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# THE FOOD SAFETY MODERNIZATION ACT:

**A COMPREHENSIVE, PRACTICAL GUIDE  
TO THE LANDMARK LEGISLATION**

Edited by James William Woodlee

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# THE FOOD SAFETY MODERNIZATION ACT:

A COMPREHENSIVE, PRACTICAL GUIDE TO THE LANDMARK LEGISLATION

*Edited by James William Woodlee*



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ISBN 978-1-935065-45-6

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## About This Book

Since even before President Obama signed the FDA Food Safety Modernization Act (FSMA) into law in January 2011, stakeholders have sought to understand how this landmark legislation's wide-ranging requirements will affect their day-to-day operations, both immediately and in the future.

This is no small task.

As FDA Deputy Commissioner for Foods Mike Taylor observes in his thoughtful Foreword to this book, FSMA “establishes in law a new public health paradigm for the Food and Drug Administration's ... food safety program and overhauls for the first time in more than 70 years the basic statutory tools on which we have relied.”

To help stakeholders navigate FSMA and understand how it changes the existing regulatory regime, the Food and Drug Law Institute (FDLI) has published this comprehensive guide to the legislation. The book features contributions from experts on the law and leaders in the food safety field, including:

- a history of federal food safety regulation in the United States leading up to FSMA;
- a history of FSMA's development and passage;
- in-depth analyses of FSMA's major and noteworthy provisions;
- a review of the Food and Drug Administration's implementation strategy, including its accomplishments to date and the challenges ahead; and
- two “stakeholder perspective” pieces, one focused on FSMA's impact on the dietary supplement industry and one on its impact on the food industry.

In addition, FDLI has included an appendix that provides, in a single, convenient location, reproductions of a number of significant FSMA-related documents, including the full text of the legislation.

## About the Editor

**James William Woodlee** practices law as an associate with Kleinfeld, Kaplan and Becker, LLP, in Washington, DC. He primarily counsels and advocates on behalf of clients regulated by FDA, DEA, USDA, FTC and related state and federal agencies. Before entering private practice, he served as an Attorney Advisor in the United States Department of Labor's Office of Administrative Law Judges. He earned a JD from Wake Forest University School of Law, where he served as an Executive Editor for the *Wake Forest Law Review*, and a BA from Wake Forest University. He has contributed to several FDLI publications.

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# Foreword

*By Michael R. Taylor, Deputy Commissioner for Foods, Food and Drug Administration*

The FDA Food Safety Modernization Act (FSMA) is historic legislation. It establishes in law a new public health paradigm for the Food and Drug Administration's (FDA's) food safety program and overhauls for the first time in more than 70 years the basic statutory tools on which we have relied. With FSMA, we have a historic opportunity to build a food safety system that meets rising public expectations for safe food. FSMA also is historic for the broad coalition of consumer and industry groups that made its enactment possible.

The public health imperative for the new paradigm is clear. Data from the Centers for Disease Control and Prevention show that every year, 1 out of 6 people in the United States—48 million people—suffers from foodborne illness, 128,000 are hospitalized and 3,000 die. Foodborne illness places a special burden on immune-compromised individuals, a growing segment of our population, and we know that foodborne illness can be more than a transitory gastrointestinal illness. It can cause life-long, chronic disease and disability, including arthritis and kidney failure.

To compound the challenge, we know that the food supply is constantly changing. The volume of imported food has more than doubled in the last decade. New products and methods of production are introduced rapidly. In the dynamic world of microbiology, pathogens themselves evolve and new hazards emerge.

To meet today's food safety challenges, Congress has made prevention the foundational principle of the new law. FSMA shifts our food safety focus from reaction and response to prevention—from catching food safety problems after the fact to systematically building in prudent preventive measures across the food system. Prevention itself is not new, but Congress has given FDA an explicit mandate to make modern preventive controls the norm across the food system. The law also codifies the principle that the primary responsibility for prevention rests with the food industry. Within the preventive controls framework, FDA plays its role most effectively by setting science-based, prevention-oriented standards and working to ensure high rates of industry compliance with the new standards.

Importantly, FSMA strengthens FDA's inspection mandate and compliance tools to enhance accountability for meeting food safety standards, and it calls for enhanced partnerships with state and local governments as part of a more integrated national food safety system that makes optimal use of public resources to oversee industry practices.

Recognizing the globalization of the food supply, FSMA embraces the prevention principle for imported foods and calls for a fundamental paradigm shift in how FDA oversees the rapidly rising volume of food imports. Rather than relying on FDA's port-of-entry inspectors to detect problems, FSMA makes importers accountable for verifying that their foreign suppliers have prevented problems to the same degree as U.S.-based producers and processors. Congress provides multiple means of verifying that importers and foreign suppliers are doing their jobs, including a new accredited third-party certification program that could bring both greater rigor and greater efficiency to our system for assuring the safety of food imports.

The new food safety system envisioned by FSMA will not be built overnight. And it will take investment—including investment in science to better understand hazards and effective interventions, training of FDA staff, state and local capacity, new information-sharing systems and an expanded global presence for FDA. Building the new system will require hard work at FDA and by people throughout the food system, but the results will be well worth the effort. We'll have a food safety system that is more effective and efficient for government and industry alike, and a system that consumers can trust is doing everything reasonably possible to make food safe. Those are goals on which we all agree.

# 1. FDA Food Safety Modernization Act: The Road to Passage

By Joseph A. Levitt and Stuart M. Pape

## Introduction

For more than a century, the Food and Drug Administration (FDA) implemented a food safety program based largely on concepts first embodied in the Pure Food and Drugs Act of 1906,<sup>1</sup> and later carried over and enhanced in the Federal Food, Drug, and Cosmetic Act of 1938 (FDCA).<sup>2</sup>

The 1906 law was the first federal law governing food adulteration and misbranding, and it largely sought to ensure the accurate labeling of food and drugs and to prevent the substitution of quality ingredients with inferior and, sometimes, unsafe, ones. Food was adulterated if it contained an “added poisonous or other added deleterious ingredient which may render ... [the food] injurious to health.”<sup>3</sup> Passed in the aftermath of Upton Sinclair’s scathing portrayal of the meatpacking industry, the early food safety laws viewed the meat (and later poultry) industries as needing strict regulation through a system of continuous governmental inspection, and the remainder of the food supply as warranting more passive and largely reactive government oversight. The lynchpin for FDA’s original food safety authority was the general prohibitions that food may not be “adulterated” or “misbranded,” prohibitions that still exist today.

With the passage of time, it became clear that all types of food did not present the same degree of risk (or non-risk), and the advent of new technologies, starting with milk pasteurization in the 1920s, meant the food industry was already becoming much more complex than originally envisioned. Science also progressed, which allowed FDA to detect the presence of chemicals at lower and lower levels. Advances in food technology and packaging along with advances in transport facilitated the distribution of food over longer and longer distances, first from across the country and then from around the world. Food science and technology advanced at a more rapid rate than the underlying law; problems and opportunities were identified that industry and FDA needed to address in order to ensure a safe and wholesome food supply for a rapidly growing and increasingly mobile population.

FDA was creative during much of that time and found ways to adapt the law to more contemporary problems. For example, between 1938 and 1958 FDA used standards of identity to restrict the use of ingredients the agency did not consider safe; only after Congress enacted the Food Additives Amendment<sup>4</sup> in 1958 was FDA able to address ingredient safety directly. The 1938 act introduced for the first time the concept that the conditions under which a food was produced were pertinent to whether it was adulterated, so that food could not be prepared, packed or held under “insanitary conditions ... [which may render the food] ... injurious to health.”<sup>5</sup>

In the face of considerable industry opposition spanning decades (including the expression of doubt whether FDA had legal authority to issue binding good manufacturing practice (GMP) regulations), FDA finally proposed GMP regulations applicable to all packaged foods in 1968 (the first set of food GMP regulations was adopted in April 1969). Over the years, FDA continued to develop new approaches to address specific problems, such as the low-acid and acidified food regulations (set in motion in 1971 after the problems with canned soups produced by Bon Vivant Soup Company found to be contaminated with botulism due to under-processing) and later the seafood and juice Hazard Analysis and Critical Control Points (HACCP) programs. Most recently, FDA required a set of on-farm controls to prevent contamination of shell eggs.

Ultimately, it became clear that there were limits to FDA’s legal mandate, such as the lack of express authority to mandate safety standards for fresh produce or whether FDA had the legal authority to apply HACCP broadly. In addition, there were significant challenges to regulating the exponential growth of food imports from all around the world. It also became difficult to predict the risk profile of food products, as food categories long considered to be of lower risk became linked to outbreaks of foodborne illness. It was these limitations that proved to undermine public confidence—that of consumers, industry, regulators and legislators—and the need to restore public confidence was the common thread that created an environment conducive to legislation and the FDA Food Safety Modernization Act (FSMA).<sup>6</sup>

## Legislative Development Followed Series of Outbreaks

Development of FSMA followed a series of three high-profile foodborne illness outbreaks in the fall of 2006 and winter of 2007. The first outbreak, which began in September 2006, involved fresh spinach grown in central California found to be contaminated with the deadly strain of *Escherichia coli* known as O157:H7. This is the same strain of *E. coli* that caused earlier high-profile outbreaks in ground beef and apple juice, and is believed to be spread by animal feces. All told, the spinach outbreak reportedly sickened at least 199 individuals and was reportedly

associated with three deaths.<sup>7</sup> Because of the challenges in tracing the root cause of the outbreak back to the exact farm or farms, the outbreak also paralyzed the nation's entire spinach industry while the investigation into its cause was ongoing, and weakened it for even longer after the outbreak ended. This incident highlighted the challenges FDA faced in assuring the safety of fresh produce that was not subject to mandatory FDA regulations or inspections, and that was consumed raw without the benefit of a "kill step." The incident also served as a stark reminder to the industry that problems in one area or with one company's products could have serious implications for others.

The second outbreak occurred in March 2007 and involved contaminants in vegetable protein imported from China and used to produce pet food. The pet food ingredient had been made to appear to have higher protein content by the addition of melamine. Instead, the melamine-laden pet food proved quite harmful to pets in the United States.<sup>8</sup> Moreover, because this incident involved a widely used ingredient incorporated into many different finished pet foods sold under multiple brand names by multiple manufacturers, it took weeks for FDA to identify all the affected products. Ultimately, both U.S. and Chinese companies and individuals involved in the episode were indicted.

This outbreak highlighted how a tainted ingredient can spread widely throughout the marketplace to affect many different finished products. Even more significantly, this outbreak raised the specter of the massive amount of food and food ingredients that are imported into the United States each year, especially from countries (like China) with less sophisticated regulatory systems. This highlighted the nearly impossible task for FDA to effectively police food imports at the border where the agency had the resources to inspect less than 1 percent of all entries.

The third and final outbreak of this group occurred about the same time (February 2007) and was attributed to *Salmonella* contamination of a well-known packaged food—Peter Pan branded peanut butter. The Centers for Disease Control and Prevention (CDC) reported 425 illnesses to be associated within this outbreak.<sup>9</sup> As peanut butter is a processed food, this outbreak showed that the issue extended beyond fresh produce and imports, and that even products not perceived to be likely candidates for contamination could sometimes become a problem.

Taken together, these three outbreaks covered the full range of FDA's regulatory responsibility: fresh produce, food imports, food ingredients and domestic packaged finished product. It was against this background that Congress launched into a full-scale overhaul of the nation's food safety laws.

## Congressional Action Starts

Congressional action began in early fall 2007 with hearings on a food safety import bill offered by Representative John Dingell (D-MI),<sup>10</sup> then chairman of the powerful House Energy and Commerce Committee. Chairman Dingell had had a longstanding interest in food safety, particularly food imports. Chairman Dingell's efforts, together with widespread media reports and the increasing public attention to food safety, prompted the food industry, through the Grocery Manufacturers Association (GMA), to develop its own proposals. The GMA proposals were called the "Four Pillars of Food Safety" and were also devoted to strengthening the regulation of imported food.<sup>11</sup> The Dingell bill had an added, controversial provision to assess fees against all imports to fund FDA's substantial resource needs to conduct import inspections, both overseas and at the U.S. border. Although user fees had been accepted in the drug and device industries in the context of FDA's premarket review programs, the provision proved controversial to the food industry, especially as applied to inspectional and compliance activity. Initially, the food industry was opposed to any form of user fee.<sup>12</sup>

The initial emphasis on food imports was echoed by the then-President George W. Bush and his administration. Reacting to a series of high-profile import problems, including the safety of imported toys as well as pet food, the President established a government-wide task force on import safety, headed by the Secretary of Health and Human Services, Michael Leavitt, with FDA providing staff support. That task force completed its work with a formal report and recommendations. Supplementing the administration's report on import safety, FDA issued its Food Protection Plan in November 2007, which included not only import safety but also addressed food safety more broadly. The Senate soon took up the issue, but in a more bipartisan way. Led by Senator Richard Durbin (D-IL), and joined by Senators Judd Gregg (R-NH) and Richard Burr (R-NC), S. 3385 was introduced just before the August 2008 recess. The bill was more comprehensive in scope than the initial House import bill, and sought to address the full range of food safety issues, including preventive controls, inspections and enforcement, food imports and industry-based fees. Significantly, Senator Durbin's staff reached out to both industry and consumer leaders in an effort to draft a bill that would both strengthen food safety and be able to garner broad stakeholder support. This proved to be even more significant than was recognized at the time, because S. 3385 evolved into S. 510, ultimately becoming the basis for FSMA.

The year 2009 ushered in the new Obama administration, just as the largest recall in FDA history began to unfold. Caused by a small Georgia-based company (the Peanut Corporation of America (PCA)) that sold less than 1 percent of the nation's peanut butter and peanut paste, the tainted peanut butter found its way into more than 3,900 different finished products because it was

sold as an ingredient. This ingredient was contaminated with *Salmonella*, and CDC reported 691 illnesses and nine fatalities as being associated with the outbreak.<sup>13</sup> Partly due to its timing, the incident caught the attention of the new President, who announced he was ordering a “top to bottom” review of food safety, as he was concerned about the safety of his daughter’s peanut butter sandwiches.<sup>14</sup>

Invigorated by a new, supportive administration and spurred by the PCA outbreak, the House Energy and Commerce Committee again began holding hearings and developing legislation. Now chaired by Henry Waxman (D-CA), but with continued involvement and leadership of past chairman Dingell and ranking minority member Joseph Barton (R-TX), H.R. 2749 came together quickly. Prior to the bill’s introduction, the Subcommittee on Health held a legislative hearing on a discussion draft of the bill, and there were three hearings on food safety held by the Subcommittee on Oversight and Investigations. The bill marched through subcommittee and full committee with bipartisan support before passing the full House in July 2009. Although controlled by the Democrats, the bill appealed to a number of Republicans and passed by a comfortable margin (283-142).<sup>15</sup> As explained in more detail below, the House bill maintained the same basic framework as the earlier Senate bill (S. 3385, re-introduced in 2009 as S. 510), but was more enforcement-oriented and contained an industry-wide annual food facility registration fee to fund FDA’s FSMA mandate.

Following action in the House, the Senate moved reasonably quickly, with the Health, Education, Labor and Pensions (HELP) Committee, by this time chaired by Senator Tom Harkin (D-IA), marking up Senate bill S. 510 in November 2009, with relatively modest changes. For reasons explained below, more than a year passed before S. 510 received final Senate approval in December 2010.

Throughout these three years of congressional deliberations, outbreaks continued to occur, fueling continued interest in food safety legislation. In addition to the three initial outbreaks and the PCA outbreak, this time period saw at least five additional ingredient-based recalls, which collectively resulted in the withdrawal of more than 5,750 products from the marketplace. There was also a large outbreak due to peppers (which the government, mistakenly, initially attributed to tomatoes), a recall of cookie dough found to contain *E. coli* O157:H7 and the first case of botulism in canned food in nearly 40 years. Finally, in the summer before final passage, there was a large outbreak due to contaminated eggs. So notwithstanding a challenging legislative calendar and a legislative environment increasingly reluctant to enact regulatory legislation, this steady stream of outbreaks and recalls kept food safety on the forefront of legislators’ minds (and those of their constituents).

To read the full article, purchase your copy of this publication at The Food and Drug Law Institute website: [www.fdpi.org](http://www.fdpi.org).

## 5. Enforcement Tools

By Sheryl A. Marcouiller, Peter E. Tamborski and Gary Jay Kushner

### Introduction

The history of federal food regulation in the United States reflects steady, though uneven, progress toward greater government oversight of food manufacturing and more aggressive enforcement of laws and regulations designed to ensure the production and distribution of safe food.

The FDA Food Safety Modernization Act (FSMA)<sup>1</sup> is an important landmark in that evolution. Its impact on industry, consumers and the Food and Drug Administration (FDA) is expected to be profound and immediate.

Why now? Bills to modernize food safety laws have been considered in Congress for many years as food production has become increasingly complex and global. Yet nothing moves Congress faster than concerned voters. A series of major foodborne illness outbreaks in the first decade of the 21st century helped create a critical mass for advocates of tougher food safety enforcement policies.<sup>2</sup>

The publicity surrounding the outbreaks, congressional debate and later FSMA passage reflect the keen public interest in preventing foodborne illness. The publicity also shows a lack of consumer confidence in the government's ability to deploy scarce inspection resources rapidly and effectively enough to minimize the impact of the outbreaks that inevitably occur and the general discomfort with the globalization of the food supply. The government's ability to monitor the food supply under the existing statutory scheme was simply outpaced by an exponential increase in imported foods. At the same time, scientific investigative techniques advanced, particularly public health experts' ability to identify precisely the microbial sources of foodborne illness.

The highly charged political environment caused Congress to adopt new science-based substantive requirements designed to prevent foodborne illness and injury as well as tougher tools for dealing with noncompliance. For example, FSMA requires written food safety plans based on hazard analysis and identification of preventive controls as well as supplier verification programs. Other technical requirements are designed to improve the agency's Facility Registration and Reportable Food Registry (RFR) systems, so FDA has better information about the industry and is alerted as



soon as possible when a potentially serious problem may be developing. To strengthen the agency's enforcement toolbox, FSMA supplements the traditional FDA enforcement actions—injunction, criminal prosecution and seizure<sup>3</sup>—with mandatory recall authority,<sup>4</sup> the ability to suspend the registration each facility needs to operate legally<sup>5</sup> and the power to detain food while a seizure action is pending.<sup>6</sup>

Every FDA enforcement action is based upon a prohibited act listed in section 301 of the Federal Food, Drug, and Cosmetic Act (FDCA).<sup>7</sup> The “What is prohibited?” question is thus fundamentally important in defining the scope of the agency's new enforcement power. No matter what enforcement mechanism the agency selects—detention, seizure, injunction, prosecution, mandatory recall or suspension of registration—the enforcement action must be tied to the specific list of violations with supporting facts that show prohibited acts have occurred. Other chapters in this book discuss the substantive FSMA requirements in detail. This chapter explains how the new substantive requirements and the strengthened enforcement tools interact to change the scope of the agency's enforcement power. Finally, we review a few of the higher profile legislative proposals that were not incorporated in FSMA to put greater perspective on the enforcement picture.

## **Making the Case**

FSMA expands the evidence-gathering tools available to FDA in three basic ways: 1) the law expressly sets a very broad standard for records availability when FDA reasonably believes a food will cause serious adverse health consequences; 2) even during routine inspections, inspectors will review records to confirm that the facility is complying with the records maintenance requirements found in many of the FSMA substantive technical provisions, like those governing food safety plans, protection against intentional adulteration and supplier verification programs; and 3) under the RFR requirements, responsible parties are to supply relevant information quickly to FDA when they learn of a potentially harmful adulterated food, so FDA can notify the public if necessary. FSMA also sets minimum inspection frequency expectations based on the agency's assessment of whether the facility is “high-risk” and whether the inspection is domestic or in a foreign country. The new law also establishes criteria for prioritizing risk-based inspections at ports of entry.

### **Records Inspection**

To assess compliance, FDA collects evidence through inspections, including in virtually every case records from the manufacturer, packer and distributor as well as, for example, documented test results, investigator notes and consumer statements. FSMA expands the standard for

inspection of records established under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act)<sup>8</sup> by adding the following language to FDCA:

If the Secretary believes that there is a reasonable probability that the use of or exposure to an article of food, and any other article of food that the Secretary reasonably believes is likely to be affected in a similar manner, will cause serious adverse health consequences or death to humans or animals, each person (excluding farms and restaurants) who manufactures, processes, packs, distributes, receives, holds, or imports such article shall, at the request of an officer or employee duly designated by the Secretary, permit such officer or employee, upon presentation of appropriate credentials and a written notice to such person, at reasonable times and within reasonable limits and in a reasonable manner, to have access to and copy all records relating to such article and to any other article of food that the Secretary reasonably believes is likely to be affected in a similar manner, that are needed to assist the Secretary in determining whether there is a reasonable probability that the use of or exposure to the food will cause serious adverse health consequences or death to humans or animals.<sup>9</sup>

The Secretary's authority extends not only to records of an article of food for which there is a belief of a "reasonable probability" of possible serious adverse or fatal health effects, but also to "any other article of food" that may be affected in a similar manner. This may include products made on the same line, with the same ingredient or in the same plant, or articles that have been shipped or stored together. Additionally, the authority covers the scenario where a suspect food article has become a component in another food product.

Moreover, the scope of records that may be inspected is purposefully broad. The Secretary's authority applies to all records "relating to the manufacture, processing, packing, distribution, receipt, holding, or importation of such article maintained by or on behalf of such person in any format (including paper and electronic formats) and at any location."<sup>10</sup> This would include records related to the development and implementation of the food safety plan required by FSMA. In many situations, effective enforcement will require FDA to coordinate records inspection at multiple supplier plants and storage facilities where suspect food items are, or have been, present.

Consider the implications in a case where FDA determines based on the widespread outbreak of illness that food article "A" manufactured by company "ABC" is the source. ABC's records are reviewed and it becomes apparent that article "A" was sold to several customers including company "XYZ," which combined the article with a dozen other ingredients to produce yet another food

product. Assume that the component parts were present, together, on a manufacturing line, and that unused components were later worked into other products for other customers. The volume of records subject to inspection under the new standards—including records of manufacturers, further processors, storage facilities and customers—could be enormous.

Even when FDA lacks a reason to be concerned about a facility or specific product, such as when the agency is conducting a routine periodic inspection, the agency still has broad records inspection authority. For example, FSMA food safety plan provisions include extensive document maintenance requirements. Inspectors must be given access on request to confirm compliance. In particular, the compliance provision states:

The owner, operator, or agent in charge of a facility shall prepare a written plan that documents and describes the procedures used by the facility to comply with the requirements of this section, including analyzing the hazards under subsection (b) and identifying the preventive controls adopted under subsection (c) to address those hazards. Such written plan, together with the documentation described in subsection (g), shall be made promptly available to a duly authorized representative of the Secretary upon oral or written request.<sup>11</sup>

Failure to comply with this provision is a prohibited act under section 301.<sup>12</sup> In the absence of adulteration or misbranding, penalties under the updated FDCA could include injunction and prosecution. If a product is adulterated or misbranded, detention or seizure also may be appropriate. Furthermore, if FDA determines that the food has a reasonable probability of causing serious adverse health consequences or death, the agency may exercise its suspension of registration and mandatory recall authorities. A similar analysis applies to the record maintenance requirements in other FSMA substantive provisions.

## Expansion of Reportable Food Registry

Amendments to the FDCA in 2007 created the RFR.<sup>13</sup> Among other things, the amendments require a “responsible party” to report to FDA any event in which food 1) may be adulterated, and 2) presents a “reasonable probability” that exposure to the food item will “cause serious adverse health consequences or death.”<sup>14</sup> The responsible party has 24 hours to make the report following its internal determination and conduct an investigation to determine the cause of the event.

FDA is required by the RFR amendments to the FDCA to review and assess RFR submissions promptly to determine the action to be taken, if any, with respect to a reported food article. The

agency also has the discretionary right to publicize a reported event. The responsible party is not required to submit a report if it 1) determines that its own action caused the event; 2) discovers the adulteration before any “transfer to another person” of the item in question; and 3) has corrected the adulteration or destroyed the food at issue.

FSMA augments the RFR in several ways. Not later than 18 months following enactment, the Secretary “may require a responsible party to submit to the Secretary consumer-oriented information regarding a reportable food, which shall include:”

- a description of the article;
- affected product identification codes, such as UPC, SKU, or lot or batch numbers sufficient to the consumer to identify the article of food;
- contact information for the responsible party; and
- any other information the Secretary determines is necessary to enable a consumer to accurately identify whether such consumer is in possession of the reported food.<sup>15</sup>

If the Secretary requires submission of this information, FDA is then required to reduce any critical information supplied by the responsible party to a standardized one-page summary.<sup>16</sup> Fruits and vegetables that are raw agricultural commodities are exempt from the new rule.

If a grocery store sold the product that is the subject of the standardized notice and is part of a chain company of at least 15 stores, it will be required to post, within 24 hours of publication, a copy of the summary, and prominently display it for at least 14 days. The Secretary is charged, within one year of enactment, with publishing a list of acceptable conspicuous locations and manners for posting the summary that requires, at a minimum, posting the summary near the register, providing the location of the product in the store and providing targeted recall information.<sup>17</sup>

Significantly, failure to post the summary as required by the Secretary is a “prohibited act,” and “knowing and willful” failure to post is a prohibited act that in theory could result in prosecution under the FDCA.<sup>18</sup>

## Establishing a Minimum Frequency for Domestic Inspection

The Secretary is charged with the task of identifying high-risk facilities and allocating inspection resources commensurate with risk ratings.<sup>19</sup> Factors that the Secretary may take into consideration are:

- “known safety risks of the food manufactured, processed, packed, or held at the facility”<sup>20</sup>;
- “the compliance history of a facility, including with regard to food recalls, outbreaks of foodborne illness, and violations of food safety standards”<sup>21</sup>;
- “the rigor and effectiveness of the facility’s hazard analysis and risk-based preventive controls”<sup>22</sup>;
- whether the food is imported and certified<sup>23</sup>; and
- other criteria as deemed appropriate.

Domestic facilities designated “high-risk” will be inspected not less than once during the first five years after enactment of FSMA, and not less than once every three years in succeeding years.<sup>24</sup>

Domestic facilities that do not fall into the “high-risk” category will be inspected not less than once in the first seven years following enactment of FSMA, and not less than once every five years in succeeding years.<sup>25</sup>

In meeting the domestic inspection frequency requirement, FDA may rely on inspections conducted by other federal, state or local agencies.<sup>26</sup>

## Inspection of Foreign Facilities

Inspection of foreign facilities poses unique challenges. FDA has no enforcement authority in foreign jurisdictions, and cannot compel facility owners to produce records or allow the inspection of product in the facility itself. Foreign manufacturers and distributors realize, however, that non-cooperation with FDA may lead to serious issues, including denial of entry, when the food product is sent to a U.S. port of entry. Foreign facilities are required to register and must include a statement agreeing to inspection in the registration submission. With strong pressure for companies to reduce costs without compromising food safety, quality or productivity, food manufacturers are relying more on global supply chains. This accelerating trend will almost certainly require harmonization of global food safety initiatives, leading to increased cooperation and communication.

The importance of monitoring foreign manufacturers is underscored by the inspection quotas established by FSMA: no fewer than 600 in the first year after enactment and double the number of the preceding year’s total in years two through six after enactment. By 2016, the minimum number of inspections is required to be 19,200.<sup>27</sup> Compare this to the 357 facilities inspected in 2010, out of a total of 254,088 registered foreign food facilities, and it is apparent that FDA faces a herculean task.<sup>28</sup>

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## 10. FDA's Implementation: Strategy and Challenges

By Elizabeth Barr Fawell and Maile Gradison Hermida

### Introduction

The FDA Food Safety Modernization Act (FSMA)<sup>1</sup> is a historic piece of legislation that requires the Food and Drug Administration (FDA) to build a new system of food safety oversight.

Earlier chapters have discussed the need for and importance of this new law, and the tremendous work that went into its passage. They also have discussed the significant provisions in the law and provide a sense of the law's breadth and scope. Accordingly, the task before FDA is a large one—FDA must prepare more than 50 rules, guidance documents, reports and studies within strict time frames. This chapter outlines FDA's approach to implementing FSMA, the agency's initial accomplishments and some of the key issues that have emerged during the first year after enactment. We also discuss one of the key challenges to FDA's implementation efforts—funding.

### FDA's Approach to Implementation

FDA was supportive of FSMA's passage and was ready to hit the ground running once President Obama signed the law into enactment. In fact, FDA did a lot of work in anticipation of the new law, and in 2010 was working on produce safety standards, a preventive controls rule and new domestic inspection and import strategies. As a result, FDA was able to “embark on implementation with considerable momentum.”<sup>2</sup> Nonetheless, FDA recognized the broad scope of FSMA, and the number of mandates contained within it. Accordingly, from the outset FDA stated that it would prioritize its work.<sup>3</sup> And as discussed below, FDA has been committed to engaging stakeholders in the implementation process. Deputy Commissioner for Foods Mike Taylor stated, “we must not lose sight of how important consensus and coalition building were to FSMA becoming law.”<sup>4</sup> These two strategies of prioritization and stakeholder engagement are reflected throughout FDA's implementation efforts.

In terms of prioritization, the agency has acknowledged that it will be unable to meet all of the statutory deadlines in the act. Therefore, the agency has chosen to focus first on those provisions with the greatest public health benefit, such as preventive controls for packaged food and

fresh produce, inspections and compliance and the import provisions.<sup>5</sup> Prevention is a key theme in FSMA and FDA has stated that preventive controls “are the conceptual heart of it.”<sup>6</sup> A focus on prevention places the primary responsibility to make food safe on the food industry, with FDA’s role to set standards and ensure compliance with those standards.<sup>7</sup> We expect to continue to see FDA prioritize its work in the months and years ahead, particularly as it faces budgetary constraints.

While prioritizing its work, FDA also is committed to working closely with the different constituencies that brought about the law’s passage and are affected by it. FDA is working to “understand and respect the incredible diversity of operators across the food system.”<sup>8</sup> The agency has acknowledged that “one size does not fit all,” and has stated that this principle will guide its implementation efforts.<sup>9</sup> In addition, FDA’s implementation work reflects its desire to work in partnership with others—stakeholders, states and foreign governments. Deputy Commissioner for Foods Taylor has stated that partnerships are key because “neither FDA nor the food industry can achieve the goal of food safety in isolation from one another.”<sup>10</sup> FDA has undertaken an unprecedented amount of stakeholder outreach activities in the early months of implementation, seeking to build on the consensus that resulted in the law’s passage.

With these two principles guiding its efforts overall, in order to actually accomplish the numerous tasks before it, FDA implemented a matrix management system, combining FDA staff from across the regulatory, policy and scientific areas into cross-functional teams. FDA took this approach so that the teams would have specific obligations, the authority to make decisions and would have a streamlined clearance process. The agency created six implementation teams: Prevention Standards; Inspections & Compliance; Imports; Federal/State Integration; Fees; and Reports & Studies.

The Prevention Standards team is led by Don Kraemer (Acting Deputy Director, Center for Food Safety and Applied Nutrition) and oversees seven subteams addressing produce safety standards and guidance, preventive controls standards and guidance, safe food transport, food defense and contaminants. The Inspections & Compliance team is led by Barbara Cassens (Director, San Francisco District) and oversees seven subteams addressing mandatory recall and recall communications, administrative enforcement tools, registration, frequency of inspection, manner of inspection, tracing and Reportable Food Registry improvements. The Imports team is led by David Elder (Regional Operations Director, Office of Regulatory Affairs) and oversees seven subteams addressing importer verification and the voluntary qualified importer program (VQIP), import certification, accredited third-party certification, laboratory accreditation, international capacity building, comparability and prior notice. Joe Reardon (Acting Director, FDA Division of Federal-State Relations) is leading the Federal/State Integration team, which has three subteams:

operational partnership, training and capacity building. The Fees team is led by Bob Miller (Director, Office of Financial Operations) and Roxanne Schweitzer (Acting Associate Director, Office of Management, Center for Veterinary Medicine). Finally, the Reports & Studies team is led by David Dorsey (Deputy Commissioner for Policy, Planning and Budget).<sup>11</sup>

Also assisting in the FSMA implementation work is a team led by Sharon Natanblut (Director of Strategic Communications, Office of Foods), the Strategic Communications & Outreach team. This team works with the other six implementation teams. All of the teams are overseen by an Implementation Executive Committee, chaired by Deputy Commissioner for Foods Taylor. The Executive Committee also includes Mike Landa (Acting Director, Center for Food Safety and Applied Nutrition), Bernadette Dunham (Director, Center for Veterinary Medicine), Steve Solomon (Deputy Associate Commissioner for Regulatory Affairs, Office of Regulatory Affairs), Elizabeth Dickinson (Acting FDA Chief Counsel) and David Dorsey (Deputy Commissioner for Policy, Planning and Budget).

This implementation structure and FDA's two-pronged approach—prioritization and stakeholder engagement—have resulted in several accomplishments in the first year of the law.

## Initial Implementation Efforts

FDA quickly got to work after President Obama signed FSMA into law on January 4, 2011, immediately beginning preparations for its rulemakings. As discussed above, FDA has been committed to building on the consensus and coalition that resulted in the law's passage. As a result, the agency has engaged in an unprecedented amount of engagement with and outreach to stakeholders. As of October 2011, FDA had participated in more than 300 presentations and listening sessions around the country and abroad.<sup>12</sup>

In order to gain stakeholder input, FDA held a series of three day-long public meetings dedicated to FSMA's import, preventive controls, and inspection and compliance provisions. These meetings established FDA's public commitment to listen to stakeholders. The meetings also met FDA's obligations under Executive Order 13,563 to conduct pre-rulemaking activities to "seek the views of those who are likely to be affected" by a proposed rule.<sup>13</sup> In conjunction with each of these public meetings, FDA opened a docket for stakeholders to submit written comments on rulemakings related to these provisions.<sup>14</sup> FDA also opened a docket for guidance documents to support the preventive controls rulemaking.<sup>15</sup> Deputy Commissioner for Foods Taylor has stated that the agency found these meetings "enormously valuable" and the input received "is really informing our implementation of this law."<sup>16</sup>



The agency also engaged in a number of meetings with trade associations to discuss key implementation issues.<sup>17</sup> Several smaller meetings were held to pair FDA's key personnel involved with implementation with industry subject matter experts. These meetings allowed for a more detailed discussion about specific provisions in the agency's rulemaking. They also allowed issues that arose during the public meetings to be further discussed and provided FDA with the opportunity to ask industry for targeted input on certain aspects of implementation.

In addition, the agency has undertaken a significant outreach effort aimed at a variety of audiences. Mike Taylor has given numerous speeches on FSMA, as well as published an article on the new law in the *New England Journal of Medicine*.<sup>18</sup> FDA has developed a FSMA-dedicated website that is updated regularly with new developments. The agency also has created a list of Frequently Asked Questions regarding the new law, which continues to be updated with new information.<sup>19</sup> Using new media tools, FDA also has a FSMA blog<sup>20</sup> and has posted short videos on its website featuring FDA experts explaining key provisions in the act.<sup>21</sup>

Moreover, FDA has followed through on its commitment to prioritize its work, while at the same time meeting several of the numerous statutory deadlines in FSMA, as follows:

- **Recall Website.** Under FSMA, FDA was required to provide a consumer-friendly recall search engine within 90 days after the law went into effect.<sup>22</sup> The agency met this deadline and launched a consumer-friendly searchable database for recalls.<sup>23</sup> Prior to launching the database, FDA consulted with several stakeholder groups to gain their insights on how to most effectively and easily communicate recall information to consumers.
- **Interim Final Rules.** As required by FSMA,<sup>24</sup> in May 2011, FDA published interim final rules to implement the expanded prior notice requirement and the expanded administrative detention provision in the act, both originating with the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act).<sup>25</sup> These rules went into effect July 30, 2011.
- **Traceability Pilots.** In September, FDA selected the Institute of Food Technologists to conduct the traceability pilot projects.<sup>26</sup> FSMA specifies that FDA must initiate the pilot projects within nine months of enactment.<sup>27</sup>
- **Anti-Smuggling.** On July 3, 2011, FDA issued its strategy to better identify and prevent the entry of smuggled food into the United States.<sup>28</sup> FSMA required FDA and the Department of Homeland Security (DHS) to develop and implement this strategy within 180 days of the law's enactment.<sup>29</sup>

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