



FSMA 204 Readiness Checklist

Is Your Business Ready for the FDA Food Traceability Rule?

The FDA's **FSMA 204 Food Traceability Rule** requires businesses that manufacture, process, pack, hold, transport, receive, or ship foods on the **Food Traceability List (FTL)** to maintain traceability records and provide them to the FDA within **24 hours** upon request. Use this checklist to evaluate your organization's readiness before the compliance deadline.

1. Determine If FSMA 204 Applies to Your Business

- ☐ We have reviewed the FDA Food Traceability List (FTL).
- ☐ We know which of our products are covered.
- ☐ We understand our role in the food supply chain.
- ☐ We know which facilities are subject to the rule.
- ☐ We have identified all affected suppliers.
- ☐ We have identified all affected customers.

Our Role (check all that apply):

- ☐ Grower
- ☐ Harvester
- ☐ Packer
- ☐ Processor
- ☐ Manufacturer
- ☐ Distributor
- ☐ Importer

- ☐ Warehouse
- ☐ Retailer
- ☐ Food Service

2. Understand Your Supply Chain

- ☐ We have documented where covered food originates.
- ☐ We know every supplier involved.
- ☐ We know every customer receiving covered products.
- ☐ We understand how products move through our facilities.
- ☐ We have documented every transfer point.
- ☐ We know where traceability information is created.

3. Traceability Lot Codes

- ☐ We assign Traceability Lot Codes (TLCs) when required.
- ☐ We know who is responsible for assigning TLCs.
- ☐ Our lot codes remain associated with products throughout processing.
- ☐ Lot codes remain linked during shipping and receiving.
- ☐ Employees understand how lot codes are managed.

4. Critical Tracking Events (CTEs)

Can your business capture the required information for each applicable event?

- ☐ Harvesting

- ☐ Cooling
- ☐ Initial Packing
- ☐ Receiving
- ☐ Shipping
- ☐ Transformation (processing/manufacturing)
- ☐ Repacking
- ☐ First Land-Based Receiving (if applicable)

5. Key Data Elements (KDEs)

- ☐ We capture all required Key Data Elements.
- ☐ Product identification is standardized.
- ☐ Traceability Lot Codes are recorded.
- ☐ Shipping information is captured.
- ☐ Receiving information is captured.
- ☐ Supplier information is recorded.
- ☐ Customer information is recorded.
- ☐ Dates and locations are consistently captured.
- ☐ Records are complete and accurate.

6. Recordkeeping

- ☐ Traceability records are stored electronically.

- ☐ Records are organized and searchable.
- ☐ Records are backed up.
- ☐ Records are retained according to FDA requirements.
- ☐ We can retrieve records quickly.
- ☐ We know where all traceability records are stored.

7. FDA 24-Hour Response Readiness

Could your organization provide requested records within 24 hours?

- ☐ Yes
- ☐ No
- ☐ Unsure

Can you generate:

- ☐ A sortable spreadsheet
- ☐ Electronic traceability records
- ☐ Shipment history
- ☐ Lot history
- ☐ Supplier history
- ☐ Customer shipment history

8. Supplier Readiness

- ☐ Suppliers understand FSMA 204 requirements.
- ☐ Suppliers provide required traceability information.

- ☐ Supplier labels include required identifiers.
- ☐ Supplier documentation is reviewed regularly.
- ☐ Supplier traceability processes have been evaluated.

9. Customer Requirements

- ☐ We know what traceability information customers expect.
- ☐ We can provide traceability records electronically.
- ☐ Customer labeling requirements are documented.
- ☐ Customer-specific compliance requirements are understood.

10. Labeling

- ☐ Products include required lot identification.
- ☐ Barcode labels support traceability.
- ☐ Labeling is standardized across operations.
- ☐ Employees understand labeling procedures.

11. Systems & Technology

Which systems currently support traceability?

- ☐ ERP
- ☐ WMS
- ☐ MES

- ☐ Inventory Management
- ☐ Barcode Scanning
- ☐ Label Printing
- ☐ EDI
- ☐ Spreadsheet-based
- ☐ Manual Paper Records
- ☐ Dedicated Traceability Software

12. EDI & Data Exchange

If you exchange data electronically:

- ☐ Trading partners receive required shipment information.
- ☐ ASNs contain required traceability information.
- ☐ Product identifiers are consistent.
- ☐ Data exchange is automated.
- ☐ GS1 standards are supported where appropriate.
- ☐ Manual re-entry has been minimized.

13. Internal Processes

- ☐ Traceability responsibilities are clearly assigned.
- ☐ Standard operating procedures are documented.
- ☐ Employees receive regular training.
- ☐ Internal audits are performed.

- ☐ Mock recall exercises are conducted.
- ☐ Continuous improvement processes exist.

14. Traceability Plan

- ☐ A written Traceability Plan exists.
- ☐ Roles and responsibilities are documented.
- ☐ Recordkeeping procedures are documented.
- ☐ Traceability processes are reviewed regularly.
- ☐ The plan is updated when business processes change.

15. Risk Assessment

Which areas need the most improvement?

- ☐ Supplier Communication
- ☐ Customer Communication
- ☐ Recordkeeping
- ☐ Labeling
- ☐ Traceability Lot Codes
- ☐ Employee Training
- ☐ Electronic Data Exchange
- ☐ ERP Integration
- ☐ Warehouse Processes
- ☐ FDA Response Readiness

☐ Documentation

☐ Internal Ownership

Readiness Score

Count your completed items.

90–100%

Excellent

Your organization appears well positioned for FSMA 204 compliance. Continue validating processes, testing traceability, and keeping documentation current.

70–89%

Good Progress

Most foundational processes are in place, but several operational or documentation gaps should be addressed before the compliance deadline.

50–69%

Needs Attention

Your organization has begun preparing but should prioritize improvements in traceability records, data collection, supplier coordination, and internal processes.

Below 50%

High Risk

Your organization may face significant compliance challenges. Begin documenting your supply chain, assigning ownership, evaluating technology, and building a formal traceability plan as soon as possible.

Next Steps

After completing this checklist, focus on these priorities:

- Identify all products covered by the FDA Food Traceability List (FTL).
- Map your end-to-end food supply chain and identify where traceability data is created and exchanged.
- Review how Traceability Lot Codes, Critical Tracking Events (CTEs), and Key Data Elements (KDEs) are captured throughout your operations.
- Evaluate whether your current ERP, WMS, labeling, and EDI systems can support the required recordkeeping.
- Create and maintain a written Traceability Plan that defines roles, responsibilities, and procedures.
- Test your ability to produce complete electronic records, including a sortable spreadsheet within the FDA's 24-hour response window.
- Work with your suppliers, customers, and technology partners to close any remaining compliance gaps before the deadline.