



FSMA 204 & FOOD TRACEABILITY

FSMA 204 Survival Kit

Prepare with confidence:

A practical toolkit for navigating the FSMA 204
extension with STEPLogic Tracker



Tools to help you prepare and comply with the new traceability rule

The FDA Food Traceability Rule under FSMA Section 204 is still moving forward, but the timeline has shifted. FDA has proposed extending the compliance date to July 20, 2028, and has stated it does not intend to enforce the rule before that date. This survival kit helps food businesses use the added time wisely to close traceability gaps, strengthen recordkeeping, and prepare for audit-ready compliance.

What you'll get:

1. FSMA 204 compliance roadmap
2. FSMA 204 traceability data checklist
3. FSMA 204 readiness assessment
4. FSMA 204 tech buyer's guide
5. STEPLogic Tracker for food manufacturers & distributors

Why it matters:

The extension is not a reason to pause. It is an opportunity to prepare the right way. FSMA 204 is about building resilience, visibility, and trust across the food supply chain. This kit helps processors, distributors, and warehouse operators take practical, measurable steps now so compliance does not become a last-minute scramble.



Contents

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01. FSMA 204 compliance roadmap

A visual PDF guide that walks you through:

- Understanding the Food Traceability List (FTL)
- Identifying Critical Tracking Events (CTEs)
- Mapping Key Data Elements (KDEs)
- Building a traceability plan
- Preparing for FDA audits

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02. FSMA 204 traceability data checklist

A downloadable worksheet that helps you:

- Capture KDEs by supply chain step
- Identify system gaps in recordkeeping
- Standardize data fields across suppliers
- Track lot, location, handling, and transformation events

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03. FSMA 204 readiness assessment

A quick self-assessment that helps you:

- Online tool or worksheet with self-assessment questions
- Scores your FSMA traceability readiness
- Recommends next steps based on gaps
- Can be embedded on a landing page or emailed post-download

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04. FSMA 204 tech buyer's guide

Includes:

- What to look for in FSMA-ready traceability systems
- Questions to ask vendors about KDE handling, reporting, and record retention
- Signs your existing system may not be compliant
- Must-have features: no-code configuration, real-time reporting, supplier tagging, mobile workflows

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05. STEPLogic Tracker for food manufacturers & distributors

One-page solution overview featuring:

- Core capabilities for FSMA 204 (KDE/CTE capture, record lookup, audit prep)
- Mobile-friendly interface and no-code customizability
- Visual flow: ingredient → processing → packout → distribution
- Integration with upstream and downstream supply chain partners

FSMA 204 compliance roadmap

A step-by-step guide to building a
compliant, connected supply chain

1



Purpose

The FDA's Food Traceability Rule (Section 204) requires all companies handling foods on the Food Traceability List (FTL) to capture and share Key Data Elements (KDEs) at each Critical Tracking Event (CTE).

How to Use

Use this roadmap to move from basic awareness to a practical FSMA 204 compliance plan. Each step helps you identify covered products, map traceability events, capture required data, and prepare your team for audit-ready recordkeeping.

01

Identify covered products

Goal: Know which SKUs fall under FSMA 204.

- Review the **FDA's Food Traceability List (FTL)** and mark all in-scope products.
- Map affected SKUs and batches across your ERP or product master.
- Note **exemptions or special conditions** (retail, transformation, etc.).

Deliverable: Documented list of covered products and traceability pathways.

Pro tip: Use this as your master reference list for every other compliance step.

02

Map your supply chain

Goal: Visualize how each product moves from source to shelf.

- Chart each Critical Tracking Event (CTE) – harvesting, cooling, packing, shipping, receiving, transformation.
- Identify who owns or handles the product at each step.
- Note all data handoffs (EDI, portals, email, paper).

Deliverable: Supply chain flow diagram with CTEs and responsible partners.

Common pitfall: Forgetting upstream suppliers – compliance extends back to origin, not just to your own facility.

03

Define Key Data Elements (KDEs)

Goal: Know exactly what data is required and where it lives.

- List required KDEs for each CTE (lot code, location, date, quantity, etc.).
- Identify systems of record for each KDE (ERP, WMS, MES, supplier).
- Highlight manual or missing data collection points.

Deliverable: KDE matrix mapping each data point to its source and owner.

Pro tip: Start with transformation events – they're the most complex and easiest to overlook.

04

Create a traceability plan

Goal: Build your formal compliance framework.

- Document how you'll **store and retrieve** traceability data.
- Assign **ownership and roles** for recordkeeping.
- Define **retention and retrieval** standards (2 years minimum; 24-hour access rule).
- Include your **data governance** and supplier onboarding procedures.

“

If it's not documented,
it's not compliant.

”

Deliverable: Written traceability plan ready for FDA review.

Pro tip: Keep policies in a central repository accessible to QA, IT, and Operations.

05

Digitize and connect systems

Goal: Move from paper to electronic traceability.

- Evaluate tech gaps between ERP, WMS, and supplier data.
- Implement systems to **capture and share KDEs electronically**.
- Standardize **GS1-compliant formats (EPCIS)** for interoperability.
- Integrate **supplier and customer portals** to enable seamless data exchange.

Deliverable: Integrated traceability architecture that supports FSMA 204 recordkeeping.

06

Validate and test

Goal: Prove your system works before the FDA asks.

- Run **mock recall exercises** to test forward/backward traceability.
- Validate data completeness and accuracy.
- Conduct **user training and exception management** sessions.
- Store evidence of each test as proof of due diligence.

Deliverable: Verified traceability test results with audit documentation.

Pro tip: Treat mock recalls like fire drills — frequency builds confidence.

07

Maintain and monitor

Goal: Keep compliance continuous, not one-and-done.

- Conduct **periodic audits** of traceability data.
- Use dashboards or alerts to monitor **data quality**.
- Update your plan as **products, suppliers, or systems evolve**.
- Re-train teams annually to reinforce best practices.

Deliverable: Living compliance program that scales with growth.

FSMA 204 traceability data checklist

Verify that your records capture the Key Data
Elements required for each Critical Tracking Event.

2



Purpose

This checklist helps you confirm that you are capturing the right data at each Critical Tracking Event (CTE) for foods on the FDA Food Traceability List (FTL). Once enforcement begins, covered entities must be able to provide required traceability records to FDA within 24 hours of request.

How to Use

01

Review **each CTE** on page 10. Confirm whether your operation performs it.

02

For each applicable CTE, verify that your systems collect all **required Key Data Elements (KDEs)**.

03

Note any **gaps or manual processes** in the right-hand column.

04

Use the **readiness assessment** in Section 03 to score your compliance maturity.

Traceability data requirements table

Critical Tracking Event (CTE)	Key Data Elements (KDEs)	Capturing?	Gaps / notes
1. Growing / harvesting	- Commodity name - Variety/type - Growing area or field ID - Harvest date - Lot or harvest unit code - Source grower/harvest crew ID	☐ Yes ☐ No	
2. Cooling	- Product identifier / lot code - Cooling facility location - Date/time of cooling - Quantity and handling unit - Receiving supplier or facility	☐ Yes ☐ No	
3. Initial packing	- Product identifier - Lot code assignment - Packing date/time - Pack location and supplier ID - Quantity / unit of measure	☐ Yes ☐ No	
4. Shipping	- Product description & lot code - Quantity shipped - Date/time of shipment - Shipper and receiver IDs - Location identifiers (GLN, address) - Reference document (invoice, BOL, ASN)	☐ Yes ☐ No	
5. Receiving	- Product description & lot code - Quantity received - Date/time of receipt - Shipper and receiver IDs - Location identifiers - Reference document	☐ Yes ☐ No	
6. Transformation	- Input product(s) and lot codes - Output product(s) and lot codes - Date/time of transformation - Transformation location - Quantity used/produced	☐ Yes ☐ No	
7. Retail / food service sale	- Product name & lot code - Quantity sold - Date/time of sale - Retail location/outlet ID - Customer order reference (optional)	☐ Yes ☐ No	

KDE formatting and storage best practices

- Use **standard identifiers** such as GTIN, GLN, and lot code formats.
- Use a **centralized system of record** rather than disconnected spreadsheets
- Maintain **records for at least two years** from the date of creation.
- Be ready to **produce traceability data within 24 hours** of FDA request.
- Align to **GS1 EPCIS standards** for interoperability across trading partners.



Pro tip:

Even if your company is exempt from full FSMA 204 coverage, collecting KDEs now can strengthen customer confidence and prepare you for future digital traceability requirements.

Common FSMA 204 readiness gaps we see across food operations:

1. Manual entry of lot codes or dates in receiving processes
2. Missing transformation records for repack or relabel steps
3. Disconnected systems between suppliers and distributors

FSMA 204 readiness assessment

How prepared is your operation
for FDA traceability compliance?

3



Purpose

This short assessment helps you evaluate your organization's readiness for FSMA 204. Each question reflects a core pillar of traceability: data capture, connectivity, governance, and culture.

Be honest. The goal is not perfection. It is clarity.

Instructions

01

Select the answer that best describes your current state.

02

Add up your total points at the end.

03

Use your score to determine your readiness level and next steps.

Question	Answer options	Score
1. Covered products Have you identified which of your SKUs fall under the FDA Food Traceability List (FTL)?	☐ Not yet started (0) ☐ Partial list, needs review (2) ☐ Complete and validated list (4)	
2. Traceability mapping Do you have a documented supply chain map showing all Critical Tracking Events (CTEs)?	☐ None yet (0) ☐ Informal map or spreadsheet (2) ☐ Formal digital map with supplier connections (4)	
3. KDE capture How consistently are you collecting required Key Data Elements (KDEs)?	☐ Only basic product/lot info (0) ☐ Most KDEs, some manual entry (2) ☐ All KDEs digitally captured (4)	
4. System integration Are your traceability data sources (ERP, WMS, supplier systems) connected?	☐ Not connected (0) ☐ Partially integrated (2) ☐ Fully connected and automated (4)	
5. Data standardization Are KDEs formatted in GS1 EPCIS or similar standardized format?	☐ No standards used (0) ☐ Mixed formats (2) ☐ Fully standardized (4)	
6. Record retrieval Can you retrieve traceability data within 24 hours of an FDA request?	☐ No (0) ☐ Possibly, but not confident (2) ☐ Yes, verified through testing (4)	
7. Traceability plan Do you have a written traceability plan that meets FSMA 204 requirements?	☐ None (0) ☐ Draft in progress (2) ☐ Completed, reviewed annually (4)	
8. Supplier readiness How compliant are your suppliers with traceability data sharing?	☐ Not engaged (0) ☐ Some provide KDEs (2) ☐ All suppliers compliant or in progress with GS1 standards (4)	
9. Mock recalls / testing Have you tested your traceability system with mock recalls or audits?	☐ Never (0) ☐ Once or informally (2) ☐ Routinely, with results documented (4)	
10. Continuous improvement Do you have KPIs or dashboards monitoring traceability data quality?	☐ None (0) ☐ Some reports, manual checks (2) ☐ Automated data quality tracking (4)	

Scoring

Add up your total score (out of 40 possible points).

Score range	Readiness level	Interpretation
0–12	At risk	Minimal compliance structure in place. Start by identifying covered products and mapping your supply chain. Begin using the traceability data checklist.
13–24	Developing	Foundational steps underway but systems are fragmented. Focus on connecting data sources and building a formal traceability plan.
25–34	Mostly ready, but manual	You meet most FSMA 204 requirements but rely on spreadsheets or partial integrations. You're compliant but not efficient — this is an ideal stage to consider automation.
35–40	Digitally mature & future-ready	Systems are integrated, standardized, and validated. Continue monitoring supplier compliance and prepare for FDA spot audits confidently.

Next steps

If your score is below 25:

- Revisit the FSMA 204 compliance roadmap to address foundational gaps.

If your score is 25 or higher:

- You're ready to evaluate digital traceability solutions that reduce manual effort, improve record retrieval, and strengthen audit readiness.



FSMA 204 tech buyer's guide

How to evaluate traceability solutions
that truly support compliance

4

“ Compliance isn’t just about passing an audit. It’s about building a connected system that can grow with your business. ”

Purpose

With the FSMA 204 timeline extended, technology decisions made now will determine how easily your team can capture, manage, and share data when enforcement begins.

How to Use

Use this guide to help you evaluate traceability systems with both **compliance** and **long-term scalability** in mind.

Pro tip: Build your requirements around your future state, not today’s constraints.

01

Start with the end in mind

Before evaluating vendors, define the outcomes you need:

- Can your system **trace each lot** from source to consumer within 24 hours?
- Can you **exchange data electronically** with all supply chain partners?
- Can your system **scale** to handle more SKUs, sites, or trading partners next year?

02

Focus on the core capabilities

A compliant traceability system should handle both **regulatory and operational** demands. Below are the core capabilities to prioritize:

Capability area	What to look for	Why it matters
Data capture	Capture all KDEs for each CTE automatically from WMS, ERP, or supplier systems	Manual entry leads to errors and audit risk
Data standardization	Supports GS1 EPCIS or equivalent formats	Enables data exchange across suppliers and distributors
Integration	Connects easily to ERP, WMS, MES, and supplier portals	Reduces silos and ensures real-time traceability
Visualization & reporting	Provides dashboards, exception alerts, and mock recall tools	Turns compliance into actionable insight
Scalability	Flexible enough to handle new products, facilities, or trading partners	Future-proofs your investment
User experience	Simple, intuitive interface for non-technical users	Compliance only works if people actually use the system

03

Evaluate the vendor, not just the software

Traceability success depends as much on the vendor partnership as the platform itself.

Ask these questions:

- Do they **understand FSMA 204 and your industry** (food, beverage, distribution, etc.)?
- Will they **support integration** with your existing ERP or WMS?
- Is the system **configurable without heavy IT support**?
- What's their **track record** with regulatory implementations?

Pro tip: Choose a partner who can help you evolve — not just install software.

04

Watch for common red flags

Be cautious of solutions that:

- Require manual upload of KDEs via spreadsheets
- Lack GS1 or EPCIS data model support
- Offer “one-size-fits-all” traceability features
- Treat compliance as a static checklist instead of a continuous process

05

Prioritize configurability and integration

Each company's data landscape looks different. Choose a system that adapts to yours.

Look for:

- **Configurable workflows:** set up your own events, rules, and alerts
- **Low-code integration:** connect data sources without custom development
- **Role-based dashboards:** provide visibility tailored to QA, operations, and supply chain partners

Pro tip: A configurable system allows you to deploy fast, comply early, and expand easily.

Checklist reminder

Use your **completed readiness assessment** and **traceability data checklist** as inputs for your RFP or vendor demo script.

06

Demand transparency and auditability

A strong traceability system provides:

- **Full lot genealogy** (forward and backward)
- **Timestamped event history**
- **Quick-access reports** for FDA requests or partner audits
- **Automated recall simulation tools**

When a system makes compliance easy, audits become a non-event.

07

Make a shortlist

Based on your needs, narrow down vendors to 2–3 who:

- Understand FSMA 204 data models
- Offer prebuilt integrations to your existing systems
- Provide demo access or sandbox environments for testing
- Have reference customers in your sector

Final thought

Technology should make traceability simpler, not harder. Choose a solution that aligns with your operation's size, pace, and growth plans — not one that forces you to fit its mold.

STEPLogic Tracker for food manufacturers & distributors

FSMA 204 compliance.
Simplified.

5

STEPLogic Tracker

for food manufacturers and distributors

Overview

STEPLogic Tracker is a configurable traceability solution built to help food businesses prepare for FSMA 204 without disrupting daily operations.

Whether you're managing grower data, packing lines, or distribution centers, STEPLogic Tracker helps automate the capture, storage, and sharing of Key Data Elements (KDEs) across Critical Tracking Events (CTEs), delivering visibility from source to destination.

Why it matters

Once enforcement begins, the FDA Food Traceability Rule will require covered foods to have searchable records available within 24 hours of request. Manual systems may struggle to keep pace.

STEPLogic Tracker brings traceability data together in one connected platform, helping teams improve accuracy, speed, and confidence during audits or recalls.

CAPTURE → CONNECT → VALIDATE → RETRIEVE → REPORT

KDE capture & automation

Digitally records KDEs at each CTE (harvest, pack, ship, receive, transform) to eliminate paper logs and manual errors

Supplier collaboration

Secure web portal for KDE submission and verification to extend compliance across trading partners

System integration

Integrate with existing ERP, WMS, MES, and supplier systems via APIs or EDI to centralize traceability data for complete visibility

GS1 EPCIS standardization

Supports GS1-aligned data models and event structures to ensure interoperability across the supply chain

Compliance dashboard

Tracks compliance readiness, mock recalls, and data gaps with audit-ready reporting and alerts

Configurable workflows

Configurable logic for event setup, validation, and alerts that adjusts easily to your operation — no code required

Built for food industry operations

STEPLogic Tracker supports all sectors covered by the FDA Food Traceability List — from produce and seafood to ready-to-eat items. Flexible deployment options make it ideal for:

- **Growers & Packers:**
Capture field and lot data at harvest
- **Processors:**
Manage transformation and relabeling events
- **Distributors:**
Automate shipping, receiving, and recall tracking
- **Retailers & Food Service:**
Access digital traceability records instantly

Implementation highlights

- **Rapid deployment:**
Pre-built FSMA 204 templates reduce setup time
- **Flexible deployment options:**
Designed to fit your IT environment.
- **Scalable architecture:**
Expand easily to new sites or suppliers
- **User-friendly interface:**
Designed for QA, operations, and IT alike

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