

# The Food Safety Modernization Act – A Series on What is Essential for a Food Professional to Know

## *Article 1. Consumer Information and Recall; Facility Registration and Suspension; Records Access; Prior Notice for Imports; and Other Provisions That Took Effect as of November 2012*

CAROLINE SMITH DEWAAL\* AND DAVID W. PLUNKETT

<sup>1</sup>Center for Science in the Public Interest, 1220 L St. NW, Washington, D.C. 20005, USA

### ABSTRACT

The U.S. Food Safety Modernization Act (FSMA) is a significant and far reaching update of the laws and subsequent regulations that affect the safety of domestically produced and imported foods regulated by the Food and Drug Administration (FDA). Through FSMA, the U.S. Congress provides the FDA with greater powers and direct it to develop regulations that will focus the food industry on the prevention of foodborne illness. This series of articles will describe the legal “basics” for the readers of *Food Protection Trends*. This first article focuses on the first provisions of the new law to take effect, including recall and consumer notification, facility registration and suspension, records access, prior notice for imports, administrative detention, fees for recall and re-inspection, and high-risk food categories. Future articles will examine the provisions of FSMA that govern new preventive control programs, produce safety standards, imported food requirements, lab accreditation, food defense and state surveillance reforms.

A major revision of our nation’s food safety laws was advanced when President Barack Obama signed the FDA Food Safety Modernization Act (FSMA) into law on January 4, 2011. This comprehensive law will reshape the approach taken by the Food and Drug Administration (FDA) from one that was largely reactive to one that focuses on prevention. The law will require the use of food safety plans throughout the food industry, based on the Hazard Analysis and Critical Control Points (HACCP) model already implemented in the seafood, juice, meat and poultry industries. The law gives increased emphasis to surveillance activities, on-farm food safety, and food laboratory accreditation, along with more traditional FDA activities such as inspection and import controls. There are a number of innovative elements in the new law, including reliance on a foreign supplier verification program and third-party certification for imported foods that are unique to FSMA.

This article is the first in a series that will outline the provisions of FSMA and describe the elements and timing of its implementation. The series will provide a primer for non-legal food safety professionals. This first article looks at a number of provisions that have already been implemented by FDA, some of which are based on authorities first granted to the agency under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act). There are also several self-executing provisions that are reviewed such as the mandatory recall and new suspension of registration authorities. A law is said to be “self-executing” if its provisions become effective without the need for an agency to issue intervening regulations.

\*Author for correspondence: Phone: +1 202.332.9110, x366; Fax: +1 202.265.4954; E-mail: [csmithdewaal@cspinet.org](mailto:csmithdewaal@cspinet.org)

Future articles will examine the provisions governing preventive control programs, produce safety standards, imported food requirements, lab accreditation, food defense and state surveillance reforms that will occur under FSMA.

The law contains numerous instructions to FDA that require changes to its oversight and regulation of the food industry, including more than 50 different deliverables in the form of new regulations, guidance, and reports to Congress (22). Following an initial burst of activity at FDA, the process slowed to a crawl early in 2012 as deadlines for major rules on preventive controls, import verification and produce safety passed while the proposed rules were in the review process. Despite this delay, FDA has started to implement a number of provisions to improve information available to consumers and the food industry, establish systemic reforms, and expand enforcement powers.

Actions taken to date provide insight on FDA implementation of FSMA's transformative scheme for a preventive food safety system. It is clear that FDA intends to take a building block approach to rolling out FSMA programs, which is consistent with the law's structure. In the Act, Congress set forth a multi-year implementation schedule, coupled with directions for Congressional reports, studies, and public hearings on key programs to assure a cumulative and inclusive process for formulating new regulations.

**This article covers seven FSMA provisions (Table 1), many of which became effective within the first year of passage of the Act:**

1. Requirement for FDA to develop a consumer friendly web search for locating food subject to a recall;
2. Mandatory recall authority;
3. Requirement for food facilities to register in even numbered years;
4. Requirement for importers to provide notice if food they are importing has been refused entry by another country;
5. Authority for FDA to administratively detain suspect food items;
6. Expanded records access authority during emergencies; and
7. Authority to collect fees to recover the costs of re-inspections or mandatory recalls.

**Table 1. Location of Provisions in the Food Safety Modernization Act (FSMA), the Food, Drug, and Cosmetic Act (FDCA), and the U.S Code**

Provision	Location in:		
	FSMA	FDCA	U.S. CODE
1. Consumer friendly web search for locating food subject to a recall. FDA announced it had accomplished this April 4, 2011 (7).	§ 206		21 U.S.C. § 3501 (note)
2. Mandatory recall authority. Self-executing upon enactment of FSMA (9).	§ 206	§ 423	21 U.S.C. § 3501
3. Registration. Self-executing.	§ 102	§ 415	21 U.S.C. § 350d
Food categories. Guidance issued August 2012 (14).			21 U.S.C. § 350d (a) (2)
Biennial registration. Self-executing upon enactment of FSMA (10).			21 U.S.C. § 350d (a) (3)
Suspension of registration. Self-executing 180 days after enactment of FSMA (10).			21 U.S.C. § 350d (b)
4. Prior notice of Imported Food Shipments. Interim final rule issued May 5, 2011 (3).	§ 304	§ 801 (m) (1)	21 U.S.C. § 381 (m) (1)
5. Administrative detention. Interim final rule issued May 5, 2011 (4).	§ 207	§ 304 (h) (1) (A)	21 U.S.C. § 334 (h) (1) (A)
6. Records access. Interim final rule issued February 23, 2012 (5).	§ 101	§ 414 (a)	21 U.S.C. § 350c (a)
7. Re-inspection and mandatory recall fees. First fee schedule issued August 1, 2011 (2).	§ 107	§ 743	21 U.S.C. § 379j-31

## Recall and consumer notification (FSMA, Section 206)

Mandatory recall authority was one of the first provisions of FSMA to go into effect. The provision, which ideally will be used rarely, requires FDA to first give companies the opportunity to conduct a voluntary recall when the agency determines food is unsafe or produced under insanitary conditions. This provision, however, makes it clear that FDA has the authority to order a recall if a company fails to respond to the request for a voluntary one.

The mandatory recall section of FSMA establishes the process, powers and limits for using the authority. Although the agency has developed internal guidelines on using this authority, the law does not require the agency to issue guidance or regulations (18).

The legislation mandates that FDA develop a number of communications tools that will help inform consumers about recalls. For example, in one of its first actions to implement FSMA, FDA published a consumer-friendly website to help identify food that is subject to a recall (<http://www.fda.gov/safety/recalls/default.htm>). The website provides searchable, product-specific information for consumers, replacing a recall search engine that was cumbersome and not useful to consumers. In addition, the legislation requires grocery stores to post notices provided by manufacturers that provide specific information on recalls for customers when they are shopping, once FDA identifies “conspicuous locations” within a grocery store for posting such notices.

Currently consumers receive little or no in-store messaging, which leaves many standing in the grocery store wondering whether something they recently purchased was involved in a recall. The list of conspicuous locations for notices will provide targeted recall information at the point of purchase, and may ultimately extend to other types of notification, such as text, phone or email. While the overall goal of FSMA is to prevent food from becoming contaminated in the first place, these provisions will provide some immediate consumer benefits before the prevention components come on-line.

## Registration (FSMA, Section 102)

In 2001, when Congress was grappling with the aftermath of the attack on the World Trade Center, concerns were raised by then-Secretary of Health and Human Services Tommy Thompson that our food supply could become a target. In fact, Thompson told Congress that he was most concerned about food as a target because inspections were not adequate (6). In response, Congress included a number of food provisions in the Bioterrorism Act, along with \$100 million for improvements in FDA’s inspection and counter-terrorism programs. Specifically, the Bioterrorism Act gave FDA authority to register domestic and foreign facilities, detain suspect food items, and require prior notice on all imported food shipments. Each of these provisions was enhanced with the passage of FSMA.

FSMA significantly improves the registration provision. When coupled with new authority to suspend that registration, it gives FDA a powerful new enforcement tool. Understanding why requires a review of the provision’s history. Prior to 2002, FDA inspectors went into the field not knowing what companies they should be inspecting. A Government Accountability Office report once noted that FDA inspectors would refer to the Yellow Pages of the local phone book to find food plants in an area (17). The registration provision was adopted by Congress in order to give the agency a comprehensive list, with names, addresses and contact information for the food plants under its jurisdiction.

The initial registration provision under the Bioterrorism Act required registrants to “notify the Secretary in a timely manner of changes to [registration] information,” and required FDA to compile and maintain an up-to-date list of registered facilities. FDA implemented this as a one-time registration, which left facilities on an honor system for updating the registry. As a result of this implementation, the database of food processing facilities soon became out-of-date (19).

FSMA requires food facilities to re-register between October and December of each even-numbered year, starting in October 2012. While the agency does not have to issue guidance before implementing the registration system, the agency indicated it will do so in its announcement of new guidance on food categories (15).

## Suspension (FSMA, Section 102)

Authority to suspend the registration of a food facility is perhaps the most important enforcement tools the new law grants the FDA. It allows the agency to effectively shut down a food facility if foods produced there have a reasonable probability of causing illness or death if they are consumed. A facility that packed, received or held the food may also have its registration suspended if it knew or had reason to know of that probability. A facility under suspension cannot import or ship food until the business takes satisfactory corrective action.

To keep FDA from over-reaching, the authority to suspend a registration resides with the Secretary of Health and Human Services, and businesses are provided an opportunity to contest the suspension within two days of its issuance. The Secretary can reinstate the registration when the evidence shows that adequate grounds do not exist for its continuation. A facility must also submit a corrective action plan for FDA approval, and once it is approved, the facility’s registration may be reinstated.

Suspension authority is a powerful new enforcement tool for protecting the public from unsafe food. For example, FDA has stated it may suspend registration based on commission of a prohibited act, such as refusing a records access order (13). This significantly strengthens and expands administrative power to aid enforcement. Prior to FSMA, FDA escalated enforcement actions mainly through the courts.

On November 26, 2012, the FDA exercised its authority to suspend the registration of a food processor for the first time since FSMA was enacted. Products produced by this company, a producer of nuts and nut spreads, were at the heart of a multistate outbreak of *Salmonella* Bredeney infections that sickened 42 people. In the interest of public health, FDA suspended the company’s registration, thereby making it illegal for it to introduce foods into interstate commerce (16).

## Records access (FSMA, Section 101)

Another new authority under FSMA is the records access provisions. To gain access to company records under the Bioterrorism Act, FDA needed evidence of adulteration together with evidence of a serious risk to health or life. It also required that record requests be in writing. In a number of highly publicized cases, this delayed FDA's access to critical company records during outbreak investigations. Additionally, the Bioterrorism Act only allowed FDA to access records for the food under investigation, preventing inspectors from following leads to other food lines within the same facility.

The amendment to the Bioterrorism Act's records access provision should not be confused with provisions elsewhere in the law granting FDA new authority to review certain company records. For example, FSMA's preventive controls section gives FDA new authority to access a facility's written food safety plan, together with monitoring and test results, during its regular inspections of the food plant. These records must be made available to "a duly authorized representative of the Secretary upon oral or written request."

This authority will greatly aid FDA in improving the effectiveness of its inspections. No longer will the agency be doing a simple inspection, reflecting only its findings during the time inspectors are in the plant. Through a review of historical records, FDA can transition from "moment in time" inspections to conducting inspections that reflect activities in the plant over a longer time frame.

During an investigation of an outbreak, FSMA's changes to FDA's Bioterrorism Act authority allow the agency to access additional records and expand an inquiry to other food lines within a facility, provided there is a reasonable belief the food processed on them is affected in the same way as the food under investigation. The rule on records access was issued as an interim final rule in February, 2012 (an interim final rule is a regulation that becomes effective on publication without going through the notice and comment waiting period). This provision should be widely discussed with the food industry during the implementation phase, as an Inspector General investigation in 2009 found that 25% of businesses were not aware of the record-keeping requirement and almost 60% had incomplete records (20).

## Prior notice for imports; administrative detention (FSMA, Sections 304 & 207)

Two other provisions of the Bioterrorism Act were also enhanced through implementation of FSMA programs. Within four months of FSMA's enactment, FDA issued interim final rules on prior notice requirements for imported food and administrative detention. Under the Bioterrorism Act, prior notice provided FDA with information about imported food, including its source, shipment, expected arrival date and destination. FSMA's prior notice rule simply added an additional reporting requirement for importers to identify any country that had refused entry to the shipment.

Administrative detention under the Bioterrorism Act expanded FDA's ability to detain food, but the power was not used (1). This was in part because the requirement for "credible evidence or information that the food presents a threat of serious adverse health consequences or death to humans or animals" proved too high a standard.

It was only after FSMA was enacted in 2011 that FDA first used its authority to administratively detain food (11). Within six months of the effective date, FDA had exercised its administrative detention authority three times, in one instance completing the action with a court ordered seizure. Under FSMA, the legal standard for exercising this authority changed: rather than having to show credible evidence that the food presented a threat of "adverse health consequences or death," inspectors had to have a "reason to believe" the food was adulterated or misbranded. The change gave inspectors greater latitude in requesting a detention order and broadened it to cover problems analogous to a Class II recall, used when food fails to meet legal standards (a Class I recall is used when food poses a serious risk to consumer health). In fact, the first two orders were based on insanitary conditions – insect and rodent infestations in warehouses – that generally give rise to a Class II recall.

## Fees for recall and re-inspection (FSMA, Section 107)

User fees for re-inspection and mandatory recall are the final components of new FSMA authority that could have a significant effect during the earliest implementation phase. The re-inspection fee offsets the costs associated with having FDA inspectors return to facilities that had non-compliance issues in an initial inspection. The fees should improve FDA's rate of re-inspection, which had fallen to 64% of the facilities that had serious violations (21). Fees also serve as an enforcement mechanism by shifting the cost of remedial inspections or mandated recalls onto the facility that created the costs.

FDA has taken a cautious approach to implementing its fee collection program. While the first fee schedule and a request for comments on administering the fee program were issued in the fall of 2011, FDA has delayed invoicing until it publishes guidance on the process for requesting waivers. The agency is also delaying any assessment of fees on importers until it resolves issues that were raised in comments on the program (12).

## High risk food categories

Among the tasks FDA must complete, none is as all-encompassing as the requirement for the agency to define which facilities and foods fall into the high-risk category, a condition precedent for meaningful implementation of much of FSMA's risk-based prevention program. The Act requires FDA to define high-risk food or facilities and lays out criteria that the agency is to consider in six provisions affecting prevention programs, inspections, traceability and imports. FDA has developed a model for identifying high-risk facilities based on factors in FSMA's inspection provisions. Information on the process, as well as a decision tree diagram, is available on the agency's website (8). Less well-defined is how FDA will assess the category of risk for foods, which is a pre-requisite to implementing FSMA's enhanced traceability program, and the import certification program. While the agency has not released information on how it makes a high-risk food determination, presentations by agency officials suggest the agency will utilize objective public health data when available, science-based expert elicitations, the Reportable Food Registry (RFR),

and public input. From this information, the agency will likely develop hazard-food category pairings that include consideration of common pathogens and unique processing risks to rank food categories.

## CONCLUSION

This article has reviewed the provisions of FSMA that have already taken effect or will shortly. These provisions include improved consumer information during a recall and increased protection from unsafe food, like mandatory recall and record access during an outbreak investigation. The registration provision, which was available to FDA starting in 2002, has been strengthened with the addition of a biennial registration process and suspension authority. Administrative detention and prior notice for imports has also been improved since passage of FSMA. Other provisions, like those governing fees, are poised to be implemented soon, pending additional administrative action. Overall, FSMA takes lessons learned from the last decade to give the FDA enhanced tools for protecting public health.

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## ABOUT THE AUTHORS



**David W. Plunkett, JD, JM**  
is Senior Staff Attorney for the Food Safety Program at the Center for Science in the Public Interest.



**Caroline Smith DeWaal**  
is the Director of the Food Safety Program at the Center for Science in the Public Interest.

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