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Day In Washington

Food Safety: Impact of FDA Food Safety Modernization Act on Supermarket Industry

Supermarket Industry Impact

Food safety is the top priority of the supermarket industry. Why hasn't the supermarket industry "lobbied" food safety issues on recent "fly-ins"? Because food retailers and wholesalers have been focusing their energies on rulemaking and implementation of the **FDA Food Safety Modernization Act** (FSMA) that was enacted on January 4, 2011. FSMA represents the most sweeping change to U.S. food regulations in over 70 years, requiring food retailers to allocate a substantial amount of resources to prepare and adapt to the numerous regulations. FSMA has an impact on every aspect of a food retailer operation and requires additional resources for training, recordkeeping, product information/traceability systems, auditors, and food safety and legal staff. FSMA also takes corporate criminal liability to a new level by holding food retail executives, notably the CEO, accountable.

Position

While implementation of the Food Safety Modernization Act is an enormous undertaking for the entire farm-to-food retail supply-chain, the supermarket industry worked with Congress, publicly supported FSMA enactment and remains supportive of the rulemaking process that has generated the implementing regulations, many of which will be going into effect over the next year.

Any law with such size and complexity requires continued Congressional oversight, "check-ins" on the implementation process, and if necessary, technical changes to the statute to address unforeseen problems or complications. For example, the amount of recordkeeping and reporting of food protection procedures and plans is voluminous and may contain highly-sensitive proprietary information, so food retailers, wholesalers and manufacturers will be working with FDA to balance providing compliant information with ensuring data protection and trade secrets. Therefore, we ask Congress to remain alert and open to future technical modifications to FSMA if/when they arise over the next few years.

Background

The Food Safety Modernization Act (FSMA) fundamentally changes the way food is regulated in the U.S. and abroad and affects the entire supply chain from farm-to-fork. It aims to enhance the culture of food safety and requires a culture change for most food retailers, while providing consumers with important safeguards to enhance confidence in our food system. FSMA focuses more on preventing food safety problems rather than relying primarily on reacting to problems after they occur. FSMA directly impacts manufacturing facilities, central kitchens, distribution centers, food imports and even transportation. The law also provides the U.S. Food and Drug Administration (FDA) with new enforcement authorities and tools to hold imported foods to the same standards as domestic foods. These changes have a significant impact on food retailers and wholesalers.

Overview of Impact of FSMA Final and Soon-to-be-Final Rules

Preventive Controls for Human Food

Final Rule Published: September 17, 2015; Compliance Date: September 19, 2016

Key Requirements: Requires facilities that manufacture, process, pack or hold human food to register with FDA and prepare and implement a written food safety plan. The rule covers retailers' distribution

centers, manufacturing facilities, and central kitchens. Each covered facility is required to prepare and implement a written food safety plan, including a hazard analysis; preventive controls; supply-chain program in certain circumstances; recall plan; procedures for monitoring; corrective action procedures; verification procedures; and recordkeeping.

Preventive Controls for Animal Food

Final Rule Published: September 17, 2015; Compliance Date: September 19, 2016

Key Requirements: Similar to the Final Rule for Preventive Controls for Human Food, applies Good Manufacturing Practices for facilities that manufacture, process, pack or hold animal food. Additionally impacts food retailers who may divert food waste as an input source to animal food manufacturing.

Produce Safety

Final Rule Published: November 27, 2015; Compliance Date: 2017

Key Requirements: Establishes minimum standards for safe growing, harvesting, packing and holding of produce on farms and applies those standards to both domestic and imported produce but contains several exemptions for produce that FDA classified as "rarely consumed raw." Food retailers are required to label produce that qualify for FSMA's small business exemptions but retailers are allowed to include produce safety standards as part of a purchasing agreement.

Foreign Supplier Verification Program (FSVP)

Final Rule Published: November 27, 2015; Compliance Date: April-June 2017

Key Requirements: Requires all importers, including retailers who directly import, to establish a program to verify that imported food is not adulterated and is produced in compliance with FSMA's Preventive Controls rules, Produce Safety rule, or a standard that FDA has deemed as providing the same level of protection and is in compliance with allergen labeling requirements.

Third Party Certification of Auditors

Final Rule Published: November 27, 2015; Compliance Date: April-June 2017

Key Requirements: Establishes standards and system to accredit third-party auditors to conduct audits for purposes of FSVP, among other things, Voluntary Qualified Importer Program.

Sanitary Food Transportation Act

Final Rule Published April 6, 2016; Compliance Date: April 6, 2017 (2018 for small carriers) Key Requirements: Establishes criteria, definitions, and responsibilities to safeguard (both FDA and USDA-inspected) food transported by a loader, shipper, carrier by motor or rail vehicle, or receiver engaged in the transportation of food, including time/temperature monitoring and sanitation conditions.

Food Defense

Final Rule Expected May 30, 2016; Compliance Date: April-June 2017

Key requirements: Implements Food, Drug and Cosmetic Act provisions to prevent <u>intentional</u> adulteration. Applies to domestic and foreign facilities registered under the Bioterrorism Act

In addition to the significant resources that are currently being devoted to food safety, the implementation of FSMA will be a decade long undertaking for the food industry as FDA develops guidance and future regulations that impact the supermarket industry. A few examples of pending FSMA regulations that will impact food retailers include Designation of "High-Risk" Foods for Trace-Back, Reportable Food Registry, and Recall Notifications.

FSMA is incredibly complicated and the regulations comprise thousands of pages that describe new requirements in sometimes excruciating detail. The supermarket industry has devoted many resources toward best guidance practices for retailers and wholesalers to use within their facilities and with their suppliers, such as years-long development of the Safe Quality Food (SQF) Initiative, recognized by retailers and foodservice providers around the world and the only certification system recognized by the Global Food Safety Initiative (GFSI) (http://www.sqfi.com/) to offer certificates for on-farm production to food manufacturing.