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Food Safety Issues for the 113th Congress

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Summary

Congress passed comprehensive food safety legislation in December 2010 (FDA Food Safety Modernization Act (FSMA), P.L. 111-353), representing the largest expansion and overhaul of U.S. food safety authorities since the 1930s. FSMA greatly expanded food safety oversight authority at the Food and Drug Administration (FDA), within the U.S. Department of Health and Human Services (HHS), but did not alter oversight authorities within other federal agencies responsible for food safety, such as the U.S. Department of Agriculture (USDA). Given challenges facing FDA in implementing this law and also a continued prevalence of food safety incidents, Congress continues to actively address concerns of the U.S. food safety system.

Numerous agencies share responsibility for regulating food safety; however, FSMA focused on FDA-regulated foods and amended FDA's existing structure and authorities, in particular the Federal Food, Drug, and Cosmetic Act (FFDCA; 21 U.S.C. §§301 et seq.). Among its many provisions, FSMA expanded FDA's authority to conduct a mandatory recall of contaminated food products, enhanced surveillance systems for foodborne illness outbreaks, established preventive controls at some food processing facilities and farms, enhanced FDA's traceability capacity within the nation's food distribution channels, increased the number of FDA inspections at domestic and foreign food facilities, and expanded FDA's authority and oversight of foreign companies that supply food imports to the United States. Since the law was signed in January 2011, FDA has been actively engaged in developing regulations to implement FSMA.

The 113th Congress will likely continue to monitor FDA's implementation of the law, and provide oversight over how some provisions are carried out and enforced, as well as FDA's coordination with other federal agencies, such as those in USDA and the Department of Homeland Security. Under FSMA, FDA is responsible for more than 50 regulations, guidelines, and studies; however, some FDA rules under FSMA have been substantially delayed and it is uncertain whether full implementation of some provisions in the law will meet their expected deadlines. Regulations were to have been proposed or, in some cases, finalized within one to two years of enactment (roughly January 2012 and January 2013). Given delays in the rulemaking process, the Center for Food Safety filed suit in federal court against FDA and the Office of Management and Budget (OMB), citing the government's failure to implement several food safety regulations required by FSMA. As of early 2014, FDA had proposed a majority of the regulations that constitute the food safety framework under FSMA, but there are continued delays in other rules, industry guidance, and reports as required under the law. FDA's decision to re-propose the two major rules affecting farmers—the Preventive Controls for Human Food (FSMA §103) and Produce Safety Standards (FSMA §105)—raises further questions about FDA's ability to meet its deadlines under FSMA.

Congress may also continue to consider changes to other food safety laws and policies that continue to be actively debated. Among these are food safety initiatives covering meat, poultry, and seafood products; legislation intended to curtail the non-medical use of antibiotics in animal feeds and to ban the use of certain plastic components commonly used in food containers; food labeling; stricter food safety enforcement mechanisms; and the use of plant and animal biotechnology. Several of these issues were actively debated leading up to the passage of FSMA. Several bills debated in previous Congresses were reintroduced in the 112th and 113th Congress. Some in Congress also might continue to advocate for additional policy reforms to existing FDA or USDA food safety laws to address other perceived concerns about the safety of the U.S. food supply. These include concerns about the adequacy of resources and regulatory tools to combat foodborne illness, and concerns about coordination and organization among federal agencies.

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The 113th Congress will likely continue to monitor FDA's implementation of the law, but might also continue to consider additional changes to other food safety laws and policies that have been actively debated in Congress. Ongoing budgetary constraints—both at the federal and at the state and local levels—raise questions for Congress about how to fully fund and implement policies that will protect public health and ensure the safety of domestic and imported foods.

Background

The combined efforts of the food industry and government regulatory agencies often are credited with making the U.S. food supply among the safest in the world. However, critics view this system as lacking the organization, regulatory tools, and resources to adequately combat foodborne illness. The Centers for Disease Control and Prevention (CDC) reports that each year about one in six Americans—a total of 48 million people—become sick from contaminated food.¹ Of these, an estimated 128,000 cases require hospitalization and 3,000 cases result in death. It is reported that foodborne illness is associated with an estimated economic burden of \$77.7 billion in the United States each year.²

Major food safety-related incidents have heightened public and media scrutiny of the U.S. food safety system, and magnified congressional interest in the issue. Since 2007, the Government Accountability Office (GAO) has placed food safety on its biennially published list of high-risk areas, among other areas needing the concerted attention of Congress and the Administration.³

Both the Obama and Bush Administrations addressed food safety concerns. In 2007, then President Bush released the *Food Protection Plan of 2007* and *Action Plan for Import Safety* to address changes in food sources, production, and consumption. In 2009, President Obama established a Food Safety Working Group (FSWG) of Cabinet Secretaries and senior officials to provide advice on how to upgrade U.S. food safety laws, foster coordination throughout government, and ensure that food safety laws are effective and enforced. In 2010, as part of the FSWG's annual progress report, the Administration announced that it had taken steps to reduce the prevalence of certain food risks and implemented new food safety standards, among other actions. The HHS released a draft of its plans regarding specific food safety goals, setting

¹ Centers for Disease Control and Prevention (CDC), "Estimates of Foodborne Illness in the United States," December 2010, <http://www.cdc.gov/foodborneburden/2011-foodborne-estimates.html>.

² Robert Scharff, "Economic Burden from Health Losses Due to Foodborne Illness in the United States," *Journal of Food Protection*, vol. 75, No. 1: 123-131. Uses the most updated annual foodborne illness estimates from CDC.

³ GAO, *High Risk Series: An Update* (GAO-13-283), February 2013.

percentage reduction goals for major food contaminants as well as targeted reductions in the number of cases each year by 2020.⁴

Following Congress's passage of FSMA in December 2010, FDA has been actively engaged in developing new regulations to implement the law. Under FSMA, FDA is responsible for more than 50 regulations, guidelines, and studies; however, some major provisions under FSMA have been substantially delayed and it is uncertain whether full implementation of some provisions in the law will meet their expected deadlines. Implementation of the law will depend on the availability of discretionary appropriations, and some have questioned whether additional funding should be made available in the current budgetary climate.

Food Safety Incidents

Each year, state health officials report data to CDC on hundreds of foodborne outbreaks.⁵ CDC reports that more than 1,000 foodborne outbreaks are investigated by local and state health departments each year.⁶ Overall, from available outbreak data, CDC reports that roughly one-half of all outbreaks involved meat, dairy, and egg products, while another roughly one-third involved leafy greens, vine vegetables, and fruits and nuts (**Figure 1**). In general, foods often associated with foodborne illnesses include raw foods of animal origin—meat, poultry, eggs, and seafood, and also unpasteurized (raw) milk—that can cause infections if undercooked, or through cross-contamination. Other foods associated with foodborne illness include shellfish eaten raw and also fresh produce, including unpasteurized juices.⁷

Some foodborne outbreaks affect multiple states, depending on how widely the food associated with the outbreak is distributed. CDC reports that nearly 70 multistate foodborne outbreaks occurred during the five-year period from 2004 through 2008, an increase from previous years (**Figure 2**), thus continuing to raise questions about the adequacy of the U.S. food system's safeguards for ensuring the safety of both domestically produced foods and imported foods.

Examples of foodborne outbreaks involving FDA-regulated foods include multi-state outbreaks in 2012 of *Salmonella* infections involving peanut butter and cantaloupe, and *E. coli* infections linked to raw clover sprouts; multi-state outbreaks in 2011 of listeriosis linked to cantaloupe; the 2010-2011 multi-state recall of *Salmonella*-contaminated sprouts; and a 2010 nationwide recall of more than 500 million eggs associated with increased cases of *Salmonella* infection, among other outbreaks.⁸

⁴ FDA, "Strategic Priorities 2011–2015: Responding to the Public Health Challenges of the 21st Century," Draft, September 29, 2010. Part of the broader Healthy People 2020 initiative at <http://www.healthypeople.gov/2020>.

⁵ A foodborne outbreak is when two or more people get the same illness from the same contaminated food or drink. See CDC, "Multistate Foodborne Outbreak Investigations" (<http://www.cdc.gov/foodsafety/outbreaks/>); and FDA, "Outbreak Investigations" (<http://www.fda.gov/food/recallsoutbreaksemergencies/outbreaks/ucm272351.htm>) and FDA, "Recalls, Market Withdrawals, & Safety Alerts" (<http://www.fda.gov/Safety/Recalls/default.htm>).

⁶ CDC, "Food Safety," <http://www.cdc.gov/foodsafety/facts.html>.

⁷ *Ibid.* Additional information on outbreaks associated with raw milk include A.J. Langer, et al., "Nonpasteurized Dairy Products, Disease Outbreaks, and State Laws—United States, 1993–2006," *Emerging Infectious Diseases*, Vol. 18, No. 3, March 2012, <http://wwwnc.cdc.gov/eid/article/18/3/pdfs/11-1370.pdf>.

⁸ FDA, "Outbreak Investigations," <http://www.fda.gov/food/recallsoutbreaksemergencies/outbreaks/ucm272351.htm>. See also CRS Report R40916, *Food Safety: Foodborne Illness and Selected Recalls of FDA-Regulated Foods*.

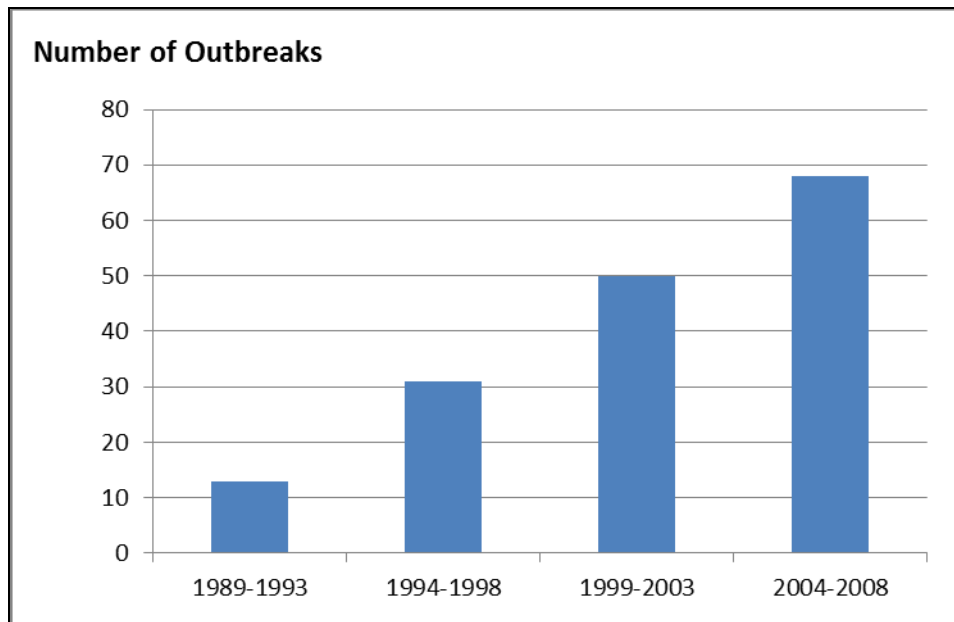
Figure 1. Causes of Illness in Foodborne Outbreaks, 2003-2008



Source: CDC, *CDC and Food Safety*, January 2011, http://www.cdc.gov/foodsafety/resources/CDCandFoodSafety_121410.pdf.

Notes: Based on causes of illnesses in 1,565 outbreaks of single food commodities, 2003-2008.

Figure 2. Multistate Foodborne Outbreaks, 1989-2008



Source: CDC, *CDC and Food Safety*, January 2011, http://www.cdc.gov/foodsafety/resources/CDCandFoodSafety_121410.pdf.

A multi-state outbreak of *Salmonella* infections that occurred in 2008-2009 was linked to an institutional brand of peanut butter and other peanut-based ingredients from a single company, resulting in a series of expanded recalls in 2009 involving thousands of peanut-containing products from more than 200 food companies. Other widespread illness outbreaks have been linked to the consumption of bagged fresh spinach grown in California contaminated with *E. coli* and to Mexican produce contaminated with *Salmonella*. There also have been large recalls of FSIS-regulated meat and poultry products due to findings of *E. coli*, *Listeria*, and other problems.⁹

CDC's Foodborne Outbreak Online Database (FOOD) provides access to limited descriptive summaries of national and state-level outbreak data by location of consumption and etiology (or cause of disease) in a web-based platform for searching the agency's Foodborne Disease Outbreak Surveillance System database.¹⁰

Foodborne Illness

CDC estimates that nearly 48 million people become sick from contaminated food each year. These estimates are for two major groups of foodborne illnesses:¹¹

- known foodborne pathogens (31 pathogens, many of them tracked by public health systems that track diseases and outbreaks); and
- “unspecified agents,” where insufficient data do not allow for the estimation of agent-specific burden.

Foodborne illnesses from known pathogens account for about one-fifth of CDC's estimate of the total number of foodborne illnesses per year and about 40% of the estimated number of illnesses resulting in either hospitalizations or death (**Table 1**). The remaining number of illnesses, hospitalizations, and deaths are attributable to foodborne illness from “unspecified agents.”

The top five pathogens contributing to foodborne illnesses annually are norovirus (58% of illnesses), *Salmonella*, nontyphoidal (11%), *Clostridium perfringens* (10%), *Campylobacter* spp. (9%), and *Staphylococcus aureus* (3%). The top five pathogens contributing to annual foodborne illnesses resulting in hospitalization are *Salmonella*, nontyphoidal (35% of illnesses), norovirus (26%), *Campylobacter* spp. (15%), *Toxoplasma gondii* (8%), and *E. coli* (STEC)¹² O157 (4%). The top five pathogens contributing to annual foodborne illnesses resulting in death are *Salmonella*, nontyphoidal (28% of deaths), *Toxoplasma gondii* (24%), *Listeria monocytogenes* (19%), norovirus (11%), and *Campylobacter* spp. (6%).¹³

⁹ FSIS, “FSIS Recalls,” http://www.fsis.usda.gov/FSIS_Recalls/index.asp. See also CRS Report RL34313, *The USDA's Authority to Recall Meat and Poultry Products*.

¹⁰ CDC, “Foodborne Outbreak Online Database (FOOD),” <http://wwwn.cdc.gov/foodborneoutbreaks/>.

¹¹ CDC, “Estimates of Foodborne Illness in the United States,” December 2010. See also CDC's fact sheet (http://www.cdc.gov/foodborneburden/PDFs/FACTSHEET_A_FINDINGS.pdf).

¹² Shiga toxin-producing *Escherichia coli* (STEC) is a type of enterohemorrhagic bacteria that can cause illness ranging from mild intestinal disease to severe kidney complications.

¹³ CDC, “Estimates of Foodborne Illness in the United States,” December 2010.

Table I. Number of Foodborne Illnesses, Hospitalizations, and Deaths

(United States, estimated annual)

Foodborne Agents	Estimated annual number of illnesses	%	Estimated annual number of hospitalizations		Estimated annual number of deaths	
			(90% credible interval) ^a	%	(90% credible interval) ^a	%
31 Known Pathogens	9.4 million (6.6–12.7 million)	20%	55,961 (39,534–75,741)	44%	1,351 (712–2,268)	44%
Unspecified Agents	38.4 million (19.8–61.2 million)	80%	71,878 (9,924–157,340)	56%	1,686 (369–3,338)	56%
Total	47.8 million (28.7–71.1 million)	100%	127,839 (62,529–215,562)	100%	3,037 (1,492–4,983)	100%

Source: CDC, “Estimates of Foodborne Illness in the United States,” December 2010, <http://www.cdc.gov/foodborneburden/2011-foodborne-estimates.html>; also http://www.cdc.gov/foodborneburden/PDFs/FACTSHEET_A_FINDINGS.pdf (Table I, Estimated annual number of domestically acquired, foodborne illnesses, hospitalizations, and deaths due to 31 pathogens and unspecified agents transmitted through food, United States).

- a. The credible interval (or Bayesian probability interval) refers to the point estimates obtained by CDC using posterior distributions to generate a posterior mean and upper and lower 5% limits for a 90% credible interval (such that the estimated posterior probability is that 90% of that population is between the interval). See E. Scallan, R. M. Hoekstra, F. J. Angulo, R. V. Tauxe, M. Widdowson, S. L. Roy, J. L. Jones, and P. M. Griffin, “Foodborne Illness Acquired in the United States—Major Pathogens,” *Emerging Infectious Diseases*, Vol. 17, No. 1, January 2011.

Other CDC reports indicate that there were 1,034 foodborne disease outbreaks in 2008.¹⁴ Norovirus was the most common disease, accounting for 49% of outbreaks and 46% of illnesses. *Salmonella* was the second-most common, accounting for 23% of outbreaks and 31% of illnesses. Beef, poultry, and finfish were the commodities associated with the largest number of foodborne outbreaks. Among most large multistate outbreaks, vine-stalk vegetables, fruits-nuts, and beef were the commodities with the most outbreak-associated illnesses.

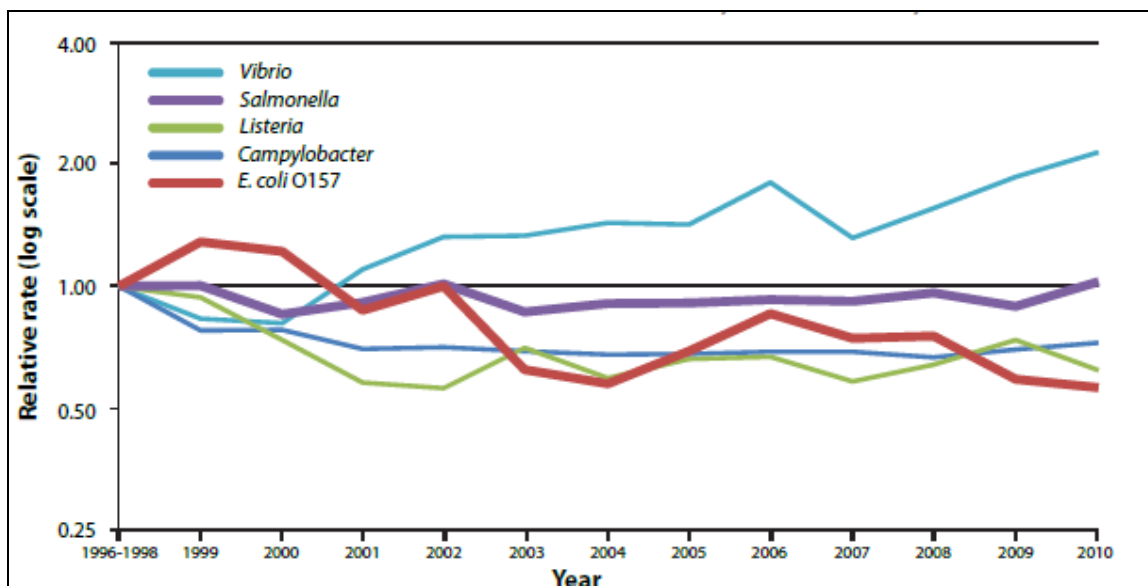
Trends in some foodborne illnesses show improvement for some pathogens, while infections caused by some pathogens have not declined or, in some cases, have increased. CDC reports that infections in 2010 caused by *Salmonella* infection had not declined compared to estimated rates in 1996-1998, while *Vibrio* infections¹⁵ increased sharply over the same period (**Figure 3**). However, CDC reports that progress has been made in reducing infections from six key foodborne pathogens, which are estimated to be more than 20% lower as a group compared to rates in 1996-1998. These include *Campylobacter* (27% decrease); *Listeria* (38% decrease); *E. coli* O157 (44% decrease); *Shigella* (57% decrease); and *Yersinia* (52% decrease).¹⁶

¹⁴ CDC, “Surveillance for Foodborne Disease Outbreaks—United States, 2008,” *Morbidity and Mortality Weekly Report* (MMWR), vol. 60, no. 35, September 9, 2011. These outbreaks resulted in about 23,152 cases of illness, 1,276 hospitalizations, and 22 deaths in 2008 (the most recent year for which data are available).

¹⁵ Caused by another leading disease-causing pathogen.

¹⁶ CDC, “Vital Signs: Incidence and Trends of Infection with Pathogens Transmitted Commonly Through Food—Foodborne Diseases Active Surveillance Network, 10 U.S. Sites, 1996–2010,” *Morbidity and Mortality Weekly Report* (MMWR), vol. 60, no. 22, June 10, 2011, pp. 749-755.

Figure 3. Relative Rates of Laboratory-Confirmed Infections, Selected Pathogens
Campylobacter, *E. coli* O157, *Listeria*, *Salmonella*, and *Vibrio*, compared with 1996-1998 rates, by year



Source: CDC, “Trends in Foodborne Illness, 1996–2010,” July 2011, http://www.cdc.gov/foodborneburden/PDFs/FACTSHEET_B_TRENDS.PDF. Data are from CDC’s Foodborne Diseases Active Surveillance Network (“FoodNet”), United States, 1996–2010. See also CDC, “Vital Signs: Incidence and Trends of Infection with Pathogens Transmitted Commonly Through Food—Foodborne Diseases Active Surveillance Network, 10 U.S. Sites, 1996–2010,” *Morbidity and Mortality Weekly Report* (MMWR), vol. 60, no. 22, June 10, 2011, pp. 749–755.

Notes: Data are preliminary, and from CDC’s Foodborne Diseases Active Surveillance Network (“FoodNet”).

Existing Food Safety Legal and Regulatory Landscape

Numerous federal, state, and local agencies share responsibilities for regulating the safety of the U.S. food supply. GAO has identified 15 federal agencies collectively administering at least 30 laws related to food safety.¹⁷ State and local food safety authorities collaborate with federal agencies for inspection and other food safety functions, and they regulate retail food establishments. This organizational complexity, coupled with trends in U.S. food markets—for example, increasing imports as a share of U.S. food consumption and increasing consumption of fresh, often unprocessed, foods—pose ongoing challenges to ensuring food safety.

Although numerous federal agencies have some responsibility, primary responsibility for food safety rests with the FDA and the USDA. FDA at the U.S. Department of Health and Human Services (HHS) is responsible for ensuring that all domestic and imported food products—except for most meats and poultry—are safe, nutritious, wholesome, and accurately labeled. FDA also has oversight of all seafood, fish, and shellfish products.¹⁸ USDA’s Food Safety and Inspection Service (FSIS) regulates most meat and poultry and some egg and fish products. The division of

¹⁷ GAO, *Food Safety Working Group Is a Positive First Step but Governmentwide Planning Is Needed to Address Fragmentation*, GAO-11-289, March 2011. Also see Institute of Medicine, National Research Council (IOM/NRC), *Enhancing Food Safety: The Role of the Food and Drug Administration*, 2010.

¹⁸ An exception is catfish. FSIS at USDA was authorized to inspect farmed catfish products under a 2008 farm bill provision (P.L. 110-246, §11016).

food safety responsibility between FDA and USDA is rooted in the early history of U.S. food regulation. (For more information, see CRS Report RS22600, *The Federal Food Safety System: A Primer*.)

In addition, the majority of both total federal funding and total staffing is with FSIS and FDA. FSIS's FY2012 budget was \$1.004 billion in appropriated funds plus another roughly \$160 million in industry-paid user fees annually.¹⁹ FDA's budget for foods was \$866 million, with another roughly \$17 million authorized user fees.²⁰ Thus, FSIS had about 57% of the two agencies' combined food safety budget, and FDA had the other approximately 43%. This discrepancy in funding exists although FSIS is responsible for between 10% and 20% of the U.S. food supply, while FDA is responsible for the remainder.²¹ Staffing levels also vary among the two agencies: FSIS staff number around 9,500 FTEs, while FDA staff working on food-related activities number about 3,800 FTEs (FY2012 estimates).

FDA Food Safety Modernization Act (P.L. 111-353)

Overview of Provisions

FSMA focused on FDA-regulated foods and amended FDA's existing structure and authorities, in particular the FFDCA (21 U.S.C. §§301 *et seq.*). FSMA does not directly address meat and poultry products under the jurisdiction of USDA. Among its many provisions, FSMA expanded FDA's authority to conduct a mandatory recall of contaminated food products; enhanced surveillance systems to investigate foodborne illness outbreaks; established new preventive controls and food safety plans at some food processing facilities and farms; enhanced FDA's traceability capacity within the nation's food distribution channels; increased inspection frequencies of high-risk food facilities (both domestic and foreign facilities); and expanded FDA's authority and oversight capabilities of foreign companies that supply food imports to the United States.

FDA has identified five key elements to FSMA:²²

- **Preventive controls**—FSMA provides FDA with a legislative mandate to require comprehensive, prevention-based controls across the food supply. As examples, the act requires mandatory preventive controls for food facilities and mandatory produce safety standards, and also gives FDA the authority to prevent intentional contamination.
- **Inspection and Compliance**—FSMA provides FDA with the ability to conduct oversight and ensure compliance with new requirements and respond when problems emerge. Examples include establishing a mandated inspection

¹⁹ USDA, "2013 Explanatory Notes, FSIS."

²⁰ HHS, "FY2013 FDA: Justification of Estimates for Appropriations Committees."

²¹ The 20% estimate is based on information reported by the Government Accountability Office (GAO) in "Revamping Oversight of Food Safety," prepared for the 2009 Congressional and Presidential Transition, and appear to represent proportions of total spending for food consumed at home. The 10% estimate is based on data from USDA's Economic Research Service (ERS) on U.S. per capita food consumption at <http://www.ers.usda.gov/data/foodconsumption/>.

²² See, for example, FDA, "Questions and Answers on the Food Safety Modernization Act," "The New FDA Food Safety Modernization Act (FSMA)," and "Background on the FDA Food Safety Modernization Act (FSMA)."

frequency (based on risk);²³ giving FDA access to industry records and food safety plans; and requiring certain testing be conducted by accredited laboratories.

- **Response**—FSMA provides FDA with the ability to respond to problems when they emerge. Examples include giving FDA mandatory recall authority for all food products; expanding FDA’s authority to administratively detain products that are in violation of the law; giving FDA the authority to suspend a facility’s registration effectively prohibiting the company from selling any products within the United States,²⁴ establishing pilot projects so FDA can enhance its product tracing capabilities; and requiring additional recordkeeping by facilities that “manufacture, process, pack or hold” foods designated as “high-risk.”
- **Imported Food Safety**—FSMA provides FDA with the ability to ensure that food imports meet U.S. food safety standards. Examples include requires importers to verify that their foreign suppliers have adequate preventive controls; establishing a third party verification system; requiring certification by a credible third party for high-risk foods as a condition for entry into the United States; establishing a voluntary qualified importer program for expedited review and entry from participating importers; and giving FDA the right to refuse entry into the United States of food from a foreign facility if FDA is denied access to the facility or the country where the facility is located.
- **Enhanced Partnerships**—FSMA provides FDA with the ability to improve training of state, local, territorial, and tribal food safety officials. Examples include requiring FDA to develop and implement strategies to enhance the food safety capacities of state and local agencies through multi-year grants, as well as strategies to enhance the capacities of foreign governments and their industries; and giving FDA the authority to rely on inspections of other federal, state, and local agencies in meeting its increased inspection mandate for domestic facilities.

FSMA authorized additional appropriations and staff for FDA’s future food safety activities. The Congressional Budget Office (CBO) estimated that implementing the newly enacted law could increase net federal spending subject to appropriations by \$1.4 billion over a five-year period (FY2011-FY2015).²⁵ FSMA authorizes an increase in FDA staff, reaching 5,000 in FY2014. (See “Funding FSMA Implementation”.)

For more detailed information, see CRS Report R40443, *The FDA Food Safety Modernization Act (P.L. 111-353)*.

²³ Specifically, all “high-risk” domestic facilities must be inspected within five years of enactment. High-risk facilities will be identified based on “known safety risks of the facilities” according to “known safety risks of the food manufactured, processed, packed, or held at the facility,... compliance history of a facility, including ... food recalls, outbreaks of foodborne illness, and violations of food safety standards” and “the rigor and effectiveness of the facility’s hazard analysis and risk-based preventive controls” among other factors stated in the law (P.L. 111-353, §201).

²⁴ If a facility’s food is found to have a “reasonable probability of causing serious adverse health consequences or death.” FDA exercised this authority for the first time in November 2012 when it suspended the registration of Sunland Inc., a peanut butter processor, because of concerns linking the plant to a *Salmonella* outbreak.

²⁵ CBO, Cost Estimate, “S. 510, Food Safety Modernization Act, as reported by the Senate Committee on Health, Education, Labor, and Pensions on December 18, 2009, incorporating a manager’s amendment released on August 12, 2010,” August 12, 2010.

Implementation Schedule

FSMA was signed into law on January 4, 2011. Under FSMA, FDA is responsible for more than 50 regulations, guidelines, and studies. However, FDA action on some major FSMA provisions—including rules specifying the requirements and conditions for establishing preventive controls in food facilities, food safety standards for produce growers, and requirements for food importers, among other provisions—have yet to be finalized, and most rules have been substantially delayed well beyond the implementation dates specified in the law. Regulations were to have been proposed or, in some cases, finalized within one to two years of enactment (roughly January 2012 and January 2013); other rules were to be submitted within 18 months of enactment (roughly mid-2012).

The **Appendix** documents the scheduled timeline for action on selected FSMA provisions, as specified in the law, and FDA-reported actions taken to date, based on available FDA press releases and publicly available progress reports. For detailed information about each of these provisions, see Appendix B in CRS Report R40443, *The FDA Food Safety Modernization Act (P.L. 111-353)*.

As of January 2014, FDA has not yet issued final rules and guidance for many of the regulations required under certain key sections of FSMA, and it remains unclear when key provisions of the law will be finalized. Several factors appear to have contributed to this delay in implementation. During 2013, FDA proposed a majority of the regulations that constitute the food safety framework under FSMA, but there are continued delays in other rules, industry guidance, and reports as required under the law. FDA's decision to re-propose the two major rules affecting farmers—the Preventive Controls for Human Food (FSMA §103) and Produce Safety Standards (FSMA §105)—raises further questions about FDA's ability to meet its deadlines under FSMA. Several factors appear to have contributed to this delay in implementation, as discussed below.

Delays in Publication of Proposed Rules

Although FDA has issued a series of proposed rules, publication of these rules often took place well after FSMA's mandated rulemaking schedule. Most of the law's key regulations were not proposed until 2013, with some proposals being delayed until later that same year. For example, proposed rules regarding Preventive Controls for Human Food (FSMA §103) and Produce Safety Standards (FSMA §105) were both released in January 2013; however, two other related rules regarding imported foods, Foreign Supplier Verification Program (FSMA §301) and Standards for Third-Party Auditors (FSMA §307), were not released until July 2013. Preventive Controls for Food for Animals (FSMA §103) was not released until October 2013. Press reports indicated that several proposed rules were held up, often for many months, by the Office of Management and Budget's (OMB) review process.²⁶ It was later reported that OMB had made changes to the proposed rules while in review.²⁷

²⁶ See, for example, D. ElBoghdady, "Food-safety rules in limbo at Office of Management and Budget," *Washington Post*, May 2, 2012; and M. Patoka, "Three Food Safety Rules Grow Moldy at OIRA as Import-related Outbreaks Continue," *Food Safety News*, June 26, 2013.

²⁷ See, for example, J. Murphy, "HHS documents reveal OMB edits of original FSMA preventive controls proposal," *Food Chemical News*, March 22, 2013; J. Murphy, "OMB removed mandatory onsite audits from FSVP proposal, internal documents show," *Food Chemical News*, October 25, 2013.

Extensions in Public Comment and Response Period

Some of the proposed rules were granted multiple extensions for public comment and review. In particular, the two proposed rules and related documents regarding Preventive Controls for Human Food (FSMA §103) and Produce Safety Standards (FSMA §105) released in January 2013 were granted a series of extensions, eventually closing on November 15, 2013. These extensions were requested by a wide range of stakeholders, given the complexity of the regulations as well as FDA's delayed release of other related FSMA rules that some groups argued needed to be considered together as a full regulatory package.

FDA's Decision to Re-propose Certain Key Provisions

Further delay is expected in FSMA's implementation following FDA's announcement that it plans to re-propose some key provisions of regulations affecting farmers in two separate rulemakings.²⁸ In the agency's December 2013 announcement, it acknowledged that "significant changes will be needed in key provisions of the two proposed rules affecting small and large farmers," namely the Preventive Controls for Human Food (FSMA §103) and Produce Safety Standards (FSMA §105). Provisions that FDA plans to change "include water quality standards and testing, standards for using raw manure and compost, certain provisions affecting mixed-use facilities, and procedures for withdrawing the qualified exemption for certain farms."²⁹ Some stakeholders expect further changes to other provisions in these proposed rules.³⁰

Congress has also tried to encourage FDA to consider rewriting these two proposed regulations. Several Members of Congress have submitted a series of letters to FDA requesting that the agency release a second set of proposed rules and solicit public comment before going final. A wide range of stakeholders have also expressed similar concerns and are supporting FDA's reexamination of some of its proposed regulations.³¹ Within Congress, two letters were sent to FDA on November 22, 2013, including a House-Senate letter from Senators Shaheen and Blunt and Representatives Courtney and Gibson, as well as a letter from members of the House Organic Caucus. A third letter was sent to FDA on November 13, 2013, by Senators Tester and Hagan expressing concerns about the proposed rules effects on small farms and facilities.³² Another letter was sent on November 15, 2013, from members from Vermont (Senators Leahy and Sanders, and Representative Welch), urging FDA to repropose these two rules.³³

²⁸ FDA, "Statement from FDA Deputy Commissioner for Foods and Veterinary Medicine, Michael Taylor, on Key Provisions of the Proposed FSMA Rules Affecting Farmers," December 19, 2013, <http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm379397.htm>.

²⁹ Ibid.

³⁰ See, for example, D. Flynn, "Letter From the Editor: Produce Growers Get Early Christmas Present," *Food Safety News*, December 22, 2013; and National Sustainable Agriculture Coalition, "Do I Operate a Facility?"

³¹ Public comments are in FDA's rulemaking docket (Docket FDA-2011-N-0920; Docket FDA-2011-N-0921). Also see comments posted by the National Association of State Departments of Agriculture (NASDA), <http://www.nasda.org/Policy/>; United Fresh Produce Association (UFP), <http://www.unitedfresh.org/>; and the National Sustainable Agriculture Coalition (NSAC), <http://sustainableagriculture.net/>.

³² D. Flynn, "Letter From the Editor: Produce Growers Get Early Christmas Present," *Food Safety News*, December 22, 2013. Online article contains links to these three Congressional letters.

³³ "Vermont Lawmakers Urge Rewrite of FSMA Rules," *Food Chemical News*, November 29, 2013.

Other congressional actions taken regarding FSMA include the addition of a provision in the 2013 farm bill that would require FDA to provide Congress with a scientific and economic analysis of FSMA, including an analysis of how the law affects farm businesses of all sizes, prior to implementing final regulations under the law.³⁴ The FY2014 Consolidated Appropriations Act (P.L. 113-76) also directs FDA to implement a “comprehensive training program” for federal and state inspectors and commends FDA for its decision to revise its proposed rules affecting farmers.³⁵ Additional discussion and description of other farm bill provisions related to food safety is provided in the section titled “Omnibus Farm Bill.”

Budgetary and Staff Resources

Limited resources and the availability of discretionary appropriations might also have affected FDA’s rollout and full implementation of FSMA.³⁶ Although the law authorized appropriations when it enacted FSMA, it did not provide the actual funding needed for FDA to perform these activities. When the law was being debated in Congress, CBO had estimated that implementing the law could increase net federal spending subject to appropriation by about \$1.4 billion over a five-year period (FY2011-FY2015).³⁷ The Administration’s budget has repeatedly requested additional user fees be implemented to cover some of these costs, which Congress has not approved. Increases in appropriated funding for FDA’s food program have not made up for the Administration’s additional requested funds, particularly given sequestration and across the board budgetary rescissions in recent years. Staff levels at FDA have also remained below levels mandated in FSMA, totaling an estimated 3,700 FDA staff working on food-related activities in FY2013.³⁸ Still, as part of its implementation of FSMA, the agency has conducted stakeholder outreach and hosted public meetings, and released web videos and other written materials and presentations.³⁹

Center for Food Safety Lawsuit

In August 2012, the Center for Food Safety filed suit in federal court against FDA and OMB, citing the government’s failure to implement seven food safety regulations required by FSMA (see text box).⁴⁰ The Center for Food Safety argues that, by not meeting statutory deadlines for

³⁴ H.R. 2642, Section 12321. For more information on the farm bill, see CRS Report R43076, *The 2013 Farm Bill: A Comparison of the Senate-Passed (S. 954) and House-Passed (H.R. 2642, H.R. 3102) Bills with Current Law*.

³⁵ House Explanatory Statement regarding the House Amendment to the Senate Amendment on H.R. 3547.

³⁶ See, for example, annual FDA Budget Explanatory Notes for Committee on Appropriations, various years, <http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/BudgetReports/default.htm>; also letter from Leslie Kux, FDA’s Assistant Commissioner for Policy, to several U.S. District Court judges regarding a food labeling policy, January 6, 2014.

³⁷ CBO, Cost Estimate, “S. 510, Food Safety Modernization Act, as reported by the Senate Committee on Health, Education, Labor, and Pensions on December 18, 2009, incorporating a manager’s amendment released on August 12, 2010,” August 12, 2010.

³⁸ FSMA, P.L. 111-353, Section 401. By fiscal year, staff level increases were authorized to a total of not fewer than 4,000 staff members (FY2011); 4,200 staff (FY2012); 4,600 staff (FY2013); and 5,000 staff (FY2014).

³⁹ For information, see FDA’s FSMA website, <http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm359450.htm>.

⁴⁰ Center for Food Safety, et al. v. Margaret E. Hamburg, M.D., et al., Case No. 12 CV 4529 (N.D. Cal. 2012), August 29, 2012.

rulemaking, FDA is breaking the law and needs to protect the public. FDA argues that careful development of complex food safety rules is more important than meeting statutory deadlines.⁴¹

FDA filed a motion to dismiss the complaint against the agency in November 2012,⁴² which was denied by the court in April 2013.⁴³ In June 2013 the following court-ordered deadlines were given:⁴⁴

- November 30, 2013 (publish all remaining proposed regulations);
- March 31, 2014 (close any comment period on these proposed regulations); and
- June 30, 2015 (finalize all regulations).

In July 2013, FDA filed a motion to reconsider, asking the court to extend the implementation timeline for two FSMA-required rules: Sanitary Transport of Food and Feed (FSMA §111) and Intentional Contamination (FSMA §106).⁴⁵ This motion was also denied in August 2013. However, the Center for Food Safety accepted a 60-day extension of the deadline for publication of the sanitary transport proposed rule (until January 31, 2014), provided that the comment period end-date not be extended beyond April 30, 2014, and that the final rule date remain June 30, 2015. The rule timeline for the intentional contamination proposal was not extended; although in November 2013 FDA was later granted a 20-day extension, until December 20, 2013, to publish the proposed rule on intentional contamination due to setbacks that were likely caused by the recent federal government shutdown in October 2013.⁴⁶ FDA was able to meet the deadline for the proposed intentional contamination rule and published the proposed sanitary transport rule in early February 2014. As part of its July submission, FDA said it was prepared to meet court-imposed deadlines for Preventive Controls for Human Food and Animal Food (FSMA §103); Produce Safety Standards (FSMA §105); Foreign Supplier Verification Program (FSMA §301); and Accreditation of Third Party Auditors (FSMA §307).⁴⁷ FDA proposals for each of these rules have been published.

On December 19, 2013, FDA announced it would re-propose some key provisions of regulations affecting farmers on the rule establishing preventive controls for human food and the rule establishing produce safety standards. FDA says it expects to issue a revised proposed rule by “early summer 2014” and that the agency will accept “additional comments only on those sections of the proposed rules that have been revised,” recognizing the “court order regarding the timelines for finalizing these rules.”⁴⁸

⁴¹ H. Bottemiller, “FDA Seeks to Dismiss Lawsuit Over Delay of Food Safety Rules,” *Food Safety News*, December 4, 2012.

⁴² FDA’s motion to dismiss is at <http://www.foodsafetynews.com/files/2012/12/FDA-motion-to-dismiss.pdf>.

⁴³ The original complaint and decision is at <http://www.centerforfoodsafety.org/issues/308/food-safety/legal-actions>.

⁴⁴ The order is available at http://www.centerforfoodsafety.org/files/fsma-remedy-order_52466.pdf.

⁴⁵ FDA’s motion to reconsider is at http://www.freeborn.com/assets/fda_motion_to_reconsider.pdf.

⁴⁶ The court order and extension is available at <http://www.centerforfoodsafety.org/issues/308/food-safety/legal-actions>.

⁴⁷ “FSMA Rule Promulgation Marches On, But Final Deadlines Remain Uncertain,” *Food Safety Magazine*, August 6, 2013.

⁴⁸ FDA, “Statement from FDA Deputy Commissioner for Foods and Veterinary Medicine, Michael Taylor, on Key Provisions of the Proposed FSMA Rules Affecting Farmers,” December 19, 2013.

Center for Food Safety Lawsuit Against FDA and OMB

In August 2012, the Center for Food Safety filed suit in federal court against FDA and OMB, citing the government's failure to implement seven food safety regulations required by FSMA:

- final regulations due July 4, 2012, to “establish science-based minimum standards for conducting a hazard analysis, documenting hazards, implementing preventive controls, and documenting the implementation of the preventive controls” (FSMA §103(a));
- notice of proposed rulemaking due October 4, 2011 (with final rule due nine months after close of public comment period), regarding activities that constitute on-farm manufacturing, processing, packing or holding of food (FSMA §103(c));
- notice of proposed rulemaking due January 4, 2012 (with final rule due nine months after close of public comment period), to establish science-based minimum standards for the safe production and harvesting of produce (FSMA §105(a)-(b));
- final regulations due July 4, 2012, regarding intentional adulteration (FSMA §106(b));
- regulations due July 4, 2012, to require shippers, carriers by motor vehicle or rail vehicle, receivers, and other persons engaged in the transportation of food to use sanitary transportation practices (FSMA §111);
- final regulations due January 4, 2012, regarding the supplier verification program for imported foods (FSMA §301(a)); and
- final regulations due July 4, 2012, regarding “model standards, including requirements for regulatory audit reports, and for each recognized accreditation body to ensure that third-party auditors and audit agents of such auditors meet such standards in order to qualify such third-party auditors as accredited third-party auditors” (FSMA §307).

In June 2013, FDA was ordered to meet the following deadlines:

- November 30, 2013 (publish all remaining proposed regulations);
- March 31, 2014 (close any comment period on these proposed regulations); and
- June 30, 2015 (finalize all regulations).

FDA was granted a 20-day extension for publishing the Intentional Contamination (FSMA §106(B)) regulations. The Center for Food Safety agreed to allow a 60-day extension on the deadline for publication of the Sanitary Transport of Food and Feed regulations (FSMA §111), until January 31, 2014), provided the comment period not be extended beyond April 30, 2014 and the final rule date remain June 30, 2015.

Source: Center for Food Safety, et al. v. Margaret E. Hamburg, M.D., et al., Case No. 12-cv-04529 PJH (N.D. Cal. 2012), November 30, 2012.

Key Issues for the 113th Congress

The 113th Congress will likely continue to provide oversight and scrutiny of food safety changes enacted under FSMA as they are developed, proposed, and implemented. In addition, the 113th Congress also may continue to consider changes to other food safety laws and policies that continue to be actively debated in Congress. Among these are food safety initiatives covering meat, poultry, and seafood products; legislation intended to curtail the non-medical use of antibiotics in animal feeds and to ban the use of certain plastic components commonly used in food containers; issues regarding food labeling; and the use of plant and animal biotechnology, as well as other issues.

FSMA Oversight and Implementation

FSMA is the largest expansion of FDA's food safety authorities since the 1930s. It includes provisions that expand the agency's authority to conduct a mandatory recall of contaminated food products; enhance surveillance systems to investigate foodborne illness outbreaks; establish and enforce new preventive controls and food safety plans at some food processing facilities and farms; enhance traceability capacity within the nation's food distribution channels; increase inspection frequencies of high-risk food facilities (both domestic and foreign facilities); and expand FDA's authority and oversight capabilities of foreign companies that supply food imports to the United States. FDA has been actively engaged in developing new regulations to implement FSMA.⁴⁹ Implementation of a number of provisions requires coordination with other federal agencies, including DHS, USDA, and EPA.

As discussed in the previous section, "Implementation Schedule," as of year-end 2013, although FDA proposed a majority of the regulations that constitute the food safety framework under FSMA, it remains unclear when key provisions of the law will be finalized and there are continued delays in other rules, industry guidance, and reports as required under the law. The **Appendix** documents the scheduled timeline for action on selected FSMA provisions, as specified in the law, and FDA-reported actions taken to date, based on available FDA press releases and publicly available progress reports.

Along with general oversight of FSMA's key provisions, some in Congress may actively follow FDA's implementation of certain other aspects of the law. For example, FSMA's risk-based approach requires FDA to identify "high-risk" facilities and designate high-risk foods as part of the law's directive for targeting food safety inspection resources (FSMA, §201 and §204). How FDA identifies and designates high-risk facilities and foods, and how the agency ultimately implements these provisions could have other far-reaching implications for some food growers and producers. In addition, FSMA excluded certain businesses from regulation as a way to mitigate the economic effects on small, organic, direct-to-market, and sustainable farming operations.⁵⁰ These provisions will exempt from federal regulation some small-sized farms and food processors that sell directly to consumers (FSMA, §§103 and 105). These exemptions require additional rulemaking by FDA to determine what constitutes a "small" and "very small" business under the new law. Some public health groups may remain vigilant of how these exemptions are implemented, particularly for growers and processors of certain perceived "high-risk" foods (to be determined by the HHS Secretary), although these operations would be subject to oversight by state and local authorities and their exemption can be withdrawn by the FDA in the event of a foodborne illness. Some agribusiness groups also remain opposed to these exemptions because of broader industry concerns about the need to preserve consumer confidence in the safety of all marketed produce; another industry concern is whether small foreign producers might also be exempt, if small U.S. producers are exempt (given prevailing U.S. equivalency standards).

⁴⁹ See, for example, FDA, "Implementation and Progress," <http://www.fda.gov/Food/FoodSafety/FSMA/ucm250568.htm> and FDA's FSMA "Progress Reports," <http://www.fda.gov/Food/FoodSafety/FSMA/ucm255893.htm>. FDA's one year progress report is at <http://www.fda.gov/Food/FoodSafety/FSMA/ucm285773.htm>.

⁵⁰ For more information, see CRS Report RL34612, *Food Safety on the Farm*.

Funding FSMA Implementation

Ongoing budgetary constraints have raised questions for Congress about how to fully fund and implement policies that will protect public health and ensure the safety of domestic and imported foods.⁵¹ Among the many provisions of FSMA is the expansion of FDA's authority to increase inspection of domestic and foreign food facilities, to increase surveillance of foodborne illness and outbreak response, to conduct mandatory recall of contaminated foods, and to enforce new requirements at food facilities and produce operations. FSMA states a "goal of not fewer than ... 5,000 staff members in fiscal year 2014" (FSMA, §401), an increase from estimated FDA field staff of about 3,400 FTEs (full-time equivalents) in 2011. CBO estimated that implementing the law could increase net federal spending subject to appropriation by about \$1.4 billion over a five-year period (FY2011-FY2015); collections from possible revenue and direct spending increases from new criminal penalties would be "insignificant, yielding a negligible net impact in each year."⁵² Given the current budgetary climate, funding to undertake many federal activities in FSMA is uncertain. Although the law authorized appropriations when it enacted FSMA, it did not provide the actual funding needed for FDA to perform these activities. These funding decisions are guided by the House and Senate Appropriations Committees, which annually fund FDA's activities in the Agriculture appropriations bill. FDA officials have indicated funding remains a concern and ongoing efforts to implement FSMA will likely need to rely on state regulators to help enforce some of the major rules under the law.⁵³

The Administration's FY2013 and FY2014 budget requests projected the need for additional funds for FDA, anticipating a total need of about \$1.1 billion, consisting of approximately \$0.9 billion in appropriations for FDA's food program and another more than \$0.2 billion in requested new user fees for the year.⁵⁴ Appropriated funding for FDA's food program in the FY2014 Consolidated Appropriations Act (P.L. 113-76) totaled \$882.8 million, along with another \$17 million in FSMA-mandated user fees.⁵⁵ Congressional appropriators did not approve the Administration's request to implement additional new user fees to fund FDA's food program. The requested establishment fee was not included in either the House or Senate bills. The majority of the Administration's proposed total fees, about \$220 million, would accrue through a proposed new "Food Establishment Registration Fee." Other proposed or expected fees in addition to appropriated funds in the Administration's budget request include food export certification user fees; food reinspection user fees; food recall user fees; and other user fees. FDA justified its requested increase based on the need to implement the various elements of FSMA.⁵⁶

⁵¹ See for example Robert Wood Johnson Foundation, *Ready or Not? Protecting the Public's Health from Diseases, Disasters, and Bioterrorism*, December 2012.

⁵² CBO, Cost Estimate, "S. 510, Food Safety Modernization Act, as reported by the Senate Committee on Health, Education, Labor, and Pensions on December 18, 2009, incorporating a manager's amendment released on August 12, 2010," August 12, 2010. Reflecting the August 2010 Senate amendment to S. 510.

⁵³ H. Bottenmiller, "Sweeping Food Safety Rules Raise More Concerns about FDA Funding," *Food Safety News*, January 8, 2013.

⁵⁴ Data from annual FDA Budget Explanatory Notes for Committee on Appropriations, various years, <http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/BudgetReports/default.htm>.

⁵⁵ For more information, see CRS Report RS22600, *The Federal Food Safety System: A Primer*.

⁵⁶ See, for example, HHS, "FY2013 FDA: Justification of Estimates for Appropriations Committees," page 30; "Hamburg Defends Request for Food Registration Fee Facing Lawmakers' Criticism," *InsideHealthPolicy.com*, February 29, 2012; and "Hamburg: Slow Going on FDA User Fees for Food Companies," *Hagstrom Report*, April 19, 2012.

The Administration's proposed establishment fee is opposed by most food industry groups; other groups are also concerned that the Administration's proposal relies too heavily on fees. Some public health groups, however, note the potential for raising additional resources to fund food safety efforts through user fee programs.⁵⁷ In President Obama's Statement of Administration Policy (SAP) regarding FY2013 appropriations, the Administration urged the House to adopt the new user fees proposed in the Administration's budget request to provide additional resources to support FDA's food safety mission.⁵⁸ The discrepancy between the Administration's request and the current congressional appropriations proposals has raised questions about how FDA will be able to implement food safety reforms authorized under FSMA, and also questions about how FDA and USDA will be able to invest in preventive efforts intended to address existing and emerging food safety threats.

Food Safety Regulations for Produce Growers

Under FSMA, FDA must develop mandatory food safety and traceability requirements affecting farmers, packers, and processors of both domestically produced and imported products. At the farm production level, these requirements would mostly affect produce growers. Most other types of food producers—such as meat, poultry and dairy farms; fisheries; and producers of raw, bulk grains—would not be subject to FSMA's farm-level requirements (§105(a)).

In January 2013, FDA proposed its produce rule.⁵⁹ Under FDA's proposed rule, covered activities include the "growing, harvesting, packing, or holding" of produce, where produce refers to "any fruit or vegetable (including specific mixes or categories of fruits and vegetables) grown for human consumption, and would include mushrooms, sprouts (irrespective of seed source), peanuts, tree nuts and herbs."⁶⁰ Not covered by the proposed rule are foods that are rarely consumed raw and foods that go to commercial processing, and foods produced for personal consumption, as well as certain foods identified as low risk. Produce that undergoes certain commercial processing, such as bagged salads and leafy greens, would be covered by FDA's concurrently proposed rule on preventive controls for human foods covering food facilities.⁶¹

FDA's proposal covers microbial contamination of produce only, and does not cover chemical, physical, or radiological contamination of produce. It proposes certain procedures, processes, and practices that FDA believes will minimize the risk of "serious adverse health consequences or death" and prevent the introduction of known or "reasonably foreseeable hazards" into produce.⁶² The rule addresses five identified routes of potential contamination: (1) agricultural water used for produce production; (2) biological soil amendments of animal origin, such as composted manure; (3) health and hygienic practices for farm personnel, including hand washing and maintaining adequate personal cleanliness; (4) domesticated and wild animal intrusions, which

⁵⁷ See, for example, Robert Wood Johnson Foundation, *Ready or Not? Protecting the Public's Health from Diseases, Disasters, and Bioterrorism*, December 2012.

⁵⁸ Executive Office of the President, "Statement of Administration Policy, H.R. 5973 – Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act, 2013," June 21, 2012.

⁵⁹ 78 *Federal Register* 3646, January 16, 2013. *Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption* (Docket Number: FDA-2011-N-0921).

⁶⁰ *Ibid.*

⁶¹ 78 *Federal Register* 3504, January 16, 2013. *Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food* (Docket Number: FDA-2011-N-0920).

⁶² 78 *Federal Register* 3646, January 16, 2013.

may introduce pathogens to produce production systems via animal feces; and (5) equipment and tools, buildings, and sanitation practices used for produce operations on farms. The rule proposes certain requirements for growing sprouts, including treating seed before sprouting and testing spent sprout irrigation water for pathogens, and monitoring the growing environment for *Listeria*. The proposal would require training for farm personnel who handle covered produce or food-contact surfaces, and also would require certain records to document that standards are being met.

FDA estimates that the proposed rule would cover an estimated 40,496 domestic farms and also 14,927 foreign farms. FDA estimates that the costs of the proposed rule could total about \$460 million annually for domestic farms and about \$170 million annually for foreign farms covered by the rule. The estimated cost of the proposed produce rule is less than FDA's estimate of \$1.04 billion in annual benefits under the rule.

The proposed rule provides flexibility in various ways. As specified in FSMA, it exempts an estimated 75,716 domestic farms from the proposed requirements, with the exception of certain labeling requirements (estimated to cost \$3.82 million annually). In addition, FDA would exempt another 34,433 farms with average annual sales of \$25,000 or less. The proposal's requirements would be implemented on a staggered compliance timetable, depending on farm size, giving more time to smaller farms. Under some circumstances, the proposal would allow for the establishment and use of an alternative approach to the requirements established in proposal, as well as allow for a state or foreign country to request a variance from one or more requirements.

Since the produce rule was proposed, FDA has extended the public comment period numerous times; it closed November 15, 2013. FDA has also conducted outreach and public meetings, and released web videos and written materials. In March 2013, FDA corrected technical errors to the proposed rule. In August 2013, FDA announced it would prepare an environmental impact statement (EIS) to evaluate the potential environmental effects of the proposed rule for produce safety. Also, in December 2013, FDA announced it plans to re-propose some key provisions of the produce rule, as well as the rule for Preventive Controls for Human Food (FSMA §103).⁶³ Provisions that FDA plans to change “include water quality standards and testing, standards for using raw manure and compost, certain provisions affecting mixed-use facilities, and procedures for withdrawing the qualified exemption for certain farms.”⁶⁴

In addition to FDA's rulemaking under FSMA affecting produce growers, USDA had also been considering a separate proposal for selected produce growers to develop and implement USDA-administered requirements, reflecting FDA- and USDA-recommended food safety practices for leafy greens. This proposal was published in April 2011 by USDA's Agricultural Marketing Service (AMS) as part of its “National Marketing Agreement Regulating Leafy Green Vegetables.”⁶⁵ This proposed rule covers the handling of fresh leafy green vegetables—spinach, lettuce, cabbage—only. The AMS proposal has been under consideration at USDA for the past few years and reflects an industry-led effort to establish a voluntary program requiring compliance of its signatories (marketing agreement), including importers, in meeting certain commercial food quality and safety requirements. Following the enactment of FSMA, it was

⁶³ FDA, “Statement from FDA Deputy Commissioner for Foods and Veterinary Medicine, Michael Taylor, on Key Provisions of the Proposed FSMA Rules Affecting Farmers,” December 19, 2013, <http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm379397.htm>.

⁶⁴ *Ibid.*

⁶⁵ 76 *Federal Register* 24292, April 29, 2011.

unclear how USDA's proposed voluntary efforts for leafy greens will interact with FDA's rulemaking process to develop mandatory safety standards for a wider range of fruits and vegetables subject to FSMA. In December 2013, AMS announced it has terminating the rulemaking proceeding to establish a marketing agreement for leafy green vegetables, in part because FDA had published and was moving forward on its proposed produce rule.⁶⁶

Meat and Poultry Inspection

FSMA focused on FDA-regulated foods and did not directly address foods under the jurisdiction of USDA. USDA's FSIS regulates most meat and poultry and some egg products. Some Members of Congress have long claimed that once FDA's food safety laws were amended and updated, it would be expected that Congress would next turn to amending laws and regulations governing USDA's meat and poultry products.⁶⁷ Food safety incidents and concerns regarding USDA-regulated meat and poultry products are similarly well-documented. In addition, a series of bills were introduced and debated in the 111th Congress regarding the safety of meat and poultry products, and several bills were re-introduced in the 112th Congress (for example, S. 1529 and H.R. 1487) and 113th Congress (S. 1502).

USDA's proposal to modernize its poultry inspection system has also been debated in the 113th Congress. The proposed system would be an expansion of the FSIS HACCP-Based Inspections Models Project (HIMP) if implemented.⁶⁸ The new system would reduce the number of online FSIS carcass inspectors, rely on poultry plant personnel to sort carcasses, and allow for faster line speeds. FSIS inspectors would focus on pathogen reduction and offline food safety inspection activities. A reported 20 broiler and 5 young turkey slaughter plants participate in HIMP. USDA's evaluation of HIMP has shown improved safety and consumer protection in the current HIMP plants.⁶⁹ Some food safety advocates have questioned the advisability of adopting the proposed system.⁷⁰ Other food safety issues regarding meat and poultry products are the safety of the meat and poultry being supplied to school feeding programs; FSIS protocols for handling food recalls and related enforcement issues; improved meat traceability capabilities and animal identification systems; FSIS budgetary and staffing constraints; animal diseases and other related sanitary issues; and humane slaughter and animal welfare concerns, and the continued implementation of state meat inspection rules.⁷¹ In May 2013, USDA's Office of the Inspector General released a report critical of USDA's existing enforcement policies, including those under HIMP.⁷² In August 2013, GAO released a study recommending that USDA collect and analyze information to determine if the agency's young hog pilot project is meeting its purpose, and to clearly disclose to the public limitations in the information used for the proposed rule to modernize poultry slaughter inspections.⁷³ USDA is expected to report its findings on the proposal in 2014.

⁶⁶ 78 *Federal Register* 73111, December 5, 2013.

⁶⁷ See, for example, Statement by Representative Rosa DeLauro, *Congressional Record*, December 21, 2010, p. H8887.

⁶⁸ HIMP began as a pilot program in 1999. USDA published a proposed rule in 2012 (77 *Federal Register* 4408, January 27, 2012. Docket: FSIS-2011-0012).

⁶⁹ FSIS, "Modernization of Poultry Slaughter Inspection," 77 *Federal Register* 4414, January 27, 2012.

⁷⁰ Helena Bottemiller, "Debate Heats Up Over Poultry Inspection Proposal," *Food Safety News*, April 9, 2012.

⁷¹ For more information, see CRS Report RL32922, *Meat and Poultry Inspection: Background and Selected Issues*, or contact CRS analyst Joel L. Greene (7-9877).

⁷² Food Safety and Inspection Service—Inspection and Enforcement Activities at Swine Slaughter plants, Audit Report 24601-0001-41, May 2013.

⁷³ GAO, *More Disclosure and Data Needed to Clarify Impact of Changes to Poultry and Hog Inspections*, GAO-13- (continued...)

Antibiotic Use in Animal Agriculture

Public health experts have expressed concern about growing resistance of infectious diseases to antibiotics, and about patients whose infections were difficult or impossible to treat as a result. Antibiotic resistance has been linked to a number of causes, including the overuse of antibiotics by medical professionals, and the use of antibiotics for non-medical purposes in food animals. Antibiotics are added to feed for some types of food-producing animals not only to treat and prevent diseases, but also to improve growth and efficient use of feed rations. Some public health advocates argue that non-medical uses in food animals should be limited to drugs that are not useful in human medicine. Others oppose this approach, arguing that animal production may not be commercially viable without the drugs' routine use, and that the linkage between such use and antimicrobial resistance in humans lacks a strong scientific basis. In the past several Congresses, bills have been introduced that would curtail the non-medical use of antibiotics in animal feeds, including the Preservation of Antibiotics for Medical Treatment Act (PAMTA) introduced in both the House and Senate. These bills were offered again in the 112th Congress (H.R. 965; S. 1211) and in the 113th Congress (H.R. 1150; S. 1256).

Seafood and Fisheries Products

Many food safety changes enacted in FSMA did not specifically address seafood and fisheries products.⁷⁴ Prior to FSMA, domestic and imported fish and shellfish were already regulated under a system of risk prevention controls known as HACCP (for "Hazard Analysis and Critical Control Points"). However, FSMA did include some provisions affecting domestic and imported seafood products. These include interagency agreements to improve seafood safety by examining and testing seafood, coordinating inspections, standardizing data, modifying existing processes, sharing enforcement and compliance information, and conducting joint training and outreach (FSMA, §201); requirements for guidance related to post harvest processing of raw oysters (FSMA, §114); and inspections of foreign processing facilities by the Secretary of Commerce to assess practices and processes used in connection with seafood production (FSMA, §306). In addition, a number of issues related to seafood continue to be debated in Congress. These include further strengthening of federal coordination among programs concerned with seafood safety, preventing seafood fraud, using third parties to certify the safety of imported seafood, and developing a system to trace domestic and imported seafood from producer to consumer.

Omnibus Farm Bill

Although many of the food safety reforms enacted under FSMA were focused on FDA-regulated foods and programs, the law included provisions that involve coordination with USDA and may have implications for some farm bill programs. Possible farm bill programs that could be affected include provisions within the research and the horticulture titles of the 2008 bill. For example, FSMA requires FDA to coordinate with the extension activities of USDA's National Institute of Food and Agriculture (NIFA) in advising producers and small processors of food safety

(...continued)

775, August 22, 2013.

⁷⁴ For more information see CRS Report RS22797, *Seafood Safety: Background and Issues*, or contact CRS analyst Harold F. Upton (7-2264).

requirements through competitive training and technical assistance grants (FSMA, §209). FSMA also created the “National Food Safety Training, Education, Extension, Outreach and Technical Assistance Program,” whereby the NIFA will award competitive grants to carry out the extension activities under the law. Funding for these programs is authorized to be appropriated through FY2015 (FSMA, §209). The next farm bill could contain provisions regarding safety standards for produce growers (FSMA, §105), as well as updated requirements that growers and food facilities have food safety plans. These programs and other programs might be considered in the context of future farm bills.

The Federal Agriculture Reform and Risk Management Act of 2013 (H.R. 2642) seeks to reauthorize the farm bill that was last reauthorized in 2008 (Food, Conservation, and Energy Act of 2008, P.L. 110-246).⁷⁵ The final conference agreement contains a number of provisions that address food safety. First, it requires FDA, when publishing its final rule “Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption” (FSMA §105) to publish an analysis of the scientific information used to promulgate the final rule, as well as an economic impact analysis of the rule focusing on a variety of business sizes, and small and mid-sized value-added food processors. It also requires the U.S. Comptroller General submit a report to certain House and Senate congressional committees within one year after FDA promulgates the final rule, and further requires an updated report to the committees within one year after that report.⁷⁶

Second, the final conference agreement establishes training coordination for food and agriculture protection as a “high-priority” research and extension activity within USDA, and provides for competitive grants to establish a “Comprehensive Food Safety Training Network.” Eligible recipients would include nonprofit institutions that provide food safety protection training, and training centers in institutions of higher education. It further authorizes \$20 million in appropriations annually (FY2014-FY2018) to remain available until expended.⁷⁷ Similarly, the FY2014 Consolidated Appropriations Act (P.L. 113-76) includes the acknowledgment that a “critical issue facing FSMA implementation is proper training of federal and state inspection personnel,” along with the directive that FDA is “expected to implement a comprehensive training program about what the regulations require, the conduct of inspections, and the type of observations that are appropriate to include on FDA Form 483.”⁷⁸

Third, the final conference agreement directs the Federal Crop Insurance Corporation (FCIC) to conduct a “food safety insurance” study (to be submitted to Congress within one year of enactment) to determine whether policies that provide coverage for specialty crops from food safety and contamination issues benefit producers. The study shall evaluate insurance policies and plans that provide protection for production or revenue impacted by “food safety concerns including, at a minimum, government, retail, or national consumer group announcements of a health advisory, removal, or recall related to a contamination concern.”⁷⁹ Finally, the final

⁷⁵ For more information about the farm bill, see CRS Report RS22131, *What Is the Farm Bill?* and CRS Report R43076, *The 2013 Farm Bill: A Comparison of the Senate-Passed (S. 954) and House-Passed (H.R. 2642, H.R. 3102) Bills with Current Law.*

⁷⁶ H.R. 2642, §12321.

⁷⁷ H.R. 2642, §7209(f).

⁷⁸ House Explanatory Statement regarding the House Amendment to the Senate Amendment on H.R. 3547. FDA Form 483 notifies the company’s management of objectionable conditions, and is presented at the conclusion of an inspection and discussed with a company’s management (<http://www.fda.gov/ICECI/EnforcementActions/ucm256377.htm>).

⁷⁹ H.R. 2642, §11022(a)(23).

conference agreement requires USDA to finalize regulations for food safety inspections of catfish no later than 60 days after the date of enactment of the law.⁸⁰ It also requires USDA to enter into a memorandum of understanding with FDA to improve interagency cooperation on food safety and fraud prevention, and to maximize available resources.⁸¹

Another provision that was in the House-passed version of the farm bill but not included in the final agreement would have prohibited any state or local government from “setting standards or conditions on the production or manufacture of agricultural products,” including food safety requirements, among other types of standards, that might “prevent interstate sales” of the agricultural products.⁸²

Imported Foods

A steady increase in food imports, a result of globalization and consumer desire for a wider variety of foods year-round, has generated growing concerns about whether current federal programs sufficiently ensure the safety of these imports.⁸³ In FY2011, FDA physically examined (conducted field exams or analyzed samples) about 243,000 food and feed import lines, or about 2% of the total number of food import lines imported during the year.⁸⁴ In recent years, FDA has issued import alerts on a range of imported foods, including pet food ingredients, farmed seafood, and dairy products and ingredients, among other foods.⁸⁵

FSMA included several provisions on food imports (Title III) placing tighter controls over imports, setting minimum requirements for entry, requiring certification of imported foods, and raising importer accountability. FSMA creates several new programs and requirements, including a program for expedited entry and capacity building in foreign countries. The requirements will place more responsibility on U.S. trading partners, and some claim that FSMA import requirements could influence food safety efforts worldwide once implemented.⁸⁶

Since early 2011, FDA has hosted a series of public meetings to provide foreign suppliers and other interested parties with an opportunity to participate and comment prior to the release of the proposal of the rules required under FSMA.⁸⁷ FDA has issued a series of proposed regulations to address FSMA’s import provisions. In July 2013, FDA released two primary rules—namely, the

⁸⁰ Authorized in section 11016(b)(1) of the 2008 farm bill (P.L. 110-246).

⁸¹ H.R. 2642, §12106.

⁸² H.R. 2642, section 12312.

⁸³ GAO, *Food Safety: Agencies Need to Address Gaps in Enforcement and Collaboration to Enhance Safety of Imported Food*, GAO-09-873, September 15, 2009; GAO, *Food Safety: FDA Could Strengthen Oversight of Imported Food by Improving Enforcement and Seeking Additional Authorities*, GAO-10-699T, May 6, 2010. See also Center for Science in the Public Interest, “Building a Modern Food Safety System for FDA Regulated Foods,” May 2009.

⁸⁴ FDA, “2012 Annual Report on Food Facilities, Food Imports, and FDA Foreign Offices,” <http://www.fda.gov/Food/FoodSafety/FSMA/ucm315486.htm#>. The total number of food import lines was 10,439,236 in FY2011. Among the cited reasons for this low incidence of inspections were limited and declining resources, including too few inspectors to cover the more than 360 U.S. ports of entry despite ever-increasing import volumes.

⁸⁵ FDA’s import alert database is searchable by country and industry, and can be accessed at <http://www.fda.gov/forindustry/importprogram/importalerts/default.htm>.

⁸⁶ See, for example, C. Smith DeWaal, “FSMA: Import Rules May Foster Global Food Safety,” *Food Safety News*, February 14, 2011.

⁸⁷ For more information, see FDA, “Progress Reports,” <http://www.fda.gov/Food/FoodSafety/FSMA/ucm255893.htm>.

“Foreign Supplier Verification Program” (§301) and a program establishing a certification system or verification systems involving so-called third parties (§307). In May 2013, FDA issued final regulations regarding prior notice of imported food shipments (§304). Also, in January 2013, FDA released two major proposed rules under FSMA that address some aspects of the food safety requirements for food importers. These proposed rules would establish preventive controls for (human) food facilities (FSMA §103) and new food safety requirements for produce growers (FSMA §105) affecting farmers, packers, and processors of both domestically produced and imported products. See the table in the **Appendix** for more information.

FDA has entered discussions with several foreign countries to facilitate inspection of foreign facilities (§306).⁸⁸ Also, in early 2013, FDA released its plans for international food safety capacity-building and its report identifying programs and practices intended to promote the safety of the U.S. food supply. Some FSMA provisions have been largely addressed, including one for developing a strategy for addressing smuggled foods (§309) and another reporting on FDA foreign offices (§308). Other FSMA provisions have not yet been fully addressed, including FDA’s plans for its “Voluntary Qualified Importer Program” (§302) and other FSMA import provisions authorize FDA to require food imports to be accompanied by certification (§303).

Criminal Penalties and Enforcement

FSMA did not substantially alter the criminal penalties provisions within existing FDA laws. However, such provisions were actively considered as part of the broader food safety debate. For example, the House-passed food safety bill (H.R. 2749, 111th Congress) would have amended the penalties provisions of FFDCA to provide for fines and a maximum prison sentence, if any person knowingly engaged in certain prohibited acts with respect to food that is misbranded or adulterated. A similar provision was considered in the Senate, introduced by Senator Patrick Leahy (Food Safety Accountability Act of 2010, S. 3767), but was not included in its version of the food safety bill and not enacted as part of FSMA. Although these provisions were ultimately not adopted in the enacted law, some Members of Congress are concerned about the need to modify existing laws to institute stricter criminal fines and penalties as part of the U.S. food safety system. In the 112th Congress, such legislation was reintroduced and passed in the Senate (S. 216). During the farm bill debate in the 112th Congress, Senator Leahy proposed an amendment that would have increased criminal penalties for those who knowingly violate food safety laws, but it was not included in Senate-passed farm bill (S. 3240). Such provisions were not considered in the farm bill debated in the 113th Congress.

Bisphenol A (BPA)

FSMA did not alter FDA’s existing requirements regarding bisphenol A (BPA), a component of certain plastics that is commonly used in food containers, such as plastic bottles or metal can liners.⁸⁹ Food containers made with BPA are regulated by the FDA. BPA exposure has been linked to certain developmental problems in animals, and proposals to reduce or eliminate the amount of the chemical in food containers were actively considered as part of the FSMA food safety debate. For example, the House-passed food safety bill would have required FDA to

⁸⁸ FDA’s website, “Memoranda of Understanding and Other Cooperative Arrangements,” <http://www.fda.gov/InternationalPrograms/Agreements/MemorandaofUnderstanding/default.htm>.

⁸⁹ See CRS Report RS22869, *Bisphenol A (BPA) in Plastics and Possible Human Health Effects*.

determine whether there was “a reasonable certainty of no harm for infants, young children, pregnant women, and adults” for approved uses of polycarbonate plastic and epoxy resin made with BPA in food and beverage containers, among other provisions. A similar provision was debated as part of the Senate version of the bill, and it was thought by some to be the reason that earlier Senate passage of the food safety legislation was delayed.⁹⁰ The Senate provision introduced by Senator Dianne Feinstein, Ban Poisonous Additives Act of 2009 (S. 593, 111th Congress), would have banned BPA in all FDA-regulated food containers. This proposal was reintroduced in the 112th Congress (S. 136; H.R. 432) and in the 113th Congress (H.R. 2248). Also, in the 113th Congress, Senator Feinstein introduced another proposal, the BPA in Food Packaging Right to Know Act (S. 1124).

In March 2012, FDA rejected a citizen petition seeking a ban on BPA in food containers.⁹¹ In June 2012, Representative Edward J. Markey filed a petition proposing that FDA’s food additive regulations be amended to no longer allow for use of BPA-based epoxy resins as coatings in packaging for infant formula; FDA is evaluating this petition and Congress will likely continue to monitor the situation.⁹²

Dietary Supplements

FSMA provisions apply to most foods, including dietary supplements.⁹³ FSMA includes some provisions specifically affecting supplements. One provision requires FDA to notify the Drug Enforcement Administration (DEA) if, when reviewing the safety of a new dietary ingredient, the agency determines the information to be inadequate because the ingredient contains an anabolic steroid or an analog of one. Following notification, DEA can take action on the dietary ingredient as a controlled substance. FSMA’s mandatory recall authority also covers dietary supplements since it applies to all “article[s] of food” except infant formula. Another FSMA provision required FDA to publish guidelines to clarify the information manufacturers must provide when notifying the agency of the use of a “new dietary ingredient” (NDI) in a supplement. The guidelines, published in July 2011,⁹⁴ have generated controversy, with some manufacturers claiming them to be burdensome and not in keeping with the Dietary Supplement Health and Education Act (DSHEA). In late 2011, Senators Orrin Hatch and Tom Harkin asked FDA to withdraw its draft NDI guidance, but this request was reportedly rejected by FDA.⁹⁵

An issue unrelated to FSMA involves concerns regarding energy drinks, which can be marketed as a beverage or as a dietary supplement. Senators Richard Durbin and Richard Blumenthal have

⁹⁰ See, for example, Julian Pecquet, “Democrats quarrel over food safety legislation,” *The Hill*, July 19, 2010.

⁹¹ Natural Resources Defense Council (NRDC) press release, “FDA Rejects NRDC Call to Eliminate BPA from Food Packaging,” March 30, 2012. See also, FDA’s website, “Bisphenol A (BPA),” <http://www.fda.gov/food/foodingredientspackaging/ucm166145.htm#petition>.

⁹² 77 *Federal Register* 137: 41953-41954, July 17, 2012. See also FDA’s website, “Bisphenol A (BPA): Use in Food Contact Application,” <http://www.fda.gov/newsevents/publichealthfocus/ucm064437.htm>.

⁹³ Section 201(ff) of the FDCA (21 U.S.C. §321(ff)) states dietary supplements are deemed to be foods, aside from a few exceptions. For more information, see CRS Report R43062, *Regulation of Dietary Supplements*.

⁹⁴ See FDA, “Draft Guidance for Industry: Dietary Supplements: New Dietary Ingredient Notifications and Related Issues,” July 2011. For more information, see FDA, <http://www.fda.gov/Food/DietarySupplements/ucm109764.htm>.

⁹⁵ Letter to Margaret Hamburg from Senators Orrin Hatch and Tom Harkin, December 22, 2011. Also see press release from the Alliance for Natural Health USA, “FDA Says No to the Senators who Drafted DSHEA,” February 7, 2012.

asked FDA to review possible health concerns and reports of deaths linked to energy drinks.⁹⁶ In January 2014, the Institute of Medicine (IOM) published a summary report of the August 2013 workshop on caffeine in food and dietary supplements, which was requested by FDA. The report presents recommendations and opinions of individual participants, but does not reflect the consensus of the IOM, nor is it intended to constitute a comprehensive review of the subject.⁹⁷

Pesticide Residues

The Environmental Protection Agency (EPA) is responsible for regulating pesticide use on food and determining whether and under what conditions the proposed pesticide use would present an unreasonable risk to human health or the environment. In addition, when Congress enacted the Food Quality Protection Act of 1996 (FQPA), it established a new standard of safety for pesticide residues on food. Maximum pesticide residue levels (known as “tolerances”) must be set by EPA to ensure with “a reasonable certainty” that “no harm” will come to children as a result of pesticide exposure.⁹⁸ EPA regulates the labeling, sale, and use of pesticides on domestically produced and imported food toward that safety goal. FDA is responsible for ensuring that tolerance levels for food are not exceeded. Based on the data submitted by pesticide manufacturers when they apply to register a pesticide active ingredient, pesticide product, or a new use of a registered pesticide under FIFRA (§3), EPA determines whether and under what conditions the proposed pesticide use would present an unreasonable risk to human health or the environment. If the pesticide is proposed for use on a food crop, EPA also determines whether a “safe” level of pesticide residue, called a “tolerance,” can be established under the FFDC. Congress oversees EPA implementation of the FQPA and often questions EPA’s statutory authority and regulatory decisions regarding restrictions (or lack thereof) for popular pesticides. In addition, legislation has also been introduced to improve scrutiny of endocrine-disrupting chemicals, which are usually pesticides.⁹⁹

Agricultural Biotechnology

Opinions differ on whether or not agricultural biotechnology should be considered a food safety issue.¹⁰⁰ Genetically engineered (GE, sometimes called genetically modified, or GM) crop varieties first became commercially available in the mid-1990s.¹⁰¹ In recent years, the introduction and proposed deregulation of several new GE crops (e.g., alfalfa, sugar beets), and

⁹⁶ R. Cox, “Durbin, Blumenthal ask FDA to Review Energy Drinks Quickly,” *The Hill*, November 27, 2012.

⁹⁷ IOM, *Caffeine in Food and Dietary Supplements: Examining Safety: Workshop Summary* (National Academies Press).

⁹⁸ For more information see CRS Report RL31921, *Pesticide Law: A Summary of the Statutes*.

⁹⁹ See CRS Report R40177, *Environmental Exposure to Endocrine Disruptors: What Are the Human Health Risks?*

¹⁰⁰ Biotechnology issues have been debated in the World Trade Organization (WTO) under two global trade agreements addressing food safety and animal and plant health and safety, and with product standards in general: (1) the Agreement on Sanitary and Phytosanitary (SPS) Measures, and (2) the Agreement on Technical Barriers to Trade (TBT). The SPS Agreement is designed to protect animals and plants from diseases and pests, and to protect humans from animal- and plant-borne diseases and pests, and food-borne risks. The TBT Agreement covers technical regulations, voluntary standards and procedures relating to health, sanitary, animal welfare, and environmental regulations. See CRS Report RL33472, *Sanitary and Phytosanitary (SPS) Concerns in Agricultural Trade*.

¹⁰¹ CRS Report RL32809, *Agricultural Biotechnology: Background, Regulation, and Policy Issues*, and CRS Report RL33334, *Biotechnology in Animal Agriculture: Status and Current Issues*, or contact CRS analyst Tadlock Cowan (7-7600).

subsequent legal challenges to that introduction and deregulation, have raised important issues regarding the effectiveness of the USDA's deregulatory review process, as well as the continuing effectiveness of the 1986 General Framework that underlies the U.S. biotechnology regulatory structure. Concern about increased herbicide-resistant weeds associated with the widespread use of genetically engineered crop varieties was the subject of hearings in recent years. Other concerns involve the possibility of cross-contamination by GE crops with other traditional and organically grown crops.¹⁰² FDA is also nearing completion of its review to approve a genetically engineered salmon, which could be the first GE animal approved for human consumption. Various product labeling options for the salmon have also been debated. In the 113th Congress, proposed legislation would amend FFDCA to require labeling of GE fish (H.R. 584, S. 248). In addition, GE food "right-to-know" bills were proposed in the 113th Congress (H.R. 1699, S. 809). Many of these bills were reintroduced from previous Congresses.

In the 112th Congress, there were a series of attempts to alter U.S. policies regarding bioengineered crops. As part of the periodic farm bill debate, the House Agriculture Committee included several provisions (H.R. 6083, §§10012, 10014, 10015) that would amend the Plant Protection Act (PPA, 7 U.S.C. 7701 et seq.) to change the way USDA reviews deregulation permits for bioengineered plants.¹⁰³ Also, a provision in the House FY2013 Agriculture appropriations bill (H.R. 5973, §733) would have required USDA to grant temporary permits to producers to continue planting or cultivating a bioengineered crops while USDA reexamines possible petitions regarding "non-regulated status" or other deregulatory actions. These provisions were not enacted.

Single Food Agency

Some in Congress may continue to advocate for additional reforms to the nation's food safety system, particularly with respect to coordination and organization among federal agencies. Efforts to establish a single federal food safety agency were introduced and debated in the 105th and each subsequent Congress. Although the idea has the support of the Government Accountability Office (GAO)¹⁰⁴ and the National Research Council (NRC) and Institute of Medicine (IOM),¹⁰⁵ it also has its detractors. While some see consolidation as an opportunity for improvement in the efficiency and effectiveness of food safety regulation, others worry that it could unnecessarily compromise day-to-day food safety efforts. The food safety changes enacted under FSMA did not alter the existing food safety jurisdiction between FDA and USDA, so the issue may remain of interest to the Congress. Press reports suggest that Representative Rosa DeLauro intends to reintroduce legislation to create a single food safety agency.¹⁰⁶

¹⁰² See, for example, Organic Trade Association (OTA) press release, "OTA Deeply Disappointed with Failure to Protect Farmer and Consumer Choice," January 27, 2011.

¹⁰³ For more information on USDA's petition process for requesting that a particular regulated article is unlikely to pose a plant pest risk and therefore should not be regulated under PPA or regulations at 7 CFR part 340, see USDA, "Biotechnology," <http://www.aphis.usda.gov/biotechnology/petitions.shtml>.

¹⁰⁴ See, for example, GAO's reports on federal food safety oversight (GAO-11-289, March 2011; GAO-08-435T, January 2008; and GAO-05-549T, May 2005) and GAO, *Federal Food Safety and Security System: Fundamental Restructuring Is Needed to Address Fragmentation and Overlap* (GAO-04-588T, March 2004).

¹⁰⁵ NRC/IOM, *Enhancing Food Safety: The Role of the Food and Drug Administration*, 2010.

¹⁰⁶ S. Armour, "Rep. DeLauro will introduce single food safety agency bill, slams self-regulation," *Bloomberg News*, December 18, 2012. Previous version of this bill was H.R. 6552, Single Food Safety Agency Act of 2010 (111th Congress). Representatives DeLauro and Tom Latham are co-chairs of the Congressional Food Safety Caucus.

Appendix. FDA Food Safety Modernization Act (P.L. 111-353), Selected Section Provisions, Time/Schedule in Law, Implementation Status

Section(s)	Timeline/Schedule in Law (FSMA signed into law on January 4, 2011)	Regulation Guidance Report	Available Information on Implementation Status
Title I—Improving Capacity to Prevent Food Safety Problems			
Inspections of Records (§101)	Effective upon enactment of FSMA, the Department of Health and Human Service (HHS) may inspect records related to the “manufacture, processing, packing, distribution, receipt, holding, or importation” of certain foods of concern (as defined). Amends previous law which contained one standard (trigger) for records access, by creating two such standards.	x x	<p>In February 2012, FDA issued the following regarding FDA’s access to records:</p> <ul style="list-style-type: none"> • Interim Final Rule: <i>Establishment, Maintenance, and Availability of Records: Amendment to Record Availability Requirements</i> (Docket Number: FDA-2002-N-0153). • Draft Guidance for Industry: <i>FDA Records Access Authority Under Sections 414 and 704 of the Federal Food, Drug, & Cosmetic Act</i> (Docket Number: FDA-2011-D-0674). • Guidance for Industry: <i>Questions and Answers Regarding Establishment and Maintenance of Records By Persons Who Manufacture, Process, Pack, Transport, Distribute, Receive, Hold, or Import Food</i> (5th Edition) (Docket Number: FDA-2011-D-0598).
Registration of Food Facilities (§102)	<p>Among other provisions, food facilities shall be subject to biennial registration renewal (and HHS may suspend a facility’s registration in certain cases) either once HHS issues interim final regulations or 180 days after enactment of FSMA.</p> <p>HHS shall issue a small entity compliance policy guide to assist small entities in complying with registration requirements (no later than 180 days after it issues regulations).</p>	x	<p>FDA’s authority to suspend the registration of a food facility became effective on July 3, 2011. In November 2012, for the first time, FDA suspended the registration of a food facility, Sundland Inc., due to illness from <i>Salmonella</i> associated with its peanut products.</p> <p>Guidance for Industry: <i>Necessity of the Use of Food Product Categories in Food Facility Registrations and Updates to Food Product Categories</i> (Docket Number: FDA-2012-D-0585, October 2012).</p> <p>Guidance for Industry: <i>What You Need To Know About Registration of Food Facilities; Small Entity Compliance Guide</i> (Docket Number: FDA-2012-D-1003, December 2012).</p> <p>Guidance for Industry: <i>Questions and Answers Regarding Food Facility Registration</i> (5th Edition) (Docket Number: FDA-2012-D-1002, December 2012).</p> <p>In April 2013, FDA issued draft guidance, which, when finalized, will replace <i>Compliance Policy Guide Section 110.300 Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002</i>.</p>

Section(s)	Timeline/Schedule in Law (FSMA signed into law on January 4, 2011)	Regulation Guidance Report	Available Information on Implementation Status
Hazard Analysis and Risk-Based Preventive Controls (§103) **Provisions re. seafood, see (§114)	<p>Among other provisions, HHS (coordinating with DHS) shall establish mandatory preventive controls for food facilities, except for “small business” and “very small business” as defined (§103(a)). Final regulations are due no later than 18 months after enactment. HHS shall also issue proposed regulations (within 9 months after enactment) and final regulations (within 9 months after the close of the public comment period on the proposed rule) regarding certain on-farm activities (§103(c)). HHS shall issue a small entity compliance guide, within 180 days of the rules (§103(d)).</p> <p>HHS, in consultation with USDA, shall issue a report on the food processing sector (within 18 months after enactment).</p>	x x x	<p>In May 2011, FDA opened a docket for information about preventive controls and other practices. In March 2012, FDA issued information on how FDA identifies a high-risk facility.</p> <p>Proposed Rules:</p> <ul style="list-style-type: none"> • <i>Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food</i> (Docket Number: FDA-2011-N-0920, January 2013) • <i>Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals</i> (Docket Number: FDA-2011-N-09226; October 2013). <p>In August 2012, FDA published a “Draft Qualitative Risk Assessment of Risk of Activity/Food Combinations for Activities (Outside the Farm Definition) Conducted in a Facility Co-Located on a Farm” to provide a science-based risk analysis of those activity/food combinations that could be considered low risk.</p> <p>In March 2013, FDA corrected technical errors to the proposed rule for Preventive Controls for Human Food. FDA also extended the comment period on the proposed rule numerous times until November 15, 2013. FDA has also conducted outreach and public meetings, and released web videos and written materials.</p> <p>Pending: HHS study on the food processing sector.</p>
Performance Standards (§104)	<p>HHS, in coordination with USDA, shall review and evaluate relevant health data and other relevant information, to determine the most significant foodborne contaminants, and shall issue contaminant-specific and science-based guidance documents (not less frequently than every 2 years).</p>	x	<p>Status of guidance documents unknown.</p>
Standards for Produce Safety (§105)	<p>Among other provisions, HHS shall establish mandatory science-based, minimum standards for the safe production and harvesting of fruits and vegetables, except for “small business” and “very small business” as defined. Proposed regulations shall be issued within 1 year after enactment, with final regulations following 1 year after the close of the public comment period on the proposed rule (§105(a)-(b)).</p>	x x	<p>Proposed Rule: <i>Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption</i> (Docket Number: FDA-2011-N-0921, January 2013). In March 2013, FDA corrected technical errors to the proposed rule. FDA also extended the comment period on the proposed rule numerous times until November 15, 2013. FDA has also conducted outreach and public meetings, and released web videos and written materials.</p> <p>In August 2013, FDA announced it would prepare an Environmental Impact Statement (EIS) to evaluate the potential environmental effects of the proposed rule for produce safety.</p>

Section(s)	Timeline/Schedule in Law (FSMA signed into law on January 4, 2011)	Regulation Guidance Report	Available Information on Implementation Status
Protection Against Intentional Adulteration (§106)	HHS, in coordination with the Department of Homeland Security (DHS) and in consultation with USDA, shall issue regulations to protect against the intentional adulteration of food (within 18 months of enactment). HHS, in consultation with DHS and USDA, shall issue guidance documents related to the intentional adulteration, including mitigation strategies (no later than one year after enactment).	x x	Proposed Rule: <i>Focused Mitigation Strategies to Protect Food Against Intentional Adulteration</i> (Docket Number: FDA-2013-N-14254, December 2013). Status of guidance documents unknown.
Fees (§107); Funding for Food Safety (§401)	Authorizes HHS to assess and collect fees for reinspection, recall and importation activities (§107). HHS shall submit an annual report to include a description of fees assessed and collected each year and a description of the entities paying fees (no later than 120 days after each fiscal year). HHS shall increase its food safety field staff to the following levels: 4,000 staff (FY2011); 4,200 staff (FY2012); 4,600 staff (FY2013); and 5,000 staff (FY2014), with an increase of 150 field staff for food defense by FY2011 (§401).	x x	Guidance for Industry: <i>Implementation of the Fee Provisions of Section 107 of the FDA Food Safety Modernization Act</i> (Docket Number: FDA-2011-D-072135, September 2011). In August of 2011, 2012, and 2013, FDA announced, respectively, the FY2012, FY2013, and FY2014 fee schedule for certain domestic and foreign facility reinspection. FDA began collecting user fees for some activities starting with the FY2012 budget. Pending: HHS report on fees collected. HHS's Foods Program reports the following total full-time equivalents (FTEs) in recent years: about 3,600 FTEs (FY2011); about 3,500 FTEs (FY2012); and about 3,700 FTEs (FY2013).
National Agric. and Food Defense Strategy (§108)	Requires that HHS and USDA develop a "National Agriculture and Food Defense Strategy," in coordination with DHS (no later than 1 year after the enactment of FSMA), including an implementation plan and a coordinated research agenda. It shall be updated at least every 4 years.	x	In April 2013, FDA published its <i>Analysis of Results for FDA Food Defense Vulnerability Assessments and Identification of Activity Types</i> , documenting the results from 25 vulnerability assessments, conducted by FDA over several years on more than 50 products or processes, to determine if a potential "threshold" score for the implementation of mitigation strategies could be identified. Pending: HHS report on national agriculture and food defense strategy, implementation plan, and research plan.
Food & Agric. Coordinating Councils (§109)	DHS, coordinating with HHS and USDA, shall submit an annual report on the activities of the Food and Agriculture government and sector coordinating councils (within 180 days of enactment).	x	Pending: DHS report on activities of the Food and Agriculture Government Coordinating Council and the Food and Agriculture Sector Coordinating Council.

Section(s)	Timeline/Schedule in Law (FSMA signed into law on January 4, 2011)	Regulation Guidance Report	Available Information on Implementation Status
Building Domestic Capacity (§110)	HHS, in coordination with USDA and DHS, shall, submit a comprehensive report to Congress identifying programs and practices intended to promote the safety and supply chain security of food and to prevent outbreaks of foodborne illness and other food-related hazards that can be addressed through preventive activities (no later than 2 years after the enactment). The report shall include a report on traceback and surveillance, a food safety and food defense research plan (biennial), and a study regarding “unique identification numbers” (1 year after enactment).	x	In May 2013, FDA issued its report, <i>Building Domestic Capacity to Implement the FDA Food Safety Modernization Act (FSMA)</i> , a comprehensive report to Congress that identifies programs, practices and resources needed to promote the safety of the U.S. food supply.
Sanitary Transport (§111)	HHS shall issue regulations requiring shippers, carriers by motor vehicle or rail vehicle, receivers, and other persons engaged in the transportation of food to use sanitary transportation practices prescribed by HHS (due no later than 18 months after the enactment of FSMA). HHS shall also conduct a study of the transportation of food for consumption in the United States.	x	<p>x Proposed Rule: <i>Sanitary Transportation of Human and Animal Food</i> (Docket Number: FDA-2013-N-0013, February 2014).</p> <p>Pending: HHS study on food transportation.</p>
Food Allergy & Anaphylaxis Management (§112)	HHS, in consultation with the Department of Education, shall develop guidelines (not later than 1 year after the date of enactment) to be used on a voluntary basis to develop plans for individuals to manage the risk of food allergy and anaphylaxis in schools and children’s education programs.	x	In December 2012, FDA opened a docket requesting data and information to determine whether the agency can safely establish threshold levels for major food allergens.
New Dietary Ingredients (§113)	HHS shall publish guidance clarifying when a dietary supplement ingredient is a new dietary ingredient, among other things (no later than 180 days after enactment).	x	Draft Guidance for Industry: <i>New Dietary Ingredient Notifications and Related Issues</i> (Docket Number: FDA-2011-D-0376, July 2011).
Guidance, Raw Oysters (§114); Other Seafood (§103)	HHS shall prepare and submit a report on post-harvest processing of raw oysters regulation (within 90 days prior to the issuance of any guidance or regulation by FDA, as specified in FSMA §114). The Government Accountability Office (GAO) shall review and evaluate the report. HHS shall update the <i>Fish and Fisheries Products Hazards and Control Guidance</i> (within 180 days of enactment) (§103).	x	<p>x Pending: HHS report on post-harvest processing of raw oysters regulation.</p> <p>Guidance for Industry: <i>Fish and Fishery Products Hazards and Controls Guidance</i> (4th Edition) (Docket Number: FDA- 2011-D-0287, November 2011).</p>

Section(s)	Timeline/Schedule in Law (FSMA signed into law on January 4, 2011)	Regulation Guidance Report	Available Information on Implementation Status
Title II—Improving Capacity to Detect and Respond to Food Safety Problems			
Targeting of Inspection Resources (§201)	Among other provisions, HHS shall identify high-risk facilities, increase the frequency of inspection of domestic and foreign facilities (according to specified timeframe), identify and conduct inspections at ports of entry (with DHS), and improve coordination and cooperation with USDA and DHS. HHS shall issue an annual report with information about food facilities (as outlined in FSMA).	x x	HHS has sent Congress its first three annual reports, <i>Report on Food Facilities, Food Imports, and FDA Foreign Offices</i> (November 2013; August 2012; and April 2011). In March 2012, FDA issued information describing how the agency identifies a high-risk facility.
Recognition of Laboratory Accreditation for Analyses of Foods (§202)	Among other provisions, HHS shall establish a program for the testing of food by accredited laboratories (not later than 2 years after enactment of FSMA). Food testing shall be conducted by accredited labs within 30 months after enactment, unless otherwise exempted. HHS shall submit a report on the progress in implementing a national food emergency response laboratory network (within 180 days after enactment and biennially thereafter).	x x	In September 2011 and in November 2013, FDA issued its <i>Biennial Report to Congress on the Food Emergency Response Network (FERN)</i> .
Integrated Consortium of Lab Networks (§203)	DHS (in coordination with HHS and EPA) shall maintain an agreement to establish an integrated consortium of laboratory networks. DHS shall submit a report on the progress of the integrated consortium on a biennial basis.	x	The Integrated Consortium of Laboratory Networks (ICLN) was established by a Memorandum of Agreement (MOA) signed in June 2005 (https://www.icln.org/). Pending: Report on the progress of the ICLN.

Section(s)	Timeline/Schedule in Law (FSMA signed into law on January 4, 2011)	Regulation Guidance Report	Available Information on Implementation Status
Tracking and Tracing Food, Records (§204)	HHS, coordinating with USDA and state officials, shall establish pilot projects with industry to effectively and rapidly track and trace foods in an outbreak (within 270 days of enactment) (§204(a)). HHS, with USDA, shall establish a product tracing system. HHS shall publish a notice of proposed rulemaking within 2 years of enactment to establish additional recordkeeping for high-risk facilities (to be designated in 1 year of enactment), along with a list of high-risk foods (published at the time of the final rule) (§204(d)). Within a year of the effective date of the recordkeeping rule, GAO shall review and evaluate the pilot projects. HHS shall issue a small entity compliance policy guide, within 180 days of the rule. Small businesses will have 1 year and very small businesses will have 2 years to comply.	x x x	<p>In September 2011, FDA announced that the Institute of Food Technologists (IFT) would carry out two new pilot projects. In March 2012, FDA announced the types of foods for product tracing pilots.</p> <p>In March 2013, FDA called for public comment on an IFT final report, <i>Pilot Projects for Improving Product Tracing along the Food Supply System</i>, which will be considered by FDA in the development of recommendations in a report to Congress (pending).</p> <p>In February 2014, FDA published its draft methodological approach to identify high-risk foods under section 204(d)(2), <i>Requests for Information: Designation of High-Risk Foods for Tracing</i> (Docket Number: FDA-2014-N-0053; February 2014).</p>
Surveillance (§205)	HHS, acting through the CDC, shall enhance foodborne illness surveillance systems, among other things (authorized appropriations of \$24 million annually, FY2011-FY2015). HHS shall, within one year of enactment, conduct an assessment of state and local food safety and defense capacities. Reauthorizes food safety capacity grants at \$19.5 million (FY2010), and such sums as necessary (FY2011-FY2015), subject to appropriations.	x	<p>In September 2011, FDA awarded seven grants (totaling \$7.3 million) to five land-grant universities (Auburn University, Iowa State University, North Carolina State University, University of California-Davis, and University of Tennessee-Knoxville) and two training institutes.</p> <p>In December 2011, FDA established the Food Safety Preventive Controls Alliance (FSPCA) to provide training and curriculum.</p> <p>In May 2012, FDA announced it had submitted to OMB for review a survey it intends to conduct of state and local agencies to assess state and local food safety capacity.</p>
Mandatory Recall Authority (§206)	Gives HHS expanded mandatory recall authority of foods under certain circumstances. Establishes reporting requirements: GAO review (no later than 90 days after enactment); USDA feasibility study (depending on GAO's findings); and annual Report to Congress by HHS (not later than 2 years after enactment).	x	<p>Pending: HHS report on use of recall authority.</p> <p>GAO issued <i>FDA's Food Advisory and Recall Process Needs Strengthening</i> (GAO-12-589), July 2012.</p>

Section(s)	Timeline/Schedule in Law (FSMA signed into law on January 4, 2011)	Regulation Guidance Report	Available Information on Implementation Status
Administrative Detention of Food (§207)	HHS shall issue an interim final rule (not later than 120 days after enactment of FSMA), effective 180 days after enactment of FSMA, on the administrative detention of foods that FDA believes are adulterated or misbranded.	x x	<p>Final Rule: <i>Criteria Used to Order Administrative Detention of Food for Human or Animal Consumption</i> (Docket Number: FDA-2011-N-0197, February 2013). FDA issued an interim final rule in May 2011 on the criteria used to order administrative detention of food for human or animal consumption.</p> <p>Guidance for Industry: <i>What You Need to Know About Administrative Detention of Foods; Small Entity Compliance Guide</i> (Docket Number: FDA-2011-D-0643, March 2013).</p>
Decontamination and Disposal Standards and Plans (§208)	EPA shall provide support and technical assistance to states, local, and tribal governments, and shall develop standards and model plans (coordinating with HHS, DHS, and USDA) regarding decontamination and disposal.	x	Status of EPA's model plans for decontamination and disposal is not known.
Training of State, Local, Territorial, and Tribal Officials, Grants (§209)	HHS shall establish standards and administer training of state, local, territorial, and tribal food safety officials, and enter into agreements with USDA within 180 days after enactment) to establish a grant program ("National Food Safety Training, Education, Extension, Outreach and Technical Assistance Program"). Authorizes appropriations of such sums as necessary (FY2011-FY2015).	x	In July 2011, FDA and USDA entered into a MOU to collaborate on the establishment of a competitive grant program for food safety training, and other projects.
Food Safety Grants, and Centers of Excellence (§210)	HHS shall establish a grant program to "enhance food safety," authorizing appropriations of such sums as necessary (FY2011-FY2015). HHS shall designate five Centers of Excellence (within one year after enactment); HHS shall submit a report on the effectiveness of the Centers of Excellence (within two years of enactment).	x x	<p>CDC has designated five Integrated Food Safety Centers of Excellence. After a competitive process, five state health departments and their affiliated university partners were selected and notified: Colorado, Florida, Minnesota, Oregon, and Tennessee.</p> <p>Pending: Report on the effectiveness of the Centers of Excellence.</p>
Improving the Reportable Food Registry (§211)	HHS shall obtain information for reportable foods (except fruits and vegetables that are raw agricultural commodities) no later than 18 months after enactment. HHS shall prepare a one-page summary of each reportable food, to be publicly available. Within one year of enactment, HHS shall publish a list of "conspicuous locations" for posting such notifications.	x	No reported activity by FDA. FDA has a Reportable Food Registry (RFR) website (http://www.fda.gov/food/complianceenforcement/rfr/default.htm).

Section(s)	Timeline/Schedule in Law (FSMA signed into law on January 4, 2011)	Regulation Guidance Report	Available Information on Implementation Status
Title III—Improving the Safety of Imported Food			
Foreign Supplier Verification Program (§301)	HHS shall promulgate regulations to provide for the content of the foreign supplier verification (FSVP), within 1 year after enactment of FSMA, and shall issue guidance to assist importers in developing FSVPs. The program shall take effect 2 years after enactment.	x	Proposed Rule: <i>Food Supplier Verification Programs (FSVP) for Importers of Food for Humans and Animals</i> (Docket Number: FDA-2011-N-01438; July 2013). Under the proposed rules, U.S. importers would need to verify that their suppliers are meeting U.S. food safety requirements. FDA also has conducted outreach and public meetings, and released web videos and written materials.
Voluntary Qualified Importers Program (VQIP) (§302)	HHS, in consultation with DHS, shall establish a Voluntary Qualified Importer Program (VQIP) to provide for the expedited review and importation of food (beginning not later than 18 months after enactment of FSMA).	x	No reported activity by FDA.
Authority, Import Certifications (§303)	HHS may require, as a condition of granting admission to an article of food imported or offered for import into the United States, that an entity provide a certification concerning imported foods,		No reported activity by FDA.
Prior Notice, Food Imports (§304)	HHS shall issue an interim final rule regarding prior notice of imported foods (within 120 days of enactment of FSMA), which shall take effect 180 days after enactment of FSMA.	x x	Final Rule: <i>Information Required in Prior Notice of Imported Food</i> (Docket Number: FDA-2011-N-0179, May 2013), establishing requirements for submitting prior notice of imported food, including food for animals. The final rule adopts FDA's interim final rule issued in May 2011. Industry Guidance: <i>Enforcement Policy Concerning Certain Prior Notice Requirements</i> (June 2011)
Capacity Building, Foreign Govts. (§305)	HHS shall develop a comprehensive plan to expand the technical, scientific, and regulatory food safety capacity of foreign governments, and their food industries, which export foods to the U.S. (within 2 years of enactment)	x x	In February 2013, FDA issued its “International Capacity-Building Plan,” outlining goals, objectives, and key actions that will provide a strategic framework for the FDA in setting priorities and managing international food safety capacity-building programs. In May 2013, FDA released its report, <i>Building Domestic Capacity to Implement the FDA Food Safety and Modernization Act (FSMA)</i> , identifying programs and practices intended to promote the safety of the U.S. food supply.

Section(s)	Timeline/Schedule in Law (FSMA signed into law on January 4, 2011)	Regulation Guidance Report	Available Information on Implementation Status
Inspection of Foreign Food Facilities (§306)	HHS may enter into arrangements and agreements with foreign governments to facilitate inspections of registered foreign facilities and direct resources to inspections of foreign facilities, suppliers, and food types.		FDA has entered discussions with Australia, Belgium, Brazil, Canada, China, Costa Rica, Denmark, European Union (EU), Finland, France, Germany, Iceland, Ireland, Italy, Japan, Mexico, Netherlands, New Zealand, Norway, Philippines, Russia, Singapore, Spain, Sweden, Switzerland, Taiwan, and the United Kingdom. (See FDA's website, "Memoranda of Understanding and Other Cooperative Arrangements," available at http://www.fda.gov)
Accreditation of Third-Party Auditors (§307)	HHS shall develop model standards (within 18 months of enactment) and recognized accreditation bodies shall ensure third-party auditors and audit agents meet such standards to qualify third-party auditors as accredited auditors.	x	Proposed Rule: <i>Accreditation of Third-Party Auditors/Certification Bodies to Conduct Food Safety Audits and to Issue Certifications</i> (Docket Number: FDA-2011-N-014610; July 2013) to establish a program for accreditation of third-party auditors to conduct food safety audits and issue certifications of foreign facilities and the foods they produce for both humans and animals. FDA also has conducted outreach and public meetings, and released web videos and written materials.
Foreign Offices of FDA (§308)	HHS shall submit a congressional report regarding the selection of the foreign countries for established offices (no later than October 1, 2011).	x	In February 2012, FDA issued its <i>Report to Congress on the FDA Foreign Offices</i> .
Smuggled Food (§309)	HHS, coordinating with DHS, shall develop and implement a strategy to identify smuggled food and prevent its entry into the U.S. (not later than 180 days after enactment of FSMA)	x	In July 2011, HHS and DHS issued a joint anti-smuggling strategy to better identify and prevent entry of smuggled food into the United States.

Source: Compiled by CRS, as of mid-January 2014, from language in the FDA Food Safety Modernization Act (FSMA, P.L. 111-353) and FDA-reported actions taken to date, based on available FDA progress reports (FDA, "Progress Reports," <http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm255893.htm>), a listing of FSMA rules and guidance (FDA, "The Law, Rules, and Guidance," <http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm359436.htm>) and a listing of FSMA reports and studies (<http://www.fda.gov/Food/FoodSafety/FSMA/ucm271961.htm>).

Notes: For detailed information about each of these provisions, see Appendix B in CRS Report R40443, *The FDA Food Safety Modernization Act (P.L. 111-353)*. Excludes some FSMA provisions, including provisions in Title 4 (Miscellaneous Provisions) and also FSMA Section 115 (Port Shopping) and Section 116 (Alcohol-Related Facilities), which mostly cover jurisdiction issues or address conforming language requirements.

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