

FSMA 204 readiness assessment

How prepared is your operation
for FDA traceability compliance?





The FSMA Section 204 rule is now in effect, and food companies across the supply chain must meet strict recordkeeping and traceability standards. This survival kit includes practical tools, templates, and guidance to help you meet the rule – and stay audit-ready.

Why it matters:

FSMA 204 isn't just about compliance. Rather it's about building resilience, visibility, and trust in your food supply chain. This kit helps food businesses take practical, measurable steps toward full compliance, whether you're a processor, distributor, or warehouse operator.

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.



How STEPLogic Tracker can help

STEPLogic Tracker is a practical food traceability solution designed to help food companies manage receiving, transformation, and shipping traceability workflows, maintain lot-level records, and support faster FDA response under FSMA 204:

- Manage receiving traceability workflows tied to inbound product receipt.
- Support transformation traceability records as products are transformed, repacked, relabeled, or combined.

- Manage outbound traceability information to support stronger documentation and response readiness.
- Improve reporting and record retrieval when information is needed by internal teams or FDA.
- Strengthen lot-level recordkeeping for foods on the Food Traceability List.

Contact us at:

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