early can help you stay prepared and maintain market access.

Next steps for you

Start by identifying whether the foods you handle are on the Food Traceability List and how they move through your supply chain.

Even if you are unsure whether the rule applies, now is a good time to begin organizing your records and discussing traceability expectations with your buyers.

Additional resources

FDA Food Traceability Rule (At-A-Glance).
<https://www.fda.gov/media/183514/download?attachment>

Food Traceability List (FTL) – FDA. [Food Traceability List | FDA](#)

Related publications

FS-74-W, The Food Traceability Rule — Who Does It Cover?

FS-75-W, Food Traceability Rule vs. Produce Safety Rule

Disclaimer

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