BUILDING A DIGITAL STRATEGY FOR FSMA AND FOOD TRACEABILITY COMPLIANCE

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EXECUTIVE SUMMARY

As you know, the food and beverage industry is a vast and multifaceted sector that entails a wide range of activities, including food processing, packaging, and distribution to the end customer. And as you have likely experienced, the industry faces several challenges that hinder efficiency and the bottom line. Given this landscape, the question becomes: what can you do about it?

One of the most significant issues plaguing this industry is quality assurance. Maintaining high standards of quality and safety is essential to protecting consumer health and long-term confidence in a company's brand. However, ensuring consistency and product quality during sourcing, processing, and packaging can be challenging, especially for companies operating on a large scale. Issues such as contamination, spoilage, and improper handling can compromise the integrity of food products, leading to potential health risks. This is where rigorous quality measures and compliance with regulations like the Food Safety Modernization Act (FSMA) become imperative.

The FSMA, enacted a decade ago, represents a significant overhaul of food safety regulations in the United States, aiming to shift the focus from responding to foodborne illness outbreaks to preventing them altogether. Compliance with FSMA regulations imposes additional responsibilities on food processing and packaging companies. This includes implementing risk-based preventive controls, establishing

food safety plans, and conducting regular inspections and audits. FSMA's Rule 204 (d), also known as the Food and Drug Administration (FDA) Food Traceability Final Rule, aims to improve food traceability and enable faster identification of any foodborne illnesses.

One of the key aspects of Rule 204 (d) is the creation of a Food Traceability List (FTL). Due to the nature of the type of foods listed and the potential of those foods to cause illness, Rule 204 (d) especially applies to companies that manufacture, pack, process, or hold foods on this list. Failure to comply with these regulations can result in severe penalties, fines, product recalls, and lingering legal liabilities, making FSMA compliance a top priority for food manufacturers.

While the FSMA is a U.S. act, it has broader implications worldwide. For example, Rule 204 (d) also requires enhanced traceability requirements for businesses exporting foods to the United States. Determining which foods require additional traceability, building and abiding by an appropriate traceability plan, as well as ensuring standardized tracking of events across the supply chain will be critical for food exporters. Building a robust traceability plan can help food manufacturers and suppliers worldwide comply with their local standards as well. A comprehensive and effective traceability system not only aids regulatory compliance, but also helps address quality challenges and needs that resonate with food and beverage manufacturers globally.

This brief aims to explain the transformative impact of technological innovation in ensuring FSMA Section 204 (d) compliance for food manufacturers. By leveraging real-time tracking systems, integrating siloed digital platforms, and using advanced analytics, businesses can not only meet compliance requirements, but also optimize their operations to facilitate enhanced food safety, stakeholder communication, and quality assurance.

FDA AND FSMA'S FOOD TRACEABILITY REQUIREMENTS

Of particular importance, Section 204 (d) of the FSMA pertains to the requirement for enhanced track and trace of food products throughout the supply chain. By July 20, 2028, all food manufacturers must fully comply with Section 204 (d) of the FSMA. This section titled "Enhancing Tracking and Tracing of Food and Recordkeeping" aims to improve the ability of the FDA to trace the source of contaminated food products swiftly and precisely in the event of any food safety incident. It plans to do so by enhancing recordkeeping and traceability procedures, implementing pilot projects, adjusting effectively, and calling for better stakeholder collaboration. Key provisions of Section 204 (d) include:

1. **Recordkeeping and Reporting Requirements:** Section 204 (d) mandates that certain entities in the food supply chain must maintain records related to the production, processing, distribution, and handling of food products. These records must be maintained for 2 years and must be kept on original paper, electronic, or true copies to prevent deterioration or loss. Records must be kept in a manner that enables rapid and effective tracing of the origin and movement of food products. Food manufacturers must provide records to the FDA within 24 hours, if requested. Records provided must be either in paper or electronic formats, although electronic sortable spreadsheets are advised during recalls or any public health threats.

2. **Traceability Requirements:** Section 204 (d) requires the establishment of a procedure for tracking the history, location, and distribution of food products through all stages of the supply chain, from production to consumption. This would enable the FDA to quickly identify the source of contaminated foods and take appropriate action to protect public health. One of the key requirements for food manufacturers is to assign a traceability lot code to foods on the FTL. Section 204 (d) of the FSMA has the FTL that specifically identifies the foods that require additional traceability records.

FOOD TRACEABILITY LIST

Table 1: Condensed Food Traceability List with Descriptions

(Source: FDA)

Food Traceability List	Description
Ready-to-eat foods	All types of refrigerated ready-to-eat daily salads. Examples include egg salad, potato salad, pasta salad, and seafood salads.
Cheeses	Includes all cheeses (other than hard cheese) made from unpasteurized and pasteurized milk.
Nut butters	Includes all types of tree nuts and peanut butter.
Herbs	Includes all types of fresh herbs, including parsley, cilantro, and basil.
Leafy greens	All types of leafy greens, including fresh and fresh-cut leafy greens.
Eggs	Shelled, only from domesticated chicken.
Other fresh produce	Includes cucumbers, fresh-cut fruits, melons, peppers, sprouts, tomatoes, tropical tree fruits, etc.

Table 1 shows a condensed version of the FTL. For the full FTL, please visit the FDA's website.

Section 204 (d) also requires full disclosure of traceability methods. Stakeholders within the food supply chain are also required to maintain records containing key data elements (KDEs) associated with critical tracking events (CTEs). CTEs are pivotal checkpoints in the food supply chain. This can include receiving, manufacturing, holding, repackaging, exporting, and recall. These events compel accurate track and trace of food products to ensure safety and prevent contamination.

Figure 1: KDE Requirements of Different Stakeholders Throughout the Food Supply Chain
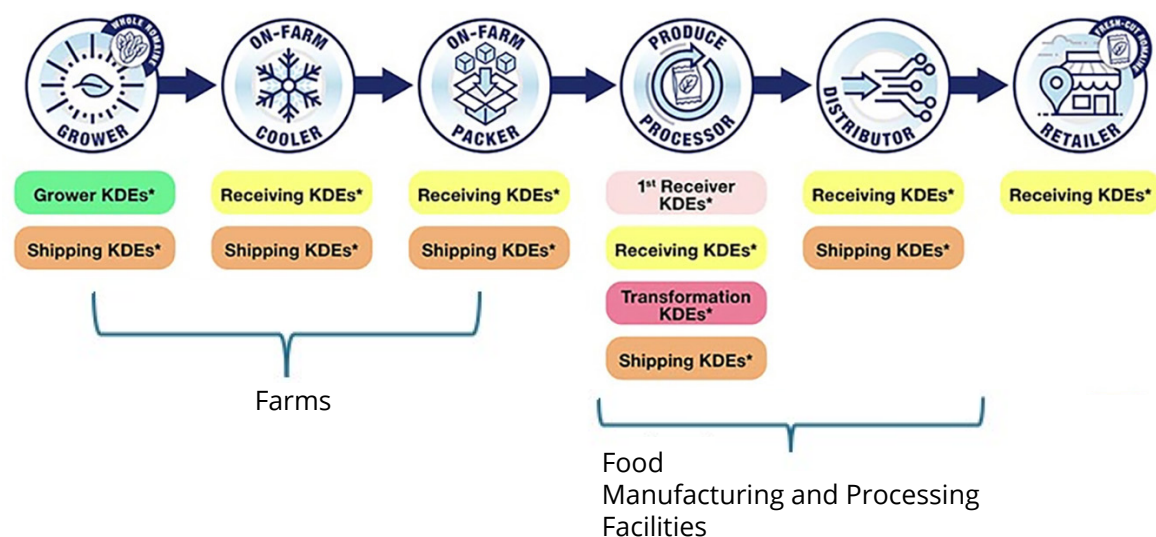
(Source: FDA)

Figure 1 shows KDE requirements by different stakeholders throughout the food supply chain.

3. **Collaboration and Consideration:** Section 204 (d) emphasizes the importance of cohesion and coordination among various stakeholders across the food supply chain. This can include food producers, processors, distributors, and retailers, as well as local, state, and federal regulatory agencies. By working cohesively, stakeholders from the buy and sell sides, as well as regulatory bodies, can enhance traceability and improve the effectiveness of food safety efforts.

4. **Pilot Projects and Rulemaking:** Section 204 (d) directs the FDA to conduct pilot projects to explore and evaluate methods for enhancing tracking and tracking capabilities within the food supply chain. Based on the initial findings, the FDA is authorized to issue regulations to establish traceability for specific types of food products.

IMPLEMENTATION CONSIDERATIONS

After understanding the above key provisions, there are steps that food manufacturers like you need to consider to ensure a robust solution implementation roadmap for FSMA Section 204 (d) compliance. First, leveraging a system that enables real-time tracking of the food manufacturing process is essential. A digital platform that integrates food manufacturing execution systems (MES) and quality management systems (QMS) with enterprise resource planning (ERP) systems that have supply chain management functionalities is key. This real-time tracking system can serve as the foundation for compliance efforts, enabling prompt identification and response to critical events such as contamination or quality issues.

Second, establishing "one up - one down" traceability within the manufacturing facility is crucial. This entails ensuring that each product can be traced back to its immediate supplier and forwarded to its immediate customer. This approach enhances accountability and transparency within the production process, enabling manufacturers to swiftly identify and address potential food safety risks.

Third, there is also a need for food manufacturers to utilize a centralized system that provides a single source of truth and lot traceability information for all stakeholders and auditors. This centralized system consolidates data from various sources, including production records, quality control reports, and supplier information, facilitating easy access and verification of compliance-related information.

Finally, change management also plays a vital role in the implementation process. Effective change management involves providing comprehensive training to employees on new processes and technologies, as well as fostering open communication channels to address any concerns or challenges that may arise.
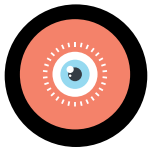
CONCLUSION

As you navigate the complexities of FSMA compliance within the food and beverage industry, the strategic adoption of advanced technologies in real-time tracking, sensor integration for quality monitoring, and improved reporting mechanisms is not just a regulatory necessity, but can also become your competitive advantage. Effectively implementing comprehensive reporting and stakeholder management tools enhances transparency and communications across the supply chain. Along with meeting compliance requirements, these innovations can also set new standards for safety and efficiency, which can address prominent needs and challenges common to the food industry, ultimately making your operations stronger than ever.

About the Sponsor: Plex Smart Manufacturing Platform

Plex Smart Manufacturing Platform™ by Rockwell Automation offers all the functionality that food processing and food manufacturing firms need to ensure compliance with the FSMA. The powerful and user-friendly lot management system and traceability reports address all the traceability requirements outlined in the FSMA Section 204 (d) rule for food manufacturers. The platform offers real-time analytics and reporting capabilities, providing insights into various intricacies of food manufacturing and processing.

Plex provides comprehensive support for all aspects of quality management, including:

- Maintenance and enforcement of Hazard Analysis Critical Control Point (HACCP) plans
- Full integration of quality check sheet enforcement in MES
- Compliance management (Safe Quality Food (SQF), British Retail Consortium (BRC))
- Statistical Process Control (SPC) charting
- Problem control and corrective actions
- Supplier management
- Document control and organization

Here is how the platform can provide real-time traceability for the food and beverage industry:

- **Lot Management:** Real-time traceability records track all receipts, transformations, and shipments of lot tracked items, supporting forward trace from source to destination through any number of production steps, and backward trace from destination to origin as well. All KTEs and CDEs as required of food and beverage producers by FSMA Section 204 (d) are supported.
- **Supplier Management:** Facilitate the management of supplier information and documentation, including certificates of analysis and compliance. Manufacturers can easily trace ingredients back to their original suppliers and verify the quality and safety of raw materials.
- **Quality Control and Testing:** The platform supports quality control processes, including testing and inspection procedures. Manufacturers can record test results and inspection findings in real time.
- **Comprehensive Reporting and Documentation**: Generate comprehensive reports and documentation, including batch records, production logs, and audit trails. This documentation provides a complete history of each product, from ingredients to distribution, which is essential for compliance with FSMA traceability requirements.
- **Recall Management:** In the event of a product recall or contamination incident, Plex enables swift and efficient traceability, allowing manufacturers to identify affected products and customers quickly.

We Empower Technology Innovation and Strategic Implementation.

ABI Research is uniquely positioned at the intersection of end-market companies and technology solution providers, serving as the bridge that seamlessly connects these two segments by driving successful technology implementations and delivering strategies that are proven to attract and retain customers.