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Beyond Compliance: Leveraging Regulatory Compliance to Drive Innovation in Food Supply Chain Traceability

Manikandan Selvaraj

Senior Product Manager: Amazon

https://orcid.org/0009-0004-8429-5084

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Abstract

Purpose: The Food Safety Modernization Act (FSMA) 204, effective January 2026, represents a transformative shift in global food supply chain management, emphasizing proactive over reactive traceability. This research investigates FSMA 204's regulatory framework, associated challenges, and its potential to drive innovation.

Methodology: Through qualitative analysis and case studies of Trustwell and Campbell Soup Company, the study identifies the dual role of FSMA 204 as both a compliance mandate and a catalyst for operational advancements. Key challenges include high compliance costs, technological integration barriers, and limited timelines. However, the regulation incentivizes the adoption of advanced technologies such as blockchain for secure record-keeping, IoT for real-time monitoring, and AI/ML for predictive analytics, which collectively enhance transparency, efficiency, and competitive differentiation. These innovations turn regulatory obligations into opportunities for businesses to optimize supply chain processes, improve consumer trust, and achieve sustainability. Case studies demonstrate how strategic planning and the use of traceability technologies enable compliance while promoting ESG goals.

Findings: The findings underscore the importance of proactive strategies and technological investments to navigate FSMA 204's requirements effectively.

Unique Contribution to Theory, Policy and Practice: This research contributes to the discourse by framing FSMA 204 compliance as a strategic enabler for businesses to foster growth and sustainability, positioning it as a global benchmark for traceability standards. By leveraging these insights, food industry stakeholders can transform compliance challenges into pathways for innovation and resilience.

Keywords: *FSMA 204, Food Supply Chain, Traceability, Blockchain, IoT*

1. INTRODUCTION:

The global food supply chain constitutes an intricately interrelated and complex ecosystem with unmatched challenges to ensure its safety, transparency, and efficiency. The globalization of food systems has amplified complications in tracing products within the value chain from origin to consumers, revealing critical and severe weaknesses in the conventional supply chain management approach (Latino et al., 2022). The Food Safety Modernization Act 204 will be in effect from January 2026 and is one of the most important regulatory mechanisms that will help to address these systemic challenges and alter the course of food traceability. The present food supply chain is beset with challenges: multidimensional, extending beyond mere logistics. Growing consumer demands for more transparency and increasing global concerns about food safety and the potential for widespread outbreaks of foodborne illness have brought an urgent need for thorough traceability solutions. Classic supply chain management methods could not provide real-time, end-to-end visibility of food product journeys, creating significant gaps in safety and mechanisms of accountability.

Historically, regulatory frameworks have been reactive, responding to incidents that have already occurred. FSMA 204 ushers in a new paradigm of proactive prevention. This regulation requires detailed record-keeping and rapid product tracing. It calls for businesses to keep critical tracking events and key data elements documented throughout the supply chain. The goal is the smallest response time regarding food safety in the event of an incident, thus safeguarding health and reducing economic loss due to contamination incidents. FSMA 204 has created immense challenges and unparalleled opportunities for innovation in the food industry. Compliance for food business operators is quite complex, given the technological, operational, and strategic transformation. Compliance does more than fulfil the legal requirement, given that it is a catalyst that leads to redesigning supply chains and technological innovation. The recent emerging technologies such as IA, machine learning and blockchain play an intricate role in providing the solution to address the challenges faced by FSMA 204. Technology will offer solutions to traceability problems, ensuring that elements such as real-time tracking and predictive analytics help in the monitoring process to ensure compliance is cost-effective and offers the business a competitive advantage over the others.

2. STUDY OBJECTIVES:

The goal and purpose of the inquiry are to explore the issue further to identify the challenges and the potential solutions. The investigation looks at different facets of the issue, including technological innovation, strategic organizational adaptation, and regulatory compliance, given that they go hand in hand. The goal is to understand how the factors relate to each other within the traceability ecosystem. The insights from the research help inform the FSMA 204 Boyd to develop a more robust and effective supply chain management system. The results will offer an opportunity for the food supply chain to become technologically adept, efficient and transparent, helping to

ensure the system's sustainability through the strategic innovations that will take place. The findings will help develop actionable insights that help businesses navigate the complex world of the food supply chain. The objectives of the study include:

2.1 To explore the historical evolution of the supply chain traceability legislative bodies
2.2 To discuss in-depth the FSMA 204 regulatory framework and draw out some of the challenges that affect the body
2.3 Identify the potential technologies key to addressing the traceability challenges within the food industry supply chain
2.4 Offer possible recommendations on how companies can optimize compliance as the key driver of organizational innovation

3. AN OVERVIEW OF THE FOOD TRACEABILITY REGULATIONS

3.1 2002: Bioterrorism Act:

In 2002, one of the policies that helped with addressing the food industry traceability issues were the Public Health Security and Bioterrorism Preparedness and Response Act. The act aimed to promote food safety and security within the United States by addressing food traceability issues specifically within the US. Section 307 of the act required the Food and Drug Administration (FDA) to receive prior notice for imported food or offered for imports into the United States (US Congress, 2002). Before the act was introduced into the US system, there was no standardized information on food imports. The gap made identifying and tracking contaminated foods or adulterated products hard. However, the requirement to enact the act allowed the FDA to gather data on food imports, including different aspects such as the name, their addresses, the type and quantity of food, and the country of origin. The information was critical in promoting traceability, allowing for rapid identification and recall of contaminated foods and products. Thus, the act helped reduce the risk of foodborne diseases within the US.

The other role that the act played was that it mandated the registration of domestic and foreign facilities that manufacture, pack, process, or hold any food that is suitable for human or animal consumption. The specific requirements played an essential role as they provided a comprehensive list of facilities, allowing the agency to inspect and audit the facilities to ensure they complied with their food safety regulations. Casino et al. (2021) show that the act effectively improved food traceability within the US system. It also reduced the time it took to identify and respond to foodborne outbreaks. It also helped to improve the accuracy and completeness of the facility information, ensuring proper inspection and compliance. The other role that the act played within the food supply chain traceability system is that it helped detain and seize food products that threaten public health (US Congres, 2002). It thus lays the foundation for the food supply chain traceability.

Despite the legislation's good intentions, it failed to contribute to food traceability in several ways, including the standardization challenge. According to US Congress, (2002), the legislation did not establish a steady food traceability system. The challenge led to inconsistencies and gaps in record keeping, which failed to ensure supply chain traceability. The other issue was the limited funding, which made it hard to tackle the complexity of the food supply chain system. The global supply chain system required adequate financing to implement and maintain the food disability systems; therefore, the lack of funding made it hard to track and trace foods from farm to table, making the act ineffective. The limited enforcement by the low authorities also led to inconsistencies in compliance and a lack of accountability. Such challenges threatened traceability, making it ineffective in promoting its relevance in the market.

3.2 2011-2014: FDA Food Safety Modernization Act (FSMA): After the failure of the Bioterrorism Act, a new regulation that helped when it came to food traceability was the FDA Food Safety Modernization Act (FSMA). The act was signed into law by then-President Barack Obama in 2011. The act aimed to reform the US food system to ensure food safety comprehensively. It shifted focus from responding to foodborne diseases to developing proactive prevention strategies (Hassanein, 2011). The act came after a dramatic change in the global food system and an issue within the healthcare system, given the burden of food-borne diseases. The Centers for Disease Control and Prevention estimated that approximately 48 million people in the US get sick from foodborne diseases. Among them, 48,128,000 were hospitalized, and 3000 died annually (Hassanein, 2011). The epidemic prompted the development of FSMA to address the concerns and provide the FDA with new authority to regulate the food industry. The new authorities played an essential role in helping to develop FDA-designated food guidelines, which contained additional elements such as record keeping and protecting public health. The food traceability lists, for example, identified the foods for which additional traceability records were required, given the high risk. The FSMA also required the FDA to develop voluntary programs that importers could subscribe to help expedite the review and entry of foods into the US from participating importers. The act played an essential role within the food industry traceability systems, which helped ensure food safety and traceability (Latino et al., 2022). It also offered guidance regulations and standards for their stakeholders to adhere to ensure compliance. Those also improved collaboration among the FDA and other foreign and domestic agencies, improving public health outcomes by observing safety measures and compliance with the guidelines.

Despite the efforts to address disability issues, the FSMA faces some challenges. An example is the complexity of the traceability issues and the cost it takes to ensure stakeholder compliance. The FSMA has been criticized for the complexity and the high costs associated with implementing the requirements. It is primarily a challenge for small farms and food businesses, which have been greatly affected by the high costs and complexity of the implementation processes. According to Wirth (2023), some critics even argue that the cost of compliance is too high to warrant any profits. There is also a lack of resources to support the programs fully. It led to delays in implementing

specific law provisions, which reduced compliance and affected food traceability. Some food industry segments also resisted the FSMA guidelines, arguing about the burdensome and cost-effective requirements for implementing such an approach. This approach, therefore, failed to consider most of its stakeholders in the food industry, who are small-scale business owners.

3.3 2023: Regulatory Context and FSMA 204: FSMA 204 is a new regulatory approach to food traceability that meets the rising complexity of the global food supply chains. The regulation was enacted to further improve food safety by introducing unparalleled levels of transparency and speed of response (Latino et al., 2022). The enforcement date is slated to be in January 2026. In particular, the rule targets foods with a history of repeated contamination that are considered high-risk, requiring end-to-end documentation and tracking mechanisms across the food production and distribution ecosystem. The regulatory framework focuses on 'critical tracking events' across the food supply chain of growing, receiving, transforming, creating, and shipping processes. Food Business Operators capture and maintain information at each stage that should provide a comprehensive traceable record of food products. This includes capturing specific key data elements such as lot codes, detailed dates of key events, product identifiers, location information, shipping details, and critical environmental conditions regarding temperature and storage specifications (Petersen, 2023). Unlike earlier regulatory approaches, FSMA 204 requires electronic record-keeping and rapid trace-back. Food businesses must provide complete product tracking information within 24 hours of a request, which requires considerable technological and operational change (Wirth, 2023). The rule applies to entities that manufacture, process, pack, or hold foods on the Food Traceability List, including products historically associated with foodborne illness outbreaks.

FSMA 204 has some unique characteristics and an emerging global trend in food safety regulation judged against international regulatory frameworks. The European Union's General Food Law Regulation and Canada's Safe Food for Canadians Regulations have similar goals, such as traceability (Petersen, 2023). Still, each jurisdiction has a unique way of implementing those regulations. Emerging global trends would include a growing emphasis on digitalization, technology-enabled traceability, and increasing standardization of food safety protocols. Food Business Operators face several obstacles while fulfilling the FSMA 204 requirements: technological issues, including incompatibility with a legacy system, high upfront costs, and the complexity of integrating data. There are operational obstacles, including cross-functional coordination, resource utilization, extended training, technical problems with data standardization, real-time tracking, cybersecurity concerns, and platform interoperability over diverse technologies (Wirth, 2023).

The traceability lot code requirement is one of the significant elements of the regulation, providing unique identifiers for each product batch that are consistently traceable throughout the entire supply chain. These facilitate fast-tracking and recall procedures and provide unrivaled visibility

into the movement of food products. Location and time specifications require precise geographic coordinates and exact timestamps for each supply chain event, creating continuous and verifiable data trails. Compliance with FSMA 204 is more than just complying with a regulation; this is an opportunity to redesign food supply chain management processes (Jovine, 2024). The regulation demands complete documentation and rapid responses so that food safety will, in effect, be proactive rather than reactive. Food Business Operators must consider these requirements not as bureaucratic obstacles but as strategic opportunities to enhance operational efficiency, build consumer trust, and differentiate themselves in an increasingly competitive global marketplace.

4. PAIN POINTS IN THE TRANSITION TO MEET THE COMPLIANCE: The Food Safety Modernization Act compliance deadline is approaching in 2026. Therefore, the food industry is gearing up to meet the requirements to ensure compliance with the rule that goes into effect in January 2026. The goal is to enhance food safety and traceability across the supply chain, while the goal is positive, which is to ensure the removal of potential contaminants. The transition can come with compliance requirements and risk challenges for users, retailers, and suppliers. Therefore, there is a need for such companies and businesses to prepare in advance to create the capacity and ensure full compliance by 2026. Some of the potential challenges that the enterprises face in the transition to meet FSMA compliance by 2026 include:

4.1 Managing the Costs of Compliance: According to Fitzsimmons et al. (2024), the cost of compliance to the regulations poses a significant challenge in terms of compliance. For most businesses, implementing the new record-keeping systems, for example, to ensure transparency and also training of employees, costs a lot of money (Wirth, 2023). Therefore, companies need to invest in technologies and infrastructures to ensure that they can provide the necessary data required promptly. Additionally, the companies must ensure that their suppliers comply with the FSMA requirements, which can also require additional costs. The aspect poses a challenge in compliance, given that the deadline is approaching in January 2026. Small and medium-sized businesses that may not have the necessary resources or infrastructure may suffer greatly. Therefore, there is a need for food businesses to carefully plan, collaborate, and budget for compliance costs, which can include training personnel, hiring personnel, and investing in different technologies.

4.2 Digitization Challenges: The Food Safety Modernization Act (FSMA) compliance requires digital efforts from companies to ensure that they comply with traceability, transparency, and data management regulations. Therefore, effective digitization is key. Data management, for example, requires companies to collect and maintain detailed information about ingredients, distribution of products, and processing methods. The process entails gathering new data, identifying the challenges and taking steps to ensure compliance, which might be difficult for companies lacking such technologies (Wirth, 2023). Moreover, the supply chain complexity makes it hard for multiple tiers within the stakeholder's unit to ensure safety as a top priority. Digitalization efforts are

essential in ensuring seamless data exchange among the different stakeholders within their supply chain networks. Integration is an issue for small and medium-sized businesses in the food industry. The reason is that the companies lacked the resources and capital to enact new technology, such as blockchain (Fitzsimmons et al., 2024). Given the facts above, small businesses may face challenges meeting the deadline nearing 2026. Thus, companies must find practical methods and ways to ensure compliance with the regulations. Collaboration is one of the strategies that can help small businesses become compliant by acquiring the required resources, such as blockchain technology (Boys et al., 2015). Collaboration across the supply chain network, including suppliers' distributors and retailers, can help acquire infrastructure to monitor, track, and mitigate risk.

4.3 Limited Timeline and Complexity of Regulations: The limited timeline and complexity are the other barriers to compliance with the regulation. According to Chuah and Farzad (2024), the two factors go hand in hand, given that the complexity of the regulation requires extensive work, time and resource limits, thus affecting the compliance that companies can fulfil by the deadline. The transition to meet compliance makes it a challenge for companies to learn how to navigate the intricate requirements of regulation. The FDA emphasized that inspections would begin by January 2027, so companies should not wait until the last minute to comply (Patel, 2024). However, for small businesses, regulation requires the entities to share information with others in their supply chain, which can be a daunting task. Given the increased competition, small companies and those with limited resources may have issues sharing such information. For example, companies with outdated data systems may fail to meet the record-keeping requirements by the deadline, given that they're using manual or updated systems. Companies with complex supply chain systems might also experience difficulties sharing information with another supply chain, making implementing the policies ineffective and challenging. Smaller companies with limited resources may also face challenges in complying within their time frame, given that it can be a significant challenge for the companies to acquire capital to ensure compliance (Boys et al., 2015). In conclusion, the transition to meet the FSMA 204 compliance by 2026 poses timeline limits given the complexity of the requirements; therefore, companies need to act swiftly and navigate the intricate requirements and ensure compliance to avoid disruptions and potential enforcement actions that may take place

5. FUTURE OF FSMA COMPLIANCE WITH EVOLVING TECHNOLOGY: Blockchain technology is one of the emerging technologies transforming supply chain networks. It is helping to enhance traceability within the food industry supply chain (Selvaraj et al., 2024). Blockchain leverages end-to-end supply chain transparency tools, making it easy to develop and implement smart contracts that facilitate business operations (Casino et al., 2021). One of the FSMA requirements is for the business to keep detailed and secure records to help ensure compliance. Recording transactions and sharing data through blockchain technology and immutable ledger systems ensure improved transparency and accountability across the supply chain networks. The decentralized nature of the technology facilitates the elimination of intermediaries who reduce the

redundancies and ensure efficiency within the system. The use of smart contracts and the automation process based on predefined rules makes the compliance process easy as it reduces costs and streamlines the operations of the supply chain systems. An example is where farmers can use the technology to harvest data that helps to detail important information regarding the quality and the location of the products as they move across the different stakeholders down the supply chain system (Wang et al., 2022). They can enact measures such as recall as quickly as possible due to the improved transparency within the system, which ensures compliance with the FSMA 204 guidelines.

The other important technology that provides a solution to traceability that FSMA 204 can adopt is the Internet of Things (IoT). IoT plays a pivotal role in transforming the food industry supply chain. Advanced sensor-based tracking technologies could monitor environmental and condition parameters around food products in real time (Bhutta & Ahmad, 2021). Such integration is expected to revolutionize food products' handling, storage, and transport methods to maintain quality and safety in value chains. One way to do that is through IoT sensors within the farm to collect data about elements such as pressure, humidity and temperatures. Farmers can then use the data to determine the product specifications by analyzing the environmental conditions and how they affect the product. Through real-time monitoring, the farmers can track the foods throughout the distribution and enforce quality control measures to ensure the product reaches the market at the desired quality (Latino, 2022). In case of any issues, it is easy to trace the root problem and issue a recall, which also helps when it comes to quality control and risk management.

IoT integration into the existing supply chain system ensures complete interconnectivity for data sharing, enabling predictive analytics and subsequent informed decision-making (Raman et al., 2024). As a result, IoT sensors may indicate when a shipment is exposed to extreme temperatures; thus, it may need route adjustment or storage at specific conditions. Similarly, IoT-based inventory management will help maintain perishable products within an optimal temperature and humidity range. The proactive approach will minimize food spoilage, contamination, and recalls and protect consumers and the environment (Mehannaoui et al., 2023). IoT in the food industry runs from innovative refrigeration units through temperature-controlled transportation containers to automated storage and retrieval systems. All those work in a complex together to monitor and control the environmental conditions to ensure that products will be handled and stored under the strictest norms of quality and safety. IoT-powered supply chain visibility enables food manufacturers to trace products throughout the journey from the point of origin, thus offering edge-to-edge transparency and responsibility (Latino, 2022). The food industry can guarantee a better, safer, more productive, and sustainable food supply chain owing to the IoT advanced sensor-based tracking technologies and real-time environmental and condition monitoring integration with existing supply chain systems. Technology thus supports the FSMA effort and facilitates compliance among the businesses.

AI and ML applications within the food industry supply chain are transforming supply chain traceability. Predictive analytics capabilities, such as anomaly detection and risk management applications, help companies detect possible issues before they happen and reduce the risk of contamination, food spoilage, and other issues that can disrupt the supply chain. Supply chain optimization strategies, enabled by AI and ML, require massive amounts of information from various sources, such as the IoT, to achieve optimal logistics, inventory management, and demand forecasting (Kler et al., 2022). Advanced sensor-based tracking technologies use real-time environmental and condition monitoring to enable fast action in case of deviations from optimal conditions. When AI and ML are integrated into the food industry, the supply chain creates a seamless integration mechanism required by the FSMA 204 legislation. It helps to facilitate data exchange, and the data analysis afterwards affects decision-making. Such a function enhances efficiency due to the visibility created by the data available and its analysis. For example, AI can help track anomalies, such as temperature or humidity conditions when transporting foods across the supply chain. Food industry supply chains can leverage technology to create resilience (Latino, 2022). The supply chain systems become efficient and responsive to changing market conditions. Ultimately, it promotes safety and quality assurance in the food industry supply chain.

6. IMPACT OF FSMA 204 COMPLIANCE ON COMPANIES BEYOND LEGAL COMPLIANCE BASED ON TWO CASE STUDIES

There are various strategies that businesses can take to comply with the FSMA 204 regulations. Companies must prepare themselves adequately before the deadline in 2026 to ensure full compliance with the act. One recommendation is for businesses to conduct comprehensive planning, which entails assigning responsibility to different individuals and teams to ensure they oversee the different tasks related to the FSMA. Another tool for compliance includes developing standard procedures for handling the documentation processes and packaging and storage, among other activities within the organization. A perfect example of a company that uses comprehensive planning is Trustwell FoodLogiq traceability software. The software company was able to help the leading dairy processor streamline its compliance by providing a scalable and comprehensive solution that will enable traceability (Patel, 2024). The software captured and shared critical tracking events and key data elements within the dairy company's supply chain. Such a move ensured compliance with the FSMA 204 record-keeping requirements. The company also used the technology to track the products at the bachelor's level along the different supply chains, both forward and backwards, which made it easy to ensure recall and withdrawal processes when something occurred. The automated data collection and sharing system helped improve supplier collaboration and reduce manual errors affecting data accuracy. Another important thing the company did due to comprehensive planning is leverage the centralized platform to help in data management (Petersen, 2023). The centralized platform was essential in providing real-time visibility and insights into the business's supply chain operations due to comprehensive planning.

The company prepared for future compliance requirements by adopting technologically enabled traceability systems that can evolve with the changing regulations and times.

The other company that has managed to comply with the FSMA as a tool for regulation is the Campbell Soup company. The company is dedicated to sustainability, and its efforts go beyond legal compliance to ensure a comprehensive approach that aligns with the FSMA 2O4 regulations and ESG principles. Its four critical pillars include a vibrant community, thriving people, a healthy environment, and trusted food (Patel, 2024). Traceability thus plays a vital role in ensuring the business's success. Regarding sustainability, Campbell has used an approach that ensures it provides trusted food to its consumers. Therefore, they are responsible for their practices, including sourcing labeling, and transportation. The company created a comprehensive traceability program to ensure it can detect and respond to food safety issues to ensure it preserve the company's name. The robust traceability plan assigns unique traceability lot codes (TLC) to products and integrates them with global trade item numbers (GT INs) (Patel, 2024). The integration allowed the company to track products from farm to table. The system offers end-to-end visibility, which is key in tracking the products and taking proactive action to ensure food safety. Moreover, the business's other actions include establishing standard operating procedures (SOPs). The SOPs help handle and document the raw materials, storage, packaging and processing elements.

7. CONCLUSION: In summary, the enforcement of FSMA 204 shows a significant and pivotal movement within the evolution of the food supply chain in the global context. By shifting from using a reactive to a proactive system, the regulation challenges the previous limitations within the regulations. It creates operational frameworks that embrace cutting-edge technologies to ensure compliance among businesses. The challenges that exist in compliance include data standardization issues, compliance costs, and technological hurdles. Such factors can hinder the company's compliance with FSMA (204) regulations. However, with comprehensive planning and collaboration among the stakeholders, compliance with the regulations is possible. The benefits go beyond compliance as companies create resilient and strong organizational systems, thus promoting food safety and traceability. Technologies such as blockchain, IoT, and AI/MI represent opportunities for companies to ensure compliance. Blockchain technology helps create secure and immutable record-keeping technology, which enhances trust across the supply chain. IoT helps with real-time environmental monitoring, which ensures quality assurance and risk mitigation. AI/ML is critical in optimizing the processes within the supply chain, guaranteeing predictive analysis that helps in risk mitigation. Companies like Trustwell and Campbell Soup have exemplified the potential that FSMA (204) compliance can bring. Therefore, there is a need for proactive strategies to transform compliance into an opportunity for growth and sustainability for businesses. As of January 2026, the deadline, the food industry must leverage this regulatory shift and use it as a catalyst for creating efficient resilience and a consumer-focused supply chain. Doing that enhances food safety and sets a global benchmark guiding companies through transparency, innovation, and sustainability.

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