

Platinum Plate Protocols

Assisting Companies In Complying With The FDA Food Safety Modernization Act



According to the Centers for Disease Control and Prevention (CDC), about 48 million people (1 in 6 Americans) get sick, 128,000 are hospitalized, and 3,000 die each year from food-borne disease. This is a significant health issue that many believe is largely preventable. In response to this public health concern, on January 4, 2011, President Obama signed the FDA Food Safety Modernization Act (FSMA) into law. This new law requires that the U.S. Food and Drug Administration (FDA) focus on preventing food-borne contamination from occurring instead of simply responding to food-borne illness after it injures consumers. This law places greater accountability on the food industry and on importers to implement world class safety programs which will protect the consuming public.

Marsh Risk Consulting (MRC) has created Platinum Plate Protocols to assist organizations, both foreign and domestic, in their efforts to comply with this new law and who want to have cutting edge process in place to meet the needs and concerns of consumers in our global economy.

What are the important powers given to the FDA by this new law?

This new law is quite complex, but can largely be explained by understanding five key areas:

Prevention

The FDA now has a legislative mandate which requires that a comprehensive, prevention-based control platform be deployed across the food supply. This will require all food producers and partners to focus on preventing contamination in the food chain.

Inspection and Compliance

This law recognizes that FDA inspections play a vital role in holding the food industry accountable for putting safe food into the stream of commerce. The FDA must now inspect high-risk food facilities at least once every five years. Currently, it averages inspections about once every ten years. The FDA will create a risk-based protocol in order to identify high-risk food facilities.

Imported Food Safety

An estimated fifteen percent of the U.S. food supply is imported. This includes approximately 60 percent of the fresh fruits and vegetables consumed by Americans and approximately 80 percent of seafood. Importers must now verify that their foreign suppliers have adequate preventive controls in place to ensure food safety. The FDA will accredit qualified third party auditors to certify that foreign food facilities are complying with U.S. Food Safety Standards. Additionally, the FDA can refuse to allow foreign and domestic suppliers to import food into the

United States if they do not allow the FDA to inspect their food facility.

Mandatory Recall Authority

For the first time in the history of the FDA, it now has mandatory recall authority which will allow the FDA to require companies to recall tainted or mislabeled food products.

Food Safety Plans

This new law now allows the FDA to require that food producers have plans in place for food safety and that these plans are updated every two years at a minimum.

Who is subject to this new law?

In order to understand which companies are subject to the jurisdiction of this new law, it is important to understand the registration requirements of The Bioterrorism Act (2002). The following defines the companies that are required to register under this act:

1. The Bioterrorism Act requires domestic and foreign facilities that manufacture/process, pack, or hold food for human or animal consumption in the United States to register with the FDA by December 12, 2003.
2. Owners, operators, or agents in charge of domestic or foreign facilities that manufacture/process, pack, or hold food for consumption in the United States are required to register the facility with the FDA.
3. Domestic facilities are required to register whether or not food from the facility enters interstate commerce.

4. Foreign facilities that manufacture/process, pack, or hold food also are required to register unless food from that facility undergoes further processing (including packaging) by another foreign facility before the food is exported to the United States. However, if the subsequent foreign facility performs only a minimal activity, such as putting on a label, both facilities are required to register.

Therefore, those companies currently required to register with the FDA under the Bioterrorism Act are now subject to the FSMA.

In addition, Section 101 of the FSMA amends the Federal Food, Drug and Cosmetic Act (FFDCA) to significantly expand the authority of the Secretary of Health and Human Services (HHS) to:

1. Allow for the inspection of records of food that the Secretary reasonably believes is likely to be affected in a similar manner as an adulterated food, and
2. Require that each entity (excluding some farms and restaurants) that manufacturers, processes, packs, distributes, receives, holds, or imports an article of food permit inspection of their records if the Secretary believes that there is a reasonable probability that the use of or exposure to such food will cause serious adverse health consequences or death.

Who is excluded from this new law?

An amendment was added to the FSMA which is referred to as the Tester-Hagan Amendment and it

exempts small farms and some producers from several of the requirements of this new law. Some of these exemptions pertain to:

1. Small farms that gross less than \$500,000 and sell more than half their products directly to consumers or restaurants within 275 miles will not have to comply with the produce safety standards of registering the farm. However, the farm must still either put a label or display a sign with the farm name and address. If the FDA directly links the farm to an outbreak, the exemption can be withdrawn for that farm.
2. Businesses that process foods and sell more than half their products directly to individual consumers (not businesses) will not have to register with the FDA nor comply with the Hazard Analysis & Critical Control Points (HACCP) requirements.
3. Businesses that process foods and sell less than half their products directly to individual consumers may also be able to exempt themselves from the requirements of the law by producing paperwork showing:
 - That they qualify like a small farm (i.e. gross under \$500,000 and sell more than half their products to consumers, local restaurants, and local retailers combined), and
 - That they comply with any applicable local and state laws.

However, these businesses may still have to register because of the existing requirements under the Bioterrorism Act, even though they do not have to go through the extensive HACCP-type requirements that will be added on under this new law.

Even small businesses are not exempt from the law if food is believed to be adulterated.

While FSMA applies predominantly to food processors and producers, restaurants may be considered a “qualified-end user”, not a producer or manufacturer, and may be excluded from several of the requirements of this law. However, restaurants may be subject to this law if they produce or manufacture their own products. The portion of their business which may fall under this new law will be the portion that produces the end food product.

What new processes will the FDA be required to set up?

The FSMA requires that the FDA create a new system of food safety oversight to prevent food problems that cause people to get sick. Prior to the enactment of this law, the FDA had a limited number of standards in place for processing seafood, fruit juices, and eggs. This law will place stricter controls across all food processing.

The new law recognizes that a breakdown in the farm to fork spectrum has caused significant harm to American consumers and even led to deaths. This law is an attempt to hold the FDA as well as farmers/growers and food producers/manufacturers accountable domestically and internationally.

The FSMA is an attempt to give the FDA more effective tools to enforce food safety. It requires that the FDA establish standards for the safe production and harvesting of fruits and vegetables, which comprise large portions of food consumed in the United States. Under the new law, the FDA will develop a proposed rule that will establish science-based minimum

standards for the safe production and harvesting of foods and will also address soil, worker health and hygiene, packaging, temperature controls, water, and other issues. Food facilities will be required to implement a written preventative control plan, which provides for monitoring of the performance of these controls and specifies the corrective actions a facility will take when a product becomes adulterated.

For the first time, the FDA has the congressional mandate to conduct risk-based inspections of food processing facilities. Specifically, within five years of the enactment of this law, all high-risk domestic facilities must be evaluated by the FDA.

One of the significant challenges that the FDA faces is that new policing capabilities as well as developing new systems, processes, and procedures will require significant funding. Currently, Congress has not yet included sufficient funding to the FDA to carry out the mandates which are now imposed and which would allow the FDA to enforce this law.

After this bill was signed into law, there was considerable controversy – while the 111th Congress passed the bill, the 112th Congress may not fund the FDA appropriately.

What protocols will food producers and manufacturers be required to have in place?

The following sections outline processes that food producers and manufacturers should have in place in order to comply with FSMA:

FSMA Section 201 – Increased Frequency of Inspections

The FDA will be required to have protocols for determining which food facilities are most in need of inspection. Additionally, the FDA will be required to increase the frequency of the inspections that it conducts.

Therefore, food manufacturers and producers must have inspection protocols in place to successfully interface with the FDA.

FSMA Section 206 – Mandatory Recall Authority

The FDA has the authority to mandate a product recall if it finds “a reasonable probability” that:

1. A food is adulterated or misbranded, and
2. There may be serious adverse health consequences.



The FDA has the authority to hold a hearing within 48 hours (2 days) after the order is issued to conduct a product recall.

However, the FDA is confident that food producers and manufacturers will conduct voluntary recalls when they learn that food is adulterated or misbranded and can cause serious adverse health consequences.

Therefore, food manufacturers and producers should have product recall protocols in place so that they can easily conduct a product recall that will take the adulterated food product out of the stream of commerce quickly. Food traceability is an essential piece of this product recall protocol.

FSMA Section 101 – Access to Records

If the FDA determines that a “reasonable probability” of “serious adverse health consequences” for the consuming public exists, it can access records of other foods affected in a similar manner. However, the FDA must provide written notice and proper credentials.

Therefore, food manufacturers and producers should have record keeping protocols which will allow easy access to the documents which the FDA inspectors may want to review.

FSMA Section 402 – Whistle Blower

This provision of the law protects employees who:

1. Object to participation in any activity, policy, practice, or assigned task they reasonably believe to be in violation of the FSMA, and/or
2. Testify, assist, or participate in proceedings that involves a violation of the FSMA, or
3. Provide information about violations of the Federal Food, Drug and Cosmetic Act.

Therefore, food manufacturers and producers should have “whistle blower” protection protocols in place to protect their employees.

FSMA Section 306 – Denies Importation of Foreign Food

Foreign food producers and manufacturers must allow FDA Inspectors entry into a facility within 24 hours after requesting entry for a foreign food or it will be denied admission into the United States.

Therefore, food manufacturers and producers importing food product to the United States should have

international food safety audit procedures in place which allow for cooperation with FDA inspections of their own facilities and/or suppliers’ facilities from which they source their products.

What is the timeline for implementing this new law?

The timeline for implementing specific provisions of this new law are expected to be as follows:

Mandatory Recall Authority

This goes into effect immediately. It is the intent of the law to reduce the length of time that the FDA spends negotiating a voluntary recall. Any company that delays in conducting a product recall can be subject to penalties.

Consumer-Friendly Website

This law requires the FDA to develop this website by April, 2011. The purpose of the website will be to identify food that is the subject of a product recall. The website is required to provide user-friendly, “searchable”, product-specific information for consumers as well as information about the current status of a recall. The current FDA search engine has been criticized for being difficult to navigate specifically when looking for brand names or other key information.

Notification of Product Recalls to Consumers

The current law requires that grocery stores provide point-of-purchase notices to customers when they are shopping. Within the next eighteen months, the FDA will identify “conspicuous locations” where retailers are required to post notices regarding recalled foods. The FDA will also indicate the type of targeted recall information to be posted at these locations. It will also provide guidance with regards to other types of notification such as text messages, phone calls, or emails to customers.

Marsh Risk Consulting's Platinum Plate Protocols include services which range from developing a safety analysis and creating a process and procedure for conducting product recalls to protecting whistleblowers.



What can food producers and manufacturers do to prepare to meet the requirements of the FSMA?

Marsh Risk Consulting's Platinum Plate Protocols include services which range from developing a safety analysis and creating a process and procedure for conducting product recalls to protecting whistleblowers.

Created by the Global Product Risk Practice of MRC, the Platinum Plate Protocols will assist organizations in complying with the FSMA in the following ways:

Food Safety Hazard Analysis

MRC will conduct an analysis of food safety hazards which are most likely to occur and are unique to the type of food being manufactured or packaged at a specific food facility. This analysis will include:

1. Defining the hazards at a specific facility
2. Implementing controls aimed at preventing the hazards from occurring

3. Creating effective controls to monitor the hazard
4. Incorporating continuous improvement techniques into the process to enhance effectiveness
5. Developing protocols for interfacing with FDA Inspectors to facilitate favorable inspection results at a food facility
6. Creating written documentation of the plan and incorporating continuous updates every two years at a minimum

Development of International Food Safety Audit Procedures

MRC can assist in developing International Food Safety Audit Procedures unique to the type of food being processed at a facility and which are compliant with the Federal Food, Drug and Cosmetic Act. This audit will include:

1. Written procedures
2. Review and analysis of foreign facilities for compliance

3. Suggestions for continuous improvement
4. Creation of food defense plans which target intentional contamination of high-risk foods

Development of FSMA Record Keeping Protocols

MRC will analyze and provide recommendations in relation to the FSMA record retention requirements. This includes:

1. Review of document retention protocols (which should have a minimum retention period of two years)
2. Review of retainment sample recordkeeping protocols
3. Identification of documents which FDA Inspectors may want to review when they audit a facility
4. Development of a backup plan for server or other storage system failures

Review and Creation of “Best in Class” Product Recall Deployment Protocols

MRC will work with an organization to assess and develop the following product recall protocols:

1. Product Recall Avoidance Procedures
 - **Supply Chain** – An assessment of suppliers’ raw material acquisitions, process change protocols, and financial feasibility
 - **Raw Material Acquisitions** – An assessment of a company’s raw material acquisitions process
 - **Tooling Protocols** – An assessment of the tooling

protocols affiliated with the manufacture of a food product

- **Process Change Protocols** – An assessment of a company’s process change protocols that are in place which protects the integrity of the food product
- **Customer Contracts** – An assessment of a company’s agreements with its upstream and downstream customers, procedures for notifying insurers, and indemnification agreements
- **Corporate Governance** – An assessment of a company’s corporate governance procedures that are in place to maintain world-class product safety
- **Testing** – An assessment of the nature and scope of product safety testing a company conducts which includes the testing of raw materials, the level of testing conducted on finished food products, and whether the testing is statistically significant
- **Issue Identification** – An assessment of a company’s procedures that are in place to identify a product safety-related issue
- **Issue Escalation** – An assessment of a company’s procedures that are in place for escalating a product safety-related issue or incident with the company and the time frame for escalation
- **Written Product Recall Manual** – An assessment of a company’s written product recall plan in the event of a product crisis or recall

2. Product Recall Infrastructure

- **Product Recall Task Force** – An assessment of the extent to which safety is a company priority i.e. whether there is a pre-established crisis management/recall task force
- **Investigation of Potential Safety Issue** – An analysis of whether a company can conduct a fishbone analysis and/or a root cause analysis to identify a problem
- **Crisis Communications** – An assessment of whether a company has an established written communication plan, a crisis management center, and a trained media spokesperson
- **Traceability/Product Mapping** – An assessment of whether a company has procedures for tracing its products to the end consumer
- **Regulatory Compliance** – An assessment of whether a company knows which regulatory authority has jurisdiction/responsibility over its products
- **Field Response Team/Sales Team** – An assessment of whether a company’s sales force has been trained to work with the product recall task force

3. Product Recall Administration

- **Web Registration** – An assessment of a company’s ability to implement a web-based site that will compile consumer information regarding the product at issue
- **Phone Centers** – An assessment of a company’s

ability to activate phone center capabilities in numerous languages in a short period of time

- **Logistic Center(s)** – An assessment of a company’s ability to coordinate web-based registration and phone centers with a logistics center to collect, redistribute, and segregate products in a warehouse as well as the ability to produce regular status updates
- **Product Disposal** – An assessment of a company’s ability to appropriately dispose of a food product that is recalled for safety reasons

Creation of Whistle Blower Protection Protocols for Employees

MRC will review any existing protocols and help an organization to develop FSMA-compliant ones that incorporate:

1. The firm’s policy on whistle blower protections
2. A toll free number to report violations
3. A written template for the firm to respond to allegations from whistle blowers

Meeting Your FSMA Compliance and Strategic Objectives

Food safety has become more complicated in the age of global supply chains and increased government regulation, media scrutiny, and public awareness, putting it among a company’s most critical areas of risk. When food products become compromised, especially given the potential deadly impact they can have on multiple consumers’ health and well-being, the management of the event is critical to mitigating resulting recalls or liability claims that can be devastating to a company’s reputation and profitability.

MRC’s Global Product Risk Practice provides the expertise, in-depth



knowledge, and worldwide footprint required to support organizations' FSMA compliance and food safety strategic objectives. Comprised of highly-experienced professionals, MRC's Global Product Risk Practice includes regulatory compliance experts, recall experts, and quality control engineers with sector specializations in areas such as automotive, food and beverage, pharmaceutical, medical devices, and consumer products. In conjunction with MRC's supply chain, business continuity, crisis management, business analytics, and forensic accounting professionals, as well as Marsh's insurance placement

experts, the Global Product Risk Practice addresses all aspects of an organization's product risk lifecycle, from risk identification and assessment, to quantification and prioritization, to prevention and resiliency, to mitigation and risk transfer.

Marsh offers end-to-end product recall solutions and is recognized as a leading authority on product safety, product risk, and product recall issues. Members of the Global Product Risk Practice have been involved in over 5,000 product recalls and travel the world assisting clients with protecting their brands and reputations.

**For more information,
please contact:**

To learn more about MRC's Platinum Plate Protocols and to enhance your FSMA-compliance efforts, please contact:

Katherine Ann Cahill

Managing Director
Global Product Risk Practice
212.345.3036, office
516.353.7947, mobile
katherine.a.cahill@marsh.com

www.marshproductrecall.com

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Compliance No. : MA11-10415