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The Food Traceability Rule — Who Does It Cover?

FSMA Section 204: A Practical Guide for Small and Midsize Operations

After growers and processors learn about the **Food Traceability Rule (FSMA Section 204)**, a common question is whether the rule applies to their operation. Coverage depends on what foods are handled, how they are sold, and where they move in the supply chain.

The Food Traceability Rule was originally scheduled for implementation beginning Jan. 20, 2026, but enforcement was delayed to allow additional time for industry readiness. Even with this extension, operations are encouraged to begin evaluating their coverage and preparing their recordkeeping systems.

This publication helps growers, processors and other food system stakeholders determine whether they are covered by the Food Traceability Rule. It is intended to support decision-making and does not provide step-by-step compliance instructions.

Why This Matters for Your Operation

Determining whether your operation is covered is the first step in preparing for the Food Traceability Rule. Even if you qualify for an exemption, buyers such as grocery stores or distributors may still expect traceability records as part of doing business.

What Determines Coverage Under the Food Traceability Rule?

An operation is covered by the Food Traceability Rule if all three of the following apply:

- The food is on the FDA's Food Traceability List (FTL)
- The operation performs covered activities (such as growing, packing, processing, shipping, or holding)
- The operation does not qualify for an exemption

Each of these factors is explained below.

Step 1: Is the Food on the Food Traceability List (FTL)?

The Food Traceability Rule applies only to foods listed on the FDA's Food Traceability List. The FTL includes foods that have been frequently linked to foodborne illness outbreaks.

Examples of foods on the FTL include:

- Leafy greens (e.g., lettuce, spinach)
- Melons
- Tomatoes, cucumbers and peppers
- Fresh herbs
- Fresh-cut fruits and vegetables
- Some processed foods, such as nut butters and certain cheeses

If none of the foods you handle are on the Food Traceability List, the rule does not apply to your operation.

Step 2: Do you perform covered activities?

The Food Traceability Rule applies to operations that perform one or more of the following activities involving foods on the FTL:

- Growing or harvesting
- Packing or repacking
- Cooling or holding
- Processing or transforming
- Shipping or receiving

These activities may occur on-farm, at a packing or holding facility, or at a food processing or distribution site.

If your operation handles FTL foods only at the retail or direct-to-consumer level, different requirements may apply.

Step 3: Do any exemptions apply to your operation?

The final step is determining whether your operation qualifies for an exemption. Many small and midsize operations may be exempt from the Food Traceability Rule. Exemptions depend on how and where food is sold and distributed, not just business size.

Quick Check:

If you handle foods on the Food Traceability List, sell into wholesale markets, and do not qualify for an exemption, the Food Traceability Rule likely applies to your operation.

Common exemptions include:

Direct-to-Consumer Sales: Operations that sell food directly to consumers (e.g., farmers markets, roadside stands, community-supported agriculture (CSA), or on-farm sales) are generally exempt from the Food Traceability Rule. This exemption applies even if annual sales exceed $25,000, as long as the food does not enter wholesale or distribution channels.

Wholesale generally refers to selling food to another business for resale, such as a grocery store, distributor, food hub, or other retail food establishment.

Very Small Businesses: Operations with average annual produce sales of $25,000 or less (calculated over the previous three years and adjusted for inflation) are exempt from the Food Traceability Rule. (FDA provides updated thresholds; see resources below.)

Commercial Processing with a Kill Step: Foods that are commercially processed using a validated kill step (such as cooking or pasteurization) may be exempt under specific conditions. This exemption applies primarily to processing operations and depends on how the food is handled and distributed.

The FDA provides a tool to help determine whether your operation is covered, exempt or partially exempt: Traceability Exemptions Flow Chart

Common Scenarios

Scenario 1: Farmers market only — likely exempt: A grower sells all produce directly to consumers at farmers markets and through a CSA.

→ Generally exempt from the Food Traceability Rule.

Scenario 2: Mixed sales (direct plus wholesale — potentially covered): A grower sells some produce directly to consumers but also sells to grocery stores or distributors.

→ Wholesale sales of foods on the FTL may trigger coverage, depending on sales volume and exemption status.

Scenario 3: On-farm packing for multiple growers — potentially covered: An operation packs produce grown on its own farm and from neighboring farms.

→ Packing and holding activities involving FTL foods may be covered, depending on exemptions.

Scenario 4: Small processor handling FTL foods — potentially covered: A small processor ($50,000 sales annually) handles foods on the FTL and sells products through wholesale channels.

→ The operation may be covered unless an exemption applies.

Important Consideration:

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.

What Does It Mean If You Are Covered?

If your operation is covered by the Food Traceability Rule, you are required to:

- Keep specific traceability records for certain activities
- Maintain records that link food movement through the supply chain
- Provide traceability records to the FDA during an outbreak investigation (typically within 24 hours)

Coverage does not automatically mean that new technology or software is required.

Next Step for You

Once you have determined whether your operation is covered, begin identifying where traceability records are created and how they are stored.

If you are unsure about your coverage status, consider using the FDA traceability tools or consulting with Extension or regulatory experts.

Additional Resources

Check whether you are covered or exempted using the FDA Traceability Exemptions Flow Chart: Traceability Exemptions Flow Chart

Related publications

FS-73-W - What is FSMA Section 204, the Food Traceability Rule?

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

Disclaimer

This publication is for educational purposes only and does not constitute legal advice. For official regulatory guidance, consult the U.S. Food and Drug Administration or a qualified professional.

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