GS1 US

Preparing for the New Era of Food Safety

Wegmans and Sysco Share Critical Learnings and Unforeseen Challenges Facing Industry for FSMA Rule 204

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Overview

Whether you are a food manufacturer, supplier, or trading partner in the supply chain, ensuring the safety of the food supply is a shared global responsibility. Recognizing this, the U.S. Food and Drug Administration (U.S. FDA) Food Safety Modernization Act (FSMA) was signed into law. Section 204(d), also referred to as FSMA Rule 204, specifically aims to enhance traceability processes today to respond more quickly to outbreaks and food contamination and build a stronger food safety culture for the future.

To protect public health, the U.S. FDA requires companies to keep additional records for items on the Food Traceability List (FTL). For FSMA Rule 204, the U.S. FDA has defined a set of metrics, called Key Data Elements (KDEs), that correspond to different events in the supply chain, known as Critical Tracking Events (CTEs).

With the January 2026 deadline for FSMA Rule 204 quickly approaching, impacted stakeholders of the food supply chain need to prepare themselves to meet requirements now. Recognizing this need, two major players in the food industry, Wegmans Food Markets, Inc. and Sysco Corporation, executed pilots on extending the use of GS1 Standards to support compliance with FSMA Rule 204.

- **Wegmans,** a supermarket chain with over 100 stores along the East Coast of the United States, mapped and tested unique scenarios involving the transformation of fish and cut vegetables into sushi trays distributed across multiple store operations.
- **Sysco,** a global leader in selling, marketing, and distributing food and non-food products to restaurants, healthcare, and other customers around the world, explored inbound and outbound receiving and shipping events to ensure consistent capture of critical information.

While their efforts focused on different scenarios for unique supply chain roles, these pilot efforts uncovered one simple truth:

Meeting requirements of FSMA Rule 204 can have operational implications and broad impacts across people, processes, and technology that need to be addressed before January 2026 to ensure the efficient traceability of food products through the supply chain.

Wegmans Food Markets

Discovering the Secret to Success Is More Than Great Food

At Wegmans, exceptional food is just the beginning. With an unwavering commitment to continuous improvement, Wegmans understands the importance of operational excellence. For instance, when certain stores do not have the square footage for a full-service kitchen, Wegmans will enlist the help of a nearby store to create certain prepared dishes and transfer them to the other store to be sold.

By preparing foods that are shipped to and sold at another location, Wegmans and other supermarkets with ghost kitchens or manufacturing facilities take on the role of a reprocessor/repackager—a role that has specific FSMA Rule 204 requirements for transformations.

As one of seven CTEs established by FSMA Rule 204, a transformation is defined by the U.S. FDA as "an event in a food's supply chain that involves manufacturing/processing a food or changing a food (e.g., by commingling, repacking, or relabeling) or its packaging or packing, when the output is a food on the Food Traceability List."

Looking at sushi—a prepared food offering that spans production, redistribution, and direct consumption—for its pilot efforts, the Wegmans team identified three specific ingredients: diced tuna, cut scallions, and cucumber spears. Tuna and cut scallions are delivered directly to the store from the distributor, while the cucumber spears flow through the Wegmans warehouse system.

FSMA Rule 204 requires a new traceability lot code to be assigned to a transformed product, but records need to also be retained for the individual ingredients that are on the FTL.

Individual ingredients are received in bulk with an inbound Advance Ship Notice[1] (ASN) that has a GS1 Serial Shipping Container Code (SSCC) and contains all GS1 Global Trade Item Number® (GTIN®) and batch/lot information to uniquely identify each product. This information gets incorporated into production records as the ingredients are "transformed" into a new product. A new GTIN and batch/lot number are created for the sushi trays and shared when they are shipped to the receiving store.

Taking these strict requirements and blending them with existing production processes, Wegmans looked to answer:

- How a team can successfully add multiple steps to ensure complete and accurate traceability records in a fast-paced, extremely well-organized production setting
- How to accommodate production, staff, and hours needed to meet these requirements in a kitchen setting with numerous restrictions due to food safety protocols and high levels of process management

Observations and Implications

By piloting in a real-world kitchen environment, Wegmans was able to get an accurate—and eye-opening—assessment of what the impact of capturing traceability requirements is for a team of chefs. More than one batch/lot number had to be created as they discovered additional transformation events than originally expected.

Wegmans also noted that due to the need to capture information with food-safe equipment, the production of the sushi trays took more time. Further investigation is needed to determine the impact this could have on operations in a real-world setting at scale.

Having a scalable solution for documenting each incoming ingredient and efficiently assigning batch/lot data based on a qualifying transformation event is something Wegmans sees as a key to successfully meeting FSMA Rule 204 requirements while continuing to serve their customers through operational excellence.

[1]All references to ASN or EDI 856 refer to X12's Supply Chain Transaction Standards. For more information refer to x12.org/products/transaction-sets

Sysco

Uncovering Gaps to Streamline Data

Running over 150 distribution centers across the United States and handling tens of thousands of food and non-food products daily, Sysco is a leading and highly valued partner for both suppliers and customers. Recognizing the critical importance of interoperability with trading partners, Sysco has prioritized creating a scalable and effective traceability plan in line with FSMA Rule 204, which is essential for meeting U.S. FDA requirements.

Sysco focused its efforts on optimizing data collection for inbound receiving and outbound shipping of FTL items. To address the diverse data collection methods of suppliers, Sysco collaborated with three suppliers, each representing different levels of complexity and technical capability. The objective was to determine how data collection and receiving processes could be adapted to meet suppliers "where they are" while still creating a robust traceability plan.

While many of Sysco's larger and more complex suppliers leverage GS1 Standards-based data and have the capability to transmit ASNs through Electronic Data Interchange (EDI), others are limited to manual processes to indicate pending shipments and provide item, lot code, and lot source KDE information as required by FSMA Rule 204. From an operational perspective, barcode scanning at the time of product receipt is required to associate the physical receipt of goods with the corresponding systematic KDE information obtained earlier. The same KDE data collected at the time of receiving is essential to tracking intra-warehouse movements, product transformations, and outbound shipments of FTL products.

Observations and Implications

While the use of GS1 Standards-based data and GS1-128 barcodes with consistent application identifiers for the GTIN and batch/lot number provides the basis for capturing specific KDEs (including lot number and lot source) for FSMA 204, Sysco discovered:

Variability in GS1 Standards Adoption

There is significant variability in the adoption and application of GS1 Standards across the food service supply chain. Technical capabilities and barcode standardization differ greatly, particularly with smaller suppliers lacking GS1-128 barcodes.

Variability in Technical Capabilities

There is significant variability in the technology capabilities of entities throughout the supply chain, which will necessitate the need for flexibility and adaptability in trading data with different entities.

Inadequate Barcode Data

Initially, there was an assumption that GS1-128 barcodes would encompass all necessary data. However, these barcodes do not provide trace lot code source information, highlighting a gap in data coverage.

Barcode Standardization Issues

Sysco found issues such as encoding problems, damaged barcodes, and multiple labels without clear scanning instructions. These issues complicated the data capture process.

Sysco has completed its pilot program but recognizes that further investment in GS1 Standards for the entire supply chain is needed to achieve greater efficiency. The diverse nature of the supplier community presents challenges in aligning outbound shipments with the necessary information. To address these challenges, Sysco is exploring partnerships with solution providers who specialize in FSMA Rule 204 and can handle various types of data. Additionally, Sysco is evaluating alternative solutions for suppliers who cannot transmit data via EDI and is working to improve the adoption of GS1 Standards and labeling best practices.

Takeaways and Next Steps for the Food Supply Chain

While Wegmans and Sysco both executed successful pilots, they uncovered operational impacts during these pilots:

- **Wegmans** is working to determine how to automate the capturing and sharing of required lot/batch details so that key data can be trusted to be available and consistent. This will enable the efficient transformation of products within their supply chain without impeding speed to market.
- **Sysco** is evaluating processes for receiving, shipping, and transforming products, focusing on how to integrate traceability measures without compromising operational efficiencies. This assessment aims to enhance processes and systems to ensure compliance with traceability requirements while maintaining seamless operational workflows.

The insights these two world-class organizations uncovered can help others on their journey to meeting FSMA Rule 204 requirements. Organizations should examine:

- Current systems and processes to determine what modifications might be required in finalizing a traceability plan
- What operational impacts may need to be considered, based upon systems and processes, to start preparing for FSMA Rule 204 requirements

As these leaders continue their efforts to meet FSMA Rule 204 requirements, they offer some advice for others in the food industry looking to meet the requirements of FSMA Rule 204:

Review
Existing processes cannot be taken for granted. Reassess everything to ensure a "fit for FSMA Rule 204" purpose is met.

Test
On paper or in transactions, a cohesive traceability system must move beyond modeling and into testing to ensure completeness of all interoperable components and steps.

Standardize
FSMA Rule 204 is complex. But it is also a basic requirement for everyone in the food ecosystem. Approaching all stakeholders with a unified industry response will support meeting the requirements with consistency. This regulation is not the path to differentiation or top-off procedures.

Sponsor
As organizations review FSMA Rule 204, their instinct is to have Food Safety or Food Quality take the lead on readiness and implementation. Our experience points to the need for a senior-level cross-functional approach that affords agency within the company as well as externally so that supply chain stakeholders align on the process changes required.

Start
No organization is immune to surprises and required changes. The sooner you and your team start, the easier your journey will be.

Ensure traceability of food products through the supply chain by preparing for FSMA Rule 204 now!

Resources you may also be interested in:

Case Study: CKE Restaurants

Resources for Applying GS1 Standards for FSMA Rule 204

Overview of GS1 Standards for FSMA Rule 204

About GS1 US

GS1 US®, a member of GS1® global, is a not-for-profit information standards organization that facilitates industry collaboration to help improve supply chain visibility and efficiency through the use of GS1 Standards, the most widely used supply chain standards system in the world. Nearly 300,000 businesses in 25 industries rely on GS1 US for trading partner collaboration that optimizes their supply chains, drives cost performance and revenue growth, while also enabling regulatory compliance. They achieve these benefits through solutions based on GS1 global unique numbering and identification systems, barcodes, Electronic Product Code (EPC®)-based RFID, data synchronization, and electronic information exchange. GS1 US also manages the United Nations Standard Products and Services Code® (UNSPSC®). For more information, visit **www.gs1us.org**.

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