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Playbook

FSMA 204 Compliance Road Map:

A guide for food producers and retailers

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The Food Safety Modernization Act (FSMA) has been upholding food safety throughout the U.S. supply chain since 2011. With many improvements since it was passed as law, FSMA enables food producers and retailers to focus on preventing food contamination incidents before they spread instead of merely reacting to incidents when it's too late.

In November of 2022, the FDA released a **final rule** for section 204 of FSMA – The Food Traceability Rule.

This rule mandates businesses to track and trace high-risk foods across the supply chain in order to mitigate public health and safety risks. It requires businesses to maintain precise records of all key data elements (KDEs) and critical tracking events (CTEs).

Companies need to understand the cost of non-compliance as there are various actions the government can take if voluntary compliance is not forthcoming. For starters, these include civil or criminal actions in Federal court. In addition, the risk of a failed audit, a costly recall, or a deadly outbreak can result in loss of revenue and costly fines, wasted product, a tarnished brand reputation, and more. While the initial costs and efforts

associated with compliance may seem burdensome, FSMA Section 204 offers several potential benefits. Strict adherence to food safety measures can enhance consumer trust. A positive reputation for safety and quality can be a powerful differentiator in a competitive market. By implementing preventive controls, businesses can reduce the risk of contamination incidents, thereby lowering potential legal liabilities and safeguarding their brand image.

What does this mean? How should your food-facing business prepare for FSMA 204? In this guide, we provide the information you need to safeguard your organization and achieve traceability compliance with the Food Traceability Rule by 2026.

Disclaimer: This guide is intended for informational purposes only and should not be construed as legal advice. It is recommended to consult with legal and regulatory experts to ensure compliance with FSMA 204 and other relevant regulations.



1 The FSMA 204 Regulation

The Food Safety Modernization Act (FSMA) 204 regulation, also known as the Food Traceability Rule, represents a significant shift in food safety.

FSMA 204 aims to ensure businesses quickly identify and take action against food contamination instances, decreasing the number of foodborne illnesses throughout the population.

The FSMA 204 requirements are:

- Any persons involved in the producing, processing, manufacturing, packing, handling, or holding of foods on the FDA's Food Traceability List must keep accurate records of key data elements (KDEs) and critical tracking events (CTEs).
- Traceability, KDE, and CTE data must be collected and stored for at least 24 months.
- When requested by the FDA, shipping and event data must be provided within 24 hours.
- Traceability, tracking, and shipping event data shall be shared with the operator's supply chain partners.

Under this rule, any company or person who “manufactures, processes, packs, or holds” foods that are considered high-risk as indicated in the Food Traceability List (FLT) is subject to FSMA 204.

The Food Traceability List (FTL)

Below are the foods that the FDA outlines as high-risk and that require traceability records.* This list is subject to change, so stay up-to-date with the latest FSMA information.

- Cheese
- Eggs
- Nut butters
- Cucumbers
- Fresh herbs
- Fresh-cut vegetables
- Fresh-cut fruits
- Leafy greens
- Melons
- Peppers
- Sprouts
- Tomatoes
- Tropical tree fruits
- Fish (fresh and frozen)
- Smoked fish (refrigerated and frozen)
- Crustaceans (fresh and frozen)
- Shellfish (fresh and frozen)
- Ready-to-eat salads

**To confirm whether or not your products are on this list, [review the complete FTL](#) from the FDA.*

Note: some brands may qualify as [Exemptions to the Food Traceability Rule](#).

All who are subject to compliance with the new traceability rule must implement operational measures by July 20, 2028.



2 Identifying CTEs and KDEs

You'll hear a lot about the importance of CTEs and KDEs in food traceability, and for good reason. CTEs and KDEs are what enable companies and suppliers to maintain records of compliance.

Critical Tracking Event (CTE)

CTEs are critical supply chain events that occur during a product's lifecycle.

- Harvesting
- Cooling (prior to packaging)
- Initial packing of produce
- First land-based receiver of seafood
- Shipping/Receiving

Key Data Element (KDE)

KDEs are product traceability data that reflect product movement and CTEs.

- Product identification
- Transportation details
- Critical tracking events
- Reference information
- Business contact
- Traceability lot code





Accurate data capture and documentation are crucial for the FSMA rule. The most important **KDEs and CTEs** to pay attention to vary by specific operation. To identify which traceability information is relevant to you, consider the following.

Your Product and Supply Chain

Which of your products contain ingredients from the Food Traceability List? What are the stages your product goes through from crop to consumer? What other companies and partners are involved?

Your Critical Tracking Events

When you review the list of CTEs along the supply chain, which apply specifically to your product and operation? Think about growing, harvesting, transforming, shipping, and receiving.

Your Key Data Elements

Each CTE you identify involves a key data element that needs to be captured and logged. What KDEs are already in place at your operation? Which KDEs do you need to start tracking? Key elements include product name, description, identifiers, lot codes, reference record information, and CTE information.

Your Current Data Capture

How does your existing system capture and store product data? Where are the gaps in your process? Where do you need to begin implementing accurate CTE and KDE tracking?



3 New Traceability Technology for Food

With the complexity of these new traceability regulations, many food brands are turning to advanced technology with track and trace capabilities that enable compliance.

These tech platforms often use RFID tags, IoT (Internet of Things) sensors, QR codes, and blockchain to achieve real-time monitoring of products.

RFID devices store KDE information which is automatically captured in a **supply chain traceability platform** via radio waves. While RFID comes with a cost to implement properly, these devices ensure real-time traceability that results in improved

inventory management, greater supply chain visibility, and reduced operating costs.

Ensuring food safety and compliance is paramount. Our commitment to providing robust traceability solutions aligns with our dedication to empower businesses in meeting FSMA 204 requirements, safeguarding consumer health, and upholding industry standards.



Even large food chains are transitioning to item-level traceability technology to secure customer safety and FSMA compliance. For example, the global company **Chipotle** adopted RFID real-time technology from BarTender to improve their food safety and quality control across more than 3,000 stores.





4 Achieving Compliance With the Food Traceability Rule

Whether you need to prepare for compliance with the Food Safety Modernization Act 204 or you want to optimize your traceability solutions long-term, here are some factors to consider.

1. Assess Current Processes and Systems

Review the Food Traceability List in-depth to determine which ingredients you handle. Evaluate the traceability system you currently use.

Clarify your customers' and partners' traceability requirements. Assess the usability of your current technology and vet whether or not it supports FSMA 204 requirements.

2. Implement Traceability Software

Explore traceability technology options that contain RFID or other advanced tracking devices. Consider compatibility and scalability with your existing track and trace systems, if necessary.

Schedule demos or set up the chosen technology internally. Test it with supply chain partners. Evaluate the results and make necessary adjustments to the traceability system.

3. Capture CTEs and KDEs

If you haven't already, develop protocols for capturing and maintaining critical tracking events and key data elements at every stage of your product's supply chain. Refine and implement procedures for data monitoring, storage, retrieval, and maintenance of traceability records.

4. Ensure Data Integrity

Take proactive measures to safeguard your data against loss, tampering, and fraud. Make sure your traceability solution empowers you with encryption, access settings, regular audits, and other forms of data integrity.

5. Enable Supply Chain Data Sharing

Define which suppliers, distributors, FDA authorities, and other supply chain partners need shared access to your food traceability data. Standardize your communication and data-sharing protocols to ensure interoperability. Schedule ongoing third-party audits and closely monitor your traceability program.

6. Educate Employees

The FDA does not yet have standards in place for training employees about FSMA 204. Take initiative and educate your workforce so they're aware of the Food Traceability Rule, its requirements, the purpose of traceability technology, data management SOPs, and more.

Foster a company culture of awareness, compliance, and accountability to safeguard your entire organization.



5 Improving & Adapting Operations for FSMA 204

Companies need to be proactive if they are to achieve long-term compliance with the Food Traceability Rule.

While upgrading your traceability technology and process is necessary for FSMA 204 readiness, you'll also need to stay on top of monitoring, auditing, data analysis, and stakeholder engagement in the future.

A lot goes into achieving FSMA compliance, especially in an industry that's constantly evolving. Food companies are likely to thrive amidst new traceability rules when they:

- Stay ahead of regulation updates and best practices.
- Embrace advanced technologies that provide real-time item-level visibility.

- Collaborate with industry experts and authorities.
- Pay attention to insights from supply chain partners, retailers, and customers.
- Encourage participation, adaptability, and innovation throughout the organization.

Fortunately, there's an all-in-one traceability platform that fosters these potentials so supply chain operators can thrive.

6 Real-Time Item-Level Traceability for the Food Supply Chain

Adhering to the FSMA's carefully chosen requirements for food traceability not only equips you with crucial supply chain data but also improves your product safety, mitigates risks, reduces costs, and builds trust with the public.

Food businesses must now leverage track and trace solutions as if their bottom lines – and the customers they serve – depend on it.

Fortunately, a **food traceability platform** that's led supply chain innovation through every change in the past two decades is ahead of these complex demands. BarTender Track & Trace puts real-time, item-level traceability intelligence into the hands of those who need it most.

Whether your organization is a small local business or a global food conglomerate, it's time to achieve accurate traceability protocols. See how real-time item-level traceability works in your food supply chain of the future. **[Contact BarTender today to set up a demo of FSMA 204-friendly technology.](#)**

About BarTender

BarTender is a brand of Seagull Software, a global leader in real-time, item-level visibility and label management solutions, dedicated to powering the world's most complex supply chains with innovative tools for traceability, authentication, and automated inventory management.

BarTender software enables businesses across all industries to design, manage, print, and automate the production of labels, barcodes, and RFID tags, ensuring seamless tracking and compliance for over 100 billion unique identifiers each year. Leveraging the Track & Trace high-security, scalable SaaS traceability platform, Seagull delivers end-to-end intelligence, harmonizing data to drive operational efficiency, enhance customer experiences, and reduce risk.

Headquartered in Redmond, Washington, with offices across the United States, Europe, Latin America, and Asia, Seagull empowers businesses worldwide to keep their products moving, traceable, and safe.

Learn more at bartendersoftware.com.

