

FSMA 204 Compliance: Requirements Checklist for the FDA's Final Rule for Additional Traceability Records



Meeting the strict requirements of the FDA's Food Traceability Final Rule without compromising efficiency is no small task—but with the right strategy, compliance doesn't have to slow you down. The Final Rule is a key component of the New Era of Smarter Food Safety Blueprint and implements section 204 of the Food Safety Modernization Act (FSMA) and requires compliance by January 20, 2026.

This checklist provides you with actionable steps to strengthen your final rule compliance strategy, reduce risks and protect your bottom line while keeping operations running smoothly in today's evolving regulatory landscape.

1

Establish End-to-End Supply Chain Traceability

Track every stage, from raw materials to delivery, to meet traceability standards.

- » Maintain complete key data elements (KDEs) for critical tracking events (CTEs) like shipping, receiving and transforming.
- » Use traceability lot codes (TLCs) to accelerate recall responses and safeguard public health.
- » Provide an electronic sortable spreadsheet to the FDA within 24 hours, including KDEs for each CTE—such as product details, event type, date, location and supply chain partner information—to trace products forward and backward.



2

Automate Data Collection for Accuracy

Automation ensures accurate, real-time data capture for seamless compliance.

- » Eliminate manual data entry errors with automated systems, including fully-managed electronic data interchange (EDI) integration for seamless exchange of KDEs.
- » Centralize KDE records, like production dates and shipping logs, for quick retrieval during FDA inspections.
- » Save time and ensure precision with barcode scanner integration.



3

Integrate Predictive Quality Control to Minimize Risks

Prevent quality issues with advanced analytics and proactive measures.

- » Detect patterns and anomalies to safeguard product integrity.
- » Focus resources on flagged issues to prevent costly recalls.
- » Ensure items on the Food Traceability List (FTL) are handled appropriately.



4

Streamline Compliance Documentation Processes

Organized, real-time documentation ensures regulatory alignment, minimizes errors and reduces costs.

- » Maintain traceability plans and KDEs for immediate access during inspections.
- » Use digital formats to facilitate compatibility and ensure KDE records are maintained for two years per FSMA 204.
- » Avoid fines by ensuring every record complies with regulatory standards.



5

Monitor Financial Impact Through Smarter Forecasting

Align regulatory obligations with financial goals using data-driven insights.

- » Leverage forecasting tools to anticipate expenses and optimize spending.
- » Avoid unexpected financial strain while meeting FDA requirements.



Simplify FSMA 204 Compliance with Purpose-Built Software

Industry-specific software consolidates data into one unified platform to enhance visibility and operational efficiency and streamline compliance. Aptean's purpose-built Food & Beverage software provides the capabilities your business needs to comply with the Food Traceability Final Rule:

- » Bidirectional traceability
- » Lot tracking and barcode scanner integration
- » Real-time data synchronization
- » Compliance document management



Compliance with regulatory standards is essential for efficient and sustainable operations. Our industry-specific technology provides the visibility food and beverage businesses need to align with regulations and safeguard brand reputation.

Take our **Food Traceability Final Rule** or learn more about the **steps your company can take to comply with FSMA 204.**