Is your supply chain FSMA 204 compliance ready?

A cloud-first approach boosts transparency, reduces labeling errors, and ensures safer products.

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Unpacking the Food Traceability Rule

Any company that manufactures, processes, packs, or holds cheeses, eggs, herbs, leafy greens, cucumbers, tomatoes, ready-to-eat deli salads, and other items on the FDA's Food Traceability List has its work cut out for it right now. Part of the broader FDA Food Safety Modernization Act (FSMA), Section 204 went into effect in January 2023.

The FDA is giving companies until January 20, 2026, to become fully compliant. Food organizations now have less than two years to ensure that their facilities and processes comply with the new rule or risk penalties, fines, and even plant shutdowns.

That's not a lot of time to get everything in order. Smart companies are taking steps now to establish recordkeeping processes and implement technology that can capture, store, and provide detailed data about the movement of these foods throughout the supply chain.

FSMA 204 is no longer just a mirage on the horizon

Every year, about 48 million people in the U.S. get sick, 128,000 are hospitalized and 3,000 die because of foodborne diseases. The national E-coli romaine lettuce outbreak, salmonella that came from imported cucumbers, Wendy's E-coli outbreak and Chipotle Mexican Grill's extended contamination crisis are just some of the high-profile foodborne illness outbreaks that drove the FDA to strengthen the national food safety system.

In place since signed into law in 2011, FSMA is a multifaceted set of laws, each of which comes with its own compliance deadlines. One of its newer components is Section 204, "Requirements for Additional Traceability Records for Certain Foods." The rule outlines certain foods that now require additional recordkeeping requirements, with the goal of quick identification and removal of potentially contaminated food from the market.

Now, the onus is on the makers and handlers of the foods in question to comply with FSMA 204 by January 2026. These companies will have to maintain records with key data elements (KDEs) for these "critical tracking events" (CTEs) in the food supply chain:

- Growing
- Receiving (including first receiver)
- Creating
- Transformation
- Shipping

Companies handling products on the Food Traceability List can't afford to waste any time getting in compliance with these new rules. That means having conversations with supply chain partners — both upstream and downstream — and technology partners. Working together, they can determine the best approach to capturing, tracking, and producing the data according to:

- The data must be captured, stored, and maintained for 24 months
- Event data must be made available to the FDA within a 24-hour window upon request
- Shipping events must be shared with supply chain partners

Effective supply chain transparency and collaboration enabled by the cloud will play a critical role in FSMA 204 compliance. The new rule also requires a more granular level of tracking across the

end-to-end supply chain. For example, the grocery chain that sells ready-to-eat salads that are produced by a specific distributor must be able to quickly identify where the salad was packed and where it was staged for shipment to the grocer's stores. This will require companies to effectively take multiple steps "backward" and look upstream into their supply chains for the required data.

"The approach to traceability in FSMA 204 replaces the method many producers have used for tracing 'one up and one back' within the supply chain," *Food Industry Executive* points out. "As global supply chains have increased in complexity, it has become much more challenging for government agencies and producers within the industry to trace issues along the supply chain effectively."

Efficient Data traceability: Replace paper, clipboards, and spreadsheets

By January 2026, all facilities that hold, pack, or produce goods listed on the Food Traceability List will have to record the required KDEs as critical events take place. Compliance will require a complete mindset shift for any organization that's been using paper, clipboards, and spreadsheets to maintain, update, and share its traceability data.

"Organizations that rely on manual paperwork can still submit paperwork to the FDA this way but may find it overwhelming to track the sheer volume of data required by the new traceability rules," the Food Industry Executive cautions. "For example, a facility must keep [KDEs] for each Critical Tracking Event. But if the facility oversees multiple foods on the Food Traceability List, it will quickly generate an enormous volume of data."

According to Lucelena Angarita, Supply Chain Optimization Director at GS1 US, while there are certain exceptions to the FSMA 204 rule — namely based on specific products or individual company revenues — all companies should be paying attention to this new requirement. Even companies whose products are not currently on the Food Traceability List should start preparing for potential inclusion and anticipate the addition of more products in the future.

To help companies comply with new governmental regulations, GS1 US has been working to establish a "common language" that all food companies can use when gathering, storing, accessing, and sharing their data. Specific to FSMA 204, Angarita says the not-for-profit global organization has been collaborating with members since before the rule even came out by providing a "mutual space." Manufacturers, distributors, retailers, operators, solution providers, and associations converged in that mutual space to brainstorm, address challenges, and create specific documentation and tools.

"Our goal was to give companies actionable guidance in terms of what exactly they needed to do and what steps they had to take to meet FSMA 204's requirements," says Angarita. "We will continue creating and adjusting the documentation as companies start to implement their FSMA 204 compliance programs."

How will FSMA 204 affect your labeling processes?

The Food Traceability Final Rule may have significant impacts on a food company's labeling processes and requirements, particularly in terms of additional recordkeeping and data management. Companies are required to maintain detailed records for listed foods, including lot numbers, supplier and buyer details, production dates, and the movement of products throughout the end-to-end supply chain.

To meet these and other requirements, food companies are adding traceability data like lot numbers and/or QR codes to their labels. Should a recall or foodborne illness occur, the related data will be readily available and easy to access and share. Organizations will also have to capture, retain, and produce CTE data, which in turn will require traceability lot codes (i.e., the product description for the food in which the traceability lock code applies).

Traceability lot codes are a new requirement that compels companies to track the quantity and unit of measure of the foods used at the plant facility where the food was made. The lot codes are assigned at the point of manufacture, or when the product is first received on land (for seafood). The rule prohibits anyone else from assigning a new lot code, which is effectively what "ties" the various pieces of the food supply chain puzzle together.

"That's why the integrity of the data is so critical," says Angarita, who adds that GS1 US has taken a proactive stance and is helping the industry create and adhere to standardized data that can be used across the food production and distribution spectrum. The organization has also produced a "readiness checklist" that clearly spells out the standards, expectations, and steps that companies should be taking now to prepare for FSMA 2024 compliance.

Although FSMA 204 doesn't mention any specific labeling or barcoding requirements, both are playing an important role in helping companies adapt their processes, leverage technology, and ultimately benefit from the rule's focus on enhanced food safety and transparency. For example, companies that adopt cloud technology solutions to replace their manual systems can also expect greatly improved stock rotation, better inventory management, more accurate and faster invoicing, and enhanced overall efficiency.

Build your success roadmap for FSMA 204 compliance

As the January 2026 deadline looms for FSMA 204, there are steps your company can start taking now to prepare for the inevitable. By promptly implementing an action plan and taking immediate steps will help you steer clear of a last-minute scramble. You can then relax, confident that your supply chain was adequately prepared well in advance. Here are seven strategies that you can use to build your own success roadmap for FSMA 204 compliance:

1. **Evaluate your current processes and people.** Examine how you identify products, the origins and destinations of these products, logistics units, and other key data points within the supply chain. Identify any gaps in your current systems: what's missing and what can be done better and more efficiently? Look at the various departments and individuals currently involved in the product tracking process to identify how they'll be impacted by the new FSMA 204 rules.

2. **Get everyone talking about FSMA 204.** Different departments should be talking about and grasping their respective roles in compliance. And once you've achieved internal alignment on the topic, you'll also want to get your trading partners and suppliers involved. Key considerations include the type of barcodes in use today; whether your trading partners can scan those barcodes; and the feedback loop that can be used if or when issues come up.

3. **Standardize the labeling process.** For example, GS1 US members are using global location numbers to identify locations and serial shipping, and container codes can be used to identify pallets. All data can be encoded on a barcode or RFID tab. As the food product moves along the supply chain, readily recognizable batch lots can be added to meet the FSMA 204 compliance requirements.

4. **Get leadership onboard and involved early.** If leadership understands from the beginning that you're going to need more warehouse and operations associates to support your company's FSMA 204 compliance efforts, then it will be more apt to approve those requests when the time comes to invest in new technology, people, and processes. Corporate leaders should also be called upon to provide the support and motivation needed to get different departments onboard and highlight "what's in it" for each of those teams.

5. **Think beyond compliance.** Organizations that see new regulations as nothing more than "boxes to tick" may be missing out on a wealth of potential benefits. This certainly applies in the FSMA 204 realm, where robust traceability practices can translate into a clear competitive advantage. You'll have visibility into precise details on who printed what, with which printer, and the exact time down to the millisecond when the print command was initiated. It also helps build trust between trading partners and consumers who expect to be able to purchase and consume foods that are safe and free from any foodborne threats. Finally, streamlined tracking enabled by cloud-based labeling helps companies better manage product recalls, minimize losses, and preserve their bottom lines.

6. **Take advantage of industry resources.** The FDA's FSMA website is well-equipped with information and resources related to the new rule. The site provides valuable tools for anyone seeking greater clarity on the ruling. It offers detailed insights into the specific requirements for their company and any exemptions of which they should be aware. The GS1 US website is another good resource for anyone who wants to better understand precisely which steps they'll have to take

to comply with the new rule. The site features an overview, FAQ, executive summary, and guidelines for the application of GS1 System of Standards to Support for the retail grocery and food service sectors.

7. **And finally, don't think you have to go it alone.** Find a solution partner that can answer your questions and point you in the direction of the right solution for your company. For example, depending on how often you'll have to make label changes (e.g., when introducing new flavors, changing ingredients, etc.) the FSMA 204 requirements may increase quickly. With the right automated cloud-based solution in place, you can easily meet complex variability to save enormous time and money, and be in compliance to avoid safety issues or recalls.

Harness the power of proactive planning

The impacts of FSMA 204 are going to vary depending on the company's size and complexity, supply chain visibility and ability to track and trace products, as well as on their position in the broader food supply chain. Some companies may need to adopt new software altogether, others will be able to upgrade existing systems, and still others will start using advanced software in lieu of manual, time-intensive data collection and recordkeeping systems.Ultimately, cloud-based labeling provides the kind of visibility needed to enable traceability and allow you to react quickly to identify associated product lines to provide the solution.

Regardless of where your company lands on the technology spectrum, now is the time to go through the action points in this report and use them to plan and prepare ahead.

"The bottom line is that the industry should begin preparing for compliance now. The road ahead is a long one, even for those that have a head start," Sharon Lindan Mayl of DLA Piper's FDA practice writes in *Food Safety News.* "And, as you move toward compliance, it is important to keep an eye toward the FDA's longer-term goal of end-to-end traceability, bearing in mind that expanded transparency in the supply chain can reap additional benefits for industry and consumers."

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