



# Food Safety Issues for the 113<sup>th</sup> 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 113<sup>th</sup> 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. Given delays in the rulemaking process, in August 2012, the Center for Food Safety filed suit in federal court against FDA and the Office of Management and Budget's (OMB), citing the government's failure to implement several food safety regulations required by FSMA. In January 2013, FDA released two major rules under FSMA that propose new requirements for food facilities and produce growers. Other FDA rules under FSMA continue to be delayed. Implementation of the law will also depend on the availability of discretionary appropriations, which remains uncertain in the current budgetary climate.

In addition, the 113<sup>th</sup> Congress 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; food labeling; stricter food safety enforcement mechanisms; and the use of plant and animal biotechnology. Several of these issues were actively debated in the 111<sup>th</sup> Congress during the food safety debate leading up to passage of the FSMA. Several bills debated in previous Congresses were reintroduced in the 112<sup>th</sup> 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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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). In the wake of these reforms, Congress continues to actively address concerns of the U.S. food safety system given challenges facing FDA in implementing this law and also continued food safety incidents.

The 113<sup>th</sup> Congress might provide oversight over how the law is implemented, but it 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.<sup>1</sup> 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.<sup>2</sup>

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.<sup>3</sup>

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.<sup>4</sup> 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

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<sup>1</sup> 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>.

<sup>2</sup> 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.

<sup>3</sup> GAO, *High Risk Series: An Update* (GAO-11-278), February 2011. In maintaining food safety as a “high risk” area, GAO acknowledges new food safety legislation expanding FDA’s oversight authority, but further notes that these legislative changes do not apply to the federal food safety system as a whole.

<sup>4</sup> FDA, *Food Protection Plan of 2007*; Interagency Working Group on Import Safety, *Action Plan for Import Safety*, November, 2007. See <http://www.fda.gov/food/foodsafety/foodsafetyprograms/foodprotectionplan2007/default.htm>.

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.<sup>5</sup> The HHS released a draft of its plans regarding specific food safety goals, setting percentage reduction goals for major food contaminants as well as targeted reductions in the number of cases each year by 2020.<sup>6</sup>

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.<sup>7</sup> CDC reports that more than 1,000 foodborne outbreaks are investigated by local and state health departments each year.<sup>8</sup> 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.<sup>9</sup>

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.

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<sup>5</sup> FSWG, "Food Safety Working Group: Progress at 1 Year," July 9, 2010, <http://www.foodsafetyworkinggroup.gov/>.

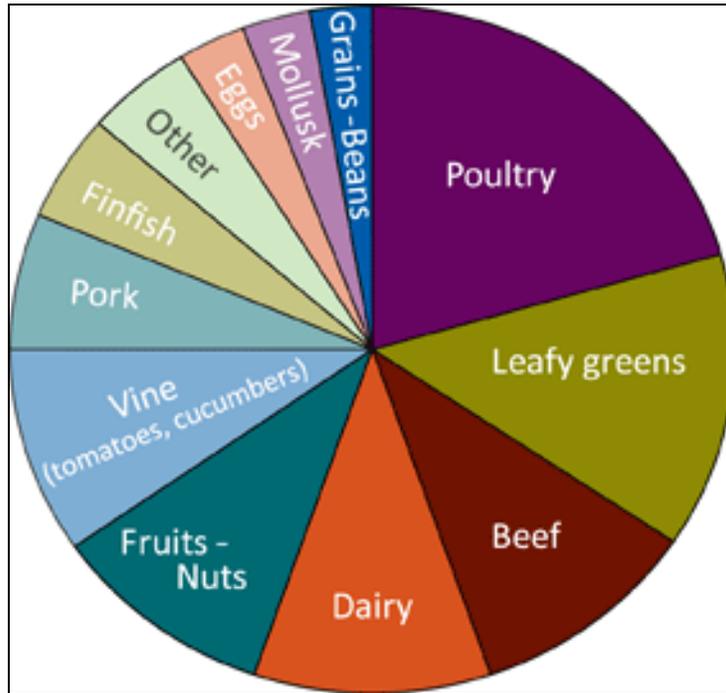
<sup>6</sup> FDA, "Strategic Priorities 2011–2015: Responding to the Public Health Challenges of the 21<sup>st</sup> Century," Draft, September 29, 2010 (part of the broader Healthy People 2020 initiative at <http://www.healthypeople.gov/2020>), <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/StrategicActionPlan/UCM226907.pdf>.

<sup>7</sup> 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/outbreaknet/outbreaks.html>; FDA, "Outbreak Investigations," <http://www.fda.gov/Food/FoodSafety/CORENetwork/ucm272351.htm>; and FDA, "Recalls, Market Withdrawals, & Safety Alerts," <http://www.fda.gov/Safety/Recalls/default.htm>.

<sup>8</sup> CDC, "Food Safety," <http://www.cdc.gov/foodsafety/facts.html>.

<sup>9</sup> *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>.

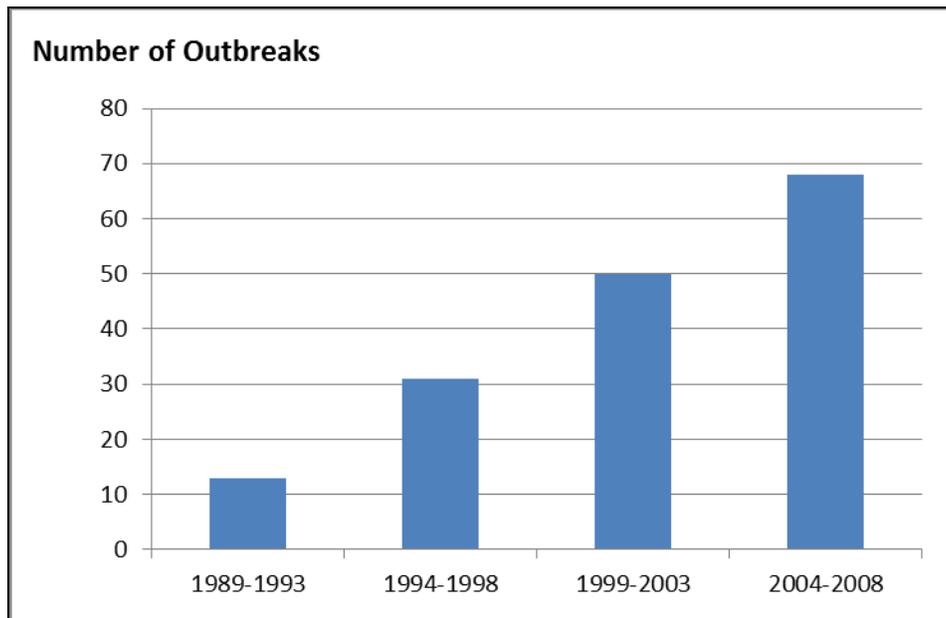
**Figure 1. Causes of Illness in Foodborne Outbreaks, 2003-2008**



**Source:** CDC, *CDC and Food Safety*, January 2011, [http://www.cdc.gov/foodsafety/resources/CDCandFoodSafety\\_121410.pdf](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](http://www.cdc.gov/foodsafety/resources/CDCandFoodSafety_121410.pdf).

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 multistate 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.<sup>10</sup> 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.<sup>11</sup>

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.<sup>12</sup>

## 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:<sup>13</sup>

- 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<sup>14</sup>) O157 (4%).

<sup>10</sup> FDA, “Outbreak Investigations,” <http://www.fda.gov/Food/FoodSafety/CORENetwork/ucm272351.htm>. See also CRS Report R40916, *Food Safety: Foodborne Illness and Selected Recalls of FDA-Regulated Foods*.

<sup>11</sup> FSIS, “FSIS Recalls,” [http://www.fsis.usda.gov/FSIS\\_Recalls/index.asp](http://www.fsis.usda.gov/FSIS_Recalls/index.asp). See also CRS Report RL34313, *The USDA's Authority to Recall Meat and Poultry Products*.

<sup>12</sup> CDC, “Foodborne Outbreak Online Database (FOOD),” <http://www.cdc.gov/foodborneoutbreaks/Default.aspx>.

<sup>13</sup> CDC, “Estimates of Foodborne Illness in the United States,” December 2010; also [http://www.cdc.gov/foodborneburden/PDFs/FACTSHEET\\_A\\_FINDINGS.pdf](http://www.cdc.gov/foodborneburden/PDFs/FACTSHEET_A_FINDINGS.pdf).

<sup>14</sup> 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.

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%).<sup>15</sup>

**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) <sup>a</sup>	%	(90% credible interval) <sup>a</sup>	%
<b>31 Known Pathogens</b>	9.4 million (6.6–12.7 million)	20%	55,961 (39,534–75,741)	44%	1,351 (712–2,268)	44%
<b>Unspecified Agents</b>	38.4 million (19.8–61.2 million)	80%	71,878 (9,924–157,340)	56%	1,686 (369–3,338)	56%
<b>Total</b>	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](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, <http://www.cdc.gov/eid/content/17/1/pdfs/7.pdf>.

Other CDC reports indicate that there were 1,034 foodborne disease outbreaks in 2008.<sup>16</sup> 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* infections<sup>17</sup> 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

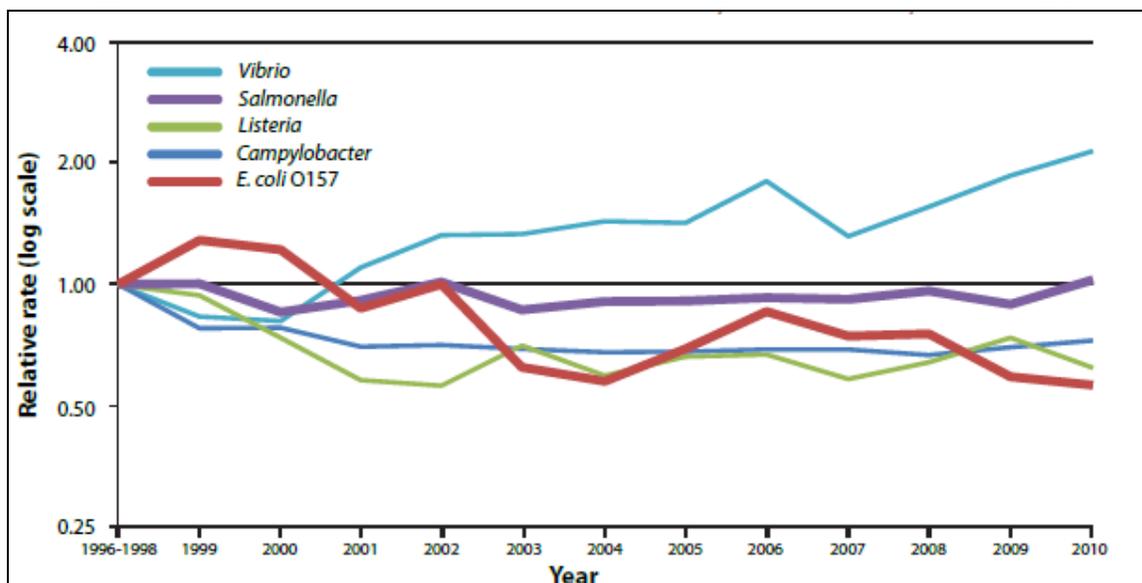
<sup>15</sup> CDC, “Estimates of Foodborne Illness in the United States,” December 2010.

<sup>16</sup> 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).

<sup>17</sup> Caused by another leading disease-causing pathogen.

rates in 1996-1998. These include *Campylobacter* (27% decrease); *Listeria* (38% decrease); *E. coli* O157 (44% decrease); *Shigella* (57% decrease); and *Yersinia* (52% decrease).<sup>18</sup>

**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](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.<sup>19</sup> 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

<sup>18</sup> 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.

<sup>19</sup> GAO, *Food Safety Working Group Is a Positive First Step but Governmentwide Planning Is Needed to Address Fragmentation*, GAO-11-289, March 2011, <http://www.gao.gov/assets/320/316742.pdf>. Also see Institute of Medicine, National Research Council (IOM/NRC), *Enhancing Food Safety: The Role of the Food and Drug Administration*, 2010.

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.<sup>20</sup> USDA’s Food Safety and Inspection Service (FSIS) regulates most meat and poultry and some egg and fish products. The division of 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.<sup>21</sup> FDA’s budget for foods was \$866 million, with another roughly \$17 million authorized user fees.<sup>22</sup> 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.<sup>23</sup> 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.

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<sup>20</sup> 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).

<sup>21</sup> USDA, “2013 Explanatory Notes, FSIS,” <http://www.obpa.usda.gov/21fsis2013notes.pdf>.

<sup>22</sup> HHS, “FY2013 FDA: Justification of Estimates for Appropriations Committees,” <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/BudgetReports/UCM291555.pdf>.

<sup>23</sup> 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/>.

FDA has identified five key elements to FSMA:<sup>24</sup>

- **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 frequency (based on risk);<sup>25</sup> 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,<sup>26</sup> 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.

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<sup>24</sup> 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).”

<sup>25</sup> 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).

<sup>26</sup> 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.

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).<sup>27</sup> 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)*.

## 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 proposed or finalized, and some 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).

Although FDA has conducted outreach, hosted public meetings, and released web videos and other written materials and presentations,<sup>28</sup> the agency has not issued some of the regulations required under certain key sections of the act. At year-end 2012, it was uncertain whether some provisions in the law would be implemented in time to meet their expected deadlines since some of the rules had not yet been proposed. Implementation of the law will depend on the availability of discretionary appropriations, which is also uncertain given the current budgetary climate.

Press reports indicate that the rules have been held up by the Office of Management and Budget's (OMB) review process.<sup>29</sup> 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:<sup>30</sup>

- 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));

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<sup>27</sup> 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.

<sup>28</sup> For information, see FDA's FSMA implementation website, <http://www.fda.gov/Food/FoodSafety/FSMA/ucm250568.htm>.

<sup>29</sup> D. ElBoghdady, "Food-safety rules in limbo at Office of Management and Budget," *Washington Post*, May 2, 2012.

<sup>30</sup> 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. Complaint is at <http://www.centerforfoodsafety.org/wp-content/uploads/2012/08/2012-08-29-FSMA-Complaint-FILED.pdf>.

- 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 November 2012, FDA filed a motion to dismiss the complaint against the agency.<sup>31</sup> The Center for Food Safety argues that, by not meeting their statutory deadlines for 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.<sup>32</sup>

In January 2013, FDA released two major proposed rules under FSMA to establish preventive controls for (human) food facilities (FSMA §103) and new food safety requirements for produce growers (FSMA §105).<sup>33</sup> These two proposals also address some aspect of the requirements under FSMA for food facilities and farms that provide imported foods to the United States, as well as address which activities constitute on-farm manufacturing, processing, packing or holding of food. Other FDA rules under FSMA continue to be delayed including requirements for food importers and third-party verifiers, and preventive controls for animal feed and pet food, among other provisions.

The table in 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 (as of early January 2013).<sup>34</sup> For

<sup>31</sup> 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. Motion to dismiss is at <http://www.foodsafetynews.com/files/2012/12/FDA-motion-to-dismiss.pdf>.

<sup>32</sup> H. Bottemiller, “FDA Seeks to Dismiss Lawsuit Over Delay of Food Safety Rules,” *Food Safety News*, December 4, 2012.

<sup>33</sup> Fact sheets and full *Federal Register* pre-publication documents for the two proposed rules (“Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Foods” and “Standards for Growing, Harvesting, Packing, and Holding of Produce for Human Consumption”) are available at <http://www.fda.gov/Food/FoodSafety/FSMA/default.htm>. Scheduled for publication on January 16, 2013.

<sup>34</sup> FDA, “Progress Reports,” <http://www.fda.gov/Food/FoodSafety/FSMA/ucm255893.htm>.

detailed information about each of these provisions, see Appendix B in CRS Report R40443, *The FDA Food Safety Modernization Act (P.L. 111-353)*.

## Key Issues for the 113<sup>th</sup> Congress

The 113<sup>th</sup> 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 113<sup>th</sup> 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.<sup>35</sup> 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 2012, FDA had not issued many of the regulations required under certain key sections of FSMA. Although FDA released two major proposed rules under FSMA in early January 2013, several other FDA rules under FSMA continue to be delayed. **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.<sup>36</sup> These provisions will exempt from federal regulation some small-sized farms and

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<sup>35</sup> 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>.

<sup>36</sup> For more information, see CRS Report RL34612, *Food Safety on the Farm*.

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).

## 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.<sup>37</sup> 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, Section 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.”<sup>38</sup> 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 an 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.<sup>39</sup>

The Administration FY2013 budget request projected the need for additional funds for FDA, anticipating a total need of \$1.084 billion, consisting of \$863 million in appropriations for FDA’s food program and another nearly \$230 billion expected user fees for the year.<sup>40</sup> Total funding (including expected user fees) is well below the amounts proposed by both the House (\$883.5 million) and Senate (\$884.5 million) committee-reported appropriations bills, H.R. 5973 and S.

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<sup>37</sup> See for example Robert Wood Johnson Foundation, *Ready or Not? Protecting the Public’s Health from Diseases, Disasters, and Bioterrorism*, December 2012, <http://www.rwjf.org/content/dam/farm/reports/reports/2012/rwjf403352>.

<sup>38</sup> 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.

<sup>39</sup> H. Bottenmiller, “Sweeping Food Safety Rules Raise More Concerns about FDA Funding,” *Food Safety News*, January 8, 2013.

<sup>40</sup> Data from “FY2013 FDA: Justification of Estimates for Appropriations Committees,” FY2010-FY2012 from p. 144, FY2013 calculated from tables on pp. 93-96; USDA, “2013 Explanatory Notes, FSIS,” p. 21-5.

2375, respectively.<sup>41</sup> The proposed establishment fee is 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.<sup>42</sup>

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.<sup>43</sup> In President Obama's Statement of Administration Policy (SAP) regarding H.R. 5973, the Administration urges the House to adopt the new user fees proposed in the FY2013 budget to provide additional resources to support FDA's food safety mission.<sup>44</sup> 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.<sup>45</sup> 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."<sup>46</sup> 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.<sup>47</sup>

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<sup>41</sup> For more information, see CRS Report RS22600, *The Federal Food Safety System: A Primer*.

<sup>42</sup> HHS, "FY2013 FDA: Justification of Estimates for Appropriations Committees," page 30. Also see "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.

<sup>43</sup> See, for example, Robert Wood Johnson Foundation, *Ready or Not? Protecting the Public's Health from Diseases, Disasters, and Bioterrorism*, December 2012, <http://www.rwjf.org/content/dam/farm/reports/reports/2012/rwjf403352>.

<sup>44</sup> 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, [http://www.whitehouse.gov/sites/default/files/omb/legislative/sap/112/saphr5973r\\_20120621.pdf](http://www.whitehouse.gov/sites/default/files/omb/legislative/sap/112/saphr5973r_20120621.pdf).

<sup>45</sup> FDA proposed rule, "Standards for Growing, Harvesting, Packing, and Holding of Produce for Human Consumption," <http://www.fda.gov/Food/FoodSafety/FSMA/default.htm>.

<sup>46</sup> *Ibid.*

<sup>47</sup> FDA proposed rule, "Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive (continued...)"

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.<sup>48</sup> 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 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, the rule 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.

FDA is accepting electronic or written comments on the agency's proposed produce rule from the public and other interested parties through May 16, 2013.

In addition to FDA's rulemaking under FSMA affecting produce growers, USDA is also 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."<sup>49</sup> 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

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(...continued)

Controls for Human Foods," <http://www.fda.gov/Food/FoodSafety/FSMA/default.htm>. FSMA § 103.

<sup>48</sup> FDA proposed rule, "Standards for Growing, Harvesting, Packing, and Holding of Produce for Human Consumption," <http://www.fda.gov/Food/FoodSafety/FSMA/default.htm>.

<sup>49</sup> 76 *Federal Register* 24292, April 29, 2011.

commercial food quality and safety requirements. It remains 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.

## 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.<sup>50</sup> 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 111<sup>th</sup> Congress regarding the safety of meat and poultry products, and several bills were re-introduced in the 112<sup>th</sup> Congress (for example, S. 1529 and H.R. 1487). These, or similar, bills may be reintroduced in the 113<sup>th</sup> Congress.

USDA's proposal to modernize its poultry inspection system could be of interest to the 113<sup>th</sup> Congress. The proposed system would be an expansion of the FSIS HACCP-Based Inspections Models Project (HIMP) if implemented. 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. Currently, 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.<sup>51</sup> Some food safety advocates have questioned the advisability of adopting the proposed system.<sup>52</sup> 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.<sup>53</sup>

## 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

<sup>50</sup> See, for example, Statement by Representative Rosa DeLauro, *Congressional Record*, December 21, 2010, p. H8887.

<sup>51</sup> FSIS, "Modernization of Poultry Slaughter Inspection," *77 Federal Register* 4414, January 27, 2012.

<sup>52</sup> Helena Bottemiller, "Debate Heats Up Over Poultry Inspection Proposal," *Food Safety News*, April 9, 2012.

<sup>53</sup> For more information, see CRS Report RL32922, *Meat and Poultry Inspection: Background and Selected Issues*, or contact CRS analyst Joel L. Greene (7-9877).

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 of 2009 (PAMTA) introduced in both the House and Senate. These bills did not advance, but were offered again in the 112<sup>th</sup> Congress (H.R. 965; S. 1211) and could be reintroduced in the 113<sup>th</sup> Congress.

## Seafood and Fisheries Products

Many food safety changes enacted in FSMA did not specifically address seafood and fisheries products.<sup>54</sup> 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 were considered during the 112<sup>th</sup> Congress and are likely to be debated in the 113<sup>th</sup> 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.

## The Next Omnibus Farm Bill

The 112<sup>th</sup> Congress considered reauthorization of the 2008 farm bill (Food, Conservation, and Energy Act of 2008, P.L. 110-246), given that much of the current law expired in 2012.<sup>55</sup> Although Congress did not approve new farm bill legislation in the 112<sup>th</sup> Congress, both the House and Senate considered certain provisions that would have addressed food safety.<sup>56</sup> The House-committee bill (H.R. 6083) and the Senate-passed bill (S. 3240) both reauthorized funding to implement a program to educate fresh produce industry personnel and consumers on ways to reduce pathogens in fresh produce. Both bills also included provisions directing USDA to study the feasibility of crop insurance to cover losses by specialty producers who are not involved with but may be negatively impacted by foodborne illness outbreaks and recalls, as well as to cover losses by poultry producers for disease outbreaks, among other things. The Senate bill also would have repealed a provision in the 2008 farm bill establishing a catfish inspection and grading program at USDA. These issues may continue to be of interest in the 113<sup>th</sup> Congress

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

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<sup>54</sup> For more information see CRS Report RS22797, *Seafood Safety: Background and Issues*, or contact CRS analyst Harold F. Upton (7-2264).

<sup>55</sup> For more information, see CRS Report RS22131, *What Is the Farm Bill?* and CRS Report RL34696, *The 2008 Farm Bill: Major Provisions and Legislative Action*.

<sup>56</sup> For information, see provisions in titles X, XI, and XII in CRS Report R42552, *The 2012 Farm Bill: A Comparison of Senate-Passed S. 3240 and the House Agriculture Committee’s H.R. 6083 with Current Law*.

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 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.

## 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.<sup>57</sup> 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.<sup>58</sup> 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.<sup>59</sup>

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.<sup>60</sup>

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.<sup>61</sup> To date, several FSMA import provisions have not yet been implemented and have missed their scheduled deadlines set out in the law. See table in **Appendix**. Specifically, as of early January 2013, two primary import programs—namely, the

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<sup>57</sup> 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.

<sup>58</sup> 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.

<sup>59</sup> 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>.

<sup>60</sup> See, for example, C. Smith DeWaal, "FSMA: Import Rules May Foster Global Food Safety," *Food Safety News*, February 14, 2011.

<sup>61</sup> For more information, see FDA, "Progress Reports," <http://www.fda.gov/Food/FoodSafety/FSMA/ucm255893.htm>.

“Foreign Supplier Verification Program” (§301) and the “Voluntary Qualified Importer Program” (§302)—have not been proposed or established. However, 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.<sup>62</sup>

FDA also has not released its “model standards” for establishing a certification system or verification systems involving so-called third parties (§307) and has not released its plans to help build capacity with foreign countries with respect to safety measures at their food facilities (§305). Other FSMA import provisions authorize FDA to require food imports to be accompanied by certification (§303), require prior notice of imported food shipments (§304), and allows FDA to enter into agreements with foreign countries to facilitate inspection of foreign facilities (§306). 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). These issues are likely to continue to be of interest to the 113<sup>th</sup> Congress through legislation or oversight.

## 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, 111<sup>th</sup> 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 112<sup>th</sup> Congress, such legislation was reintroduced and passed in the Senate (S. 216) During the farm bill debate in the 112<sup>th</sup> 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).

## 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.<sup>63</sup> Food containers made with BPA are regulated by the FDA. BPA exposure has been

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<sup>62</sup> Fact sheets and full *Federal Register* pre-publication documents for the two proposed rules (“Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Foods” and “Standards for Growing, Harvesting, Packing, and Holding of Produce for Human Consumption”) are available at <http://www.fda.gov/Food/FoodSafety/FSMA/default.htm>. Scheduled for publication on January 16, 2013.

<sup>63</sup> See CRS Report RS22869, *Bisphenol A (BPA) in Plastics and Possible Human Health Effects*, or contact CRS analysts Linda-Jo Schierow (7-7279) and Sarah A. Lister (7-7320) for more information.

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 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.<sup>64</sup> The Senate provision introduced by Senator Dianne Feinstein, Ban Poisonous Additives Act of 2009 (S. 593, 111<sup>th</sup> Congress), would have banned BPA in all FDA-regulated food containers. These proposals were reintroduced in the 112<sup>th</sup> Congress (S. 136; H.R. 432) but were not enacted.

In March 2012, FDA rejected a citizen petition seeking a ban on BPA in food containers.<sup>65</sup> 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.<sup>66</sup>

## Dietary Supplements<sup>67</sup>

FSMA provisions apply to most foods, including dietary supplements.<sup>68</sup> 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,<sup>69</sup> 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.<sup>70</sup>

<sup>64</sup> See, for example, Julian Pecquet, “Democrats quarrel over food safety legislation,” *The Hill*, July 19, 2010.

<sup>65</sup> 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>.

<sup>66</sup> *77 Federal Register* 137: 41953-41954, July 17, 2012.

<sup>67</sup> For more information, contact CRS analyst Amalia K. Corby-Edwards (7-0423).

<sup>68</sup> 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.

<sup>69</sup> 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>.

<sup>70</sup> 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.

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 asked FDA to review possible health concerns and reports of deaths linked to energy drinks.<sup>71</sup>

## 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.<sup>72</sup> 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 (Section 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 FFDCA. 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 (H.R. 2521 and S. 1361).<sup>73</sup>

## Agricultural Biotechnology

Opinions differ on whether or not agricultural biotechnology should be considered a food safety issue.<sup>74</sup> Genetically engineered (GE, sometimes called genetically modified, or GM) crop varieties first became commercially available in the mid-1990s.<sup>75</sup> In recent years, the introduction and proposed deregulation of several new GE crops (e.g., alfalfa, sugar beets), and subsequent legal challenges to that introduction and deregulation, have raised important issues regarding the effectiveness of the USDA’s environmental review process, as well as the continuing effectiveness of the 1986 General Framework that underlies the U.S. biotechnology regulatory

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<sup>71</sup> R. Cox, “Durbin, Blumenthal ask FDA to Review Energy Drinks Quickly,” November 27, 2012, <http://thehill.com/blogs/floor-action/senate/269587-durbin-blumenthal-ask-fda-to-review-energy-drinks-quickly>.

<sup>72</sup> For more information see CRS Report RL31921, *Pesticide Law: A Summary of the Statutes*, or contact CRS analyst Linda-Jo Schierow (7-7279).

<sup>73</sup> See CRS Report R40177, *Environmental Exposure to Endocrine Disruptors: What Are the Human Health Risks?*

<sup>74</sup> 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*.

<sup>75</sup> CRS Report RL32809, *Agricultural Biotechnology: Background and Recent Issues*, and CRS Report RL33334, *Biotechnology in Animal Agriculture: Status and Current Issues*, or contact CRS analyst Tadlock Cowan (7-7600).

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.<sup>76</sup> 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 112<sup>th</sup> Congress, two bills would, respectively, amend FFDCA to require labeling of GE fish (H.R. 520) and prevent the approval of GE fish (H.R. 521).

In addition, as part of the periodic farm bill debate during the 112<sup>th</sup> Congress, the House Agriculture Committee (H.R. 6083, §10012, 10014, 10015) included several provisions 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.<sup>77</sup> Also a provision in the House FY2013 Agriculture appropriations bill (H.R. 5973, §733) would require 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. Given these impending regulatory actions and concerns, Congress is likely to closely monitor biotechnology policy in the 113<sup>th</sup> Congress.

## 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 105<sup>th</sup> and each subsequent Congress. Although the idea has the support of the Government Accountability Office,<sup>78</sup> 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.<sup>79</sup>

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<sup>76</sup> See, for example, Organic Trade Association (OTA) press release, “OTA Deeply Disappointed with Failure to Protect Farmer and Consumer Choice,” January 27, 2011.

<sup>77</sup> 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>.

<sup>78</sup> 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).

<sup>79</sup> S. Armour, “Rep. DeLauro will introduce single food safety agency bill, slams self-regulation,” *Bloomberg News*, December 18, 2012. 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	Regulation Guidance Report	Available Information on Implementation Status
<b>Title I—Improving Capacity to Prevent Food Safety Problems</b>			
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:<sup>a</sup></p> <ul style="list-style-type: none"> <li>• Interim Final Rule</li> <li>• Draft Industry Guidance</li> <li>• Guidance for Industry</li> </ul>
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>FDA has issued draft industry guidance on facility registration, last updated in December 2012.</p> <p>In October 2012, FDA issued <i>Guidance for Industry: Necessity of the Use of Food Product Categories in Food Facility Registrations and Updates to Food Product Categories</i>.<sup>b</sup></p>
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>	x x x	<p>On January 4, 2013, FDA released fact sheets and full <i>Federal Register</i> pre-publication documents for its proposed rule, “Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Foods,” which are scheduled for publication on January 16, 2013 (<a href="http://www.fda.gov/Food/FoodSafety/FSMA/default.htm">http://www.fda.gov/Food/FoodSafety/FSMA/default.htm</a>). FDA has also conducted outreach and public meetings, and released web videos and written materials.</p> <p><i>**Regulations under both §103(a) and §103(c) are cited among other delayed regulations in the August 2012 Center for Food Safety complaint against FDA and OMB.</i></p> <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>

Section(s)	Timeline/Schedule in Law	Regulation Guidance Report	Available Information on Implementation Status
Performance Standards (§104)	<p>HHS, in consultation with USDA, shall issue a report on the food processing sector (within 18 months after enactment).</p> <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>Pending: HHS study on the food processing sector.<sup>c</sup></p> <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>On January 4, 2013, FDA released fact sheets and full <i>Federal Register</i> pre-publication documents for its proposed rule, "Standards for Growing, Harvesting, Packing, and Holding of Produce for Human Consumption," which are scheduled for publication on January 16, 2013 (<a href="http://www.fda.gov/Food/FoodSafety/FSMA/default.htm">http://www.fda.gov/Food/FoodSafety/FSMA/default.htm</a>). FDA has also conducted outreach and public meetings, and released web videos and written materials.</p> <p><i>**Regulations under §105(a) are cited among other delayed regulations in the August 2012 Center for Food Safety complaint against FDA and OMB.</i></p>
Protection Against Intentional Adulteration (§106)	<p>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).</p>	x x	<p><i>**Regulations under §106 are cited among other delayed regulations in the August 2012 Center for Food Safety complaint against FDA and OMB.</i></p> <p>Status of guidance documents unknown.</p>
Fees (§107); Funding for Food Safety (§401)	<p>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).</p> <p>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).</p>	x x	<p>FDA began collecting user fees for some activities starting with the FY2012 budget.</p> <p>In August-September 2011, FDA issued guidance and other information regarding FSMA fees.</p> <p>In August 2011 and August 2012, FDA announced, respectively, the FY2012 and FY2013 fee schedule for certain domestic and foreign facility reinspection, failure to comply with recall orders, and certain importer reinspections.<sup>d</sup></p> <p>Pending: HHS report on fees collected.<sup>c</sup></p> <p>HHS's Foods Program reports the following total full-time equivalents (FTEs) in recent years: about 3,600 FTEs (FY2011); about 3,800 FTEs (FY2012); and about 4,000 FTEs (FY2013).</p>

Section(s)	Timeline/Schedule in Law	Regulation Guidance Report	Available Information on Implementation Status
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	Pending: HHS report on national agriculture and food defense strategy, implementation plan, and research plan. <sup>c</sup>
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. <sup>c</sup>
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	Pending reports: <sup>c</sup> <ul style="list-style-type: none"> <li>• HHS report and evaluation of effectiveness of HHS-administered programs</li> <li>• HHS report of food safety programs, outlining successes and future programs</li> <li>• HHS study and report on unique identification numbers</li> <li>• Report on the Joint HHS/USDA food safety and food defense research plan</li> <li>• HHS report on programs and practices to promote the safety and supply chain security of food</li> </ul>
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	x <i>**Regulations under §106 are cited among other delayed regulations in the August 2012 Center for Food Safety complaint against FDA and OMB.</i> Pending: HHS study on food transportation. <sup>c</sup>
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. <sup>e</sup>

Section(s)	Timeline/Schedule in Law	Regulation Guidance Report	Available Information on Implementation Status
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	In July 2011, FDA issued draft guidance for the dietary supplement on the safety of new dietary ingredients. <sup>f</sup>
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	x Pending: HHS report on post-harvest processing of raw oysters regulation. <sup>c</sup> In April 2011, FDA issued <i>Seafood Hazard and Control Guidance</i> . <sup>g</sup>
<b>Title II—Improving Capacity to Detect and Respond to Food Safety Problems</b>			
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 In April 2011 and August 2012, HHS sent Congress its first two annual reports, <i>Report on Food Facilities, Food Imports, and FDA Foreign Offices</i> . <sup>c</sup> In March 2012, FDA issued information describing how the agency identifies a high-risk facility. <sup>h</sup>
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, <i>Biennial Report to Congress on the Food Emergency Response Network (FERN)</i> . <sup>c</sup>
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. Status of report required under FSMA is unknown. <sup>i</sup>

Section(s)	Timeline/Schedule in Law	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) will carry out two new pilot projects.</p> <p>In March 2012, FDA announced the types of foods for product tracing pilots.<sup>j</sup></p> <p>Pending: Report on pilot projects on product tracing.<sup>c</sup></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 in a <i>Federal Register</i> notice that 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.<sup>k</sup></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 congressional report by HHS (not later than 2 years after enactment).	x	<p>Pending: HHS report on use of recall authority.<sup>c</sup></p> <p>In June 2012, GAO issued <i>FDA's Food Advisory and Recall Process Needs Strengthening</i>.<sup>l</sup></p>

Section(s)	Timeline/Schedule in Law	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	In May 2011, FDA issued an interim final rule on the criteria used to order administrative detention of food for human or animal consumption. <sup>m</sup>
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 unknown.
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. <sup>n</sup>
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	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. <sup>o</sup>  Status of the HHS report on the effectiveness of the Centers of Excellence is unknown.
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 the reportable food, to be publicly available. Within one year of enactment, HHS shall publish a list of "conspicuous locations" for posting such notifications.	x	Status unknown. FDA has a Reportable Food Registry (RFR) website. <sup>p</sup>

Section(s)	Timeline/Schedule in Law	Regulation Guidance Report	Available Information on Implementation Status
<b>Title III—Improving the Safety of Imported Food</b>			
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	To date, FDA has not issued regulations under this section but has conducted outreach and public meetings, and released web videos and written materials. However, in January 2013, FDA proposed two rules under FSMA that address some aspects of the food safety requirements for food importers (“Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Foods” and “Standards for Growing, Harvesting, Packing, and Holding of Produce for Human Consumption”).  <i>**Regulations under §301 are cited among other delayed regulations in the August 2012 Center for Food Safety complaint against FDA and OMB.</i>
Voluntary Qualified Importers (§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	To date, FDA has not issued guidance to U.S. trading partners, but the agency has conducted outreach and public meetings, and released web videos and written materials. However, in January 2013, FDA proposed two rules under FSMA that address some aspects of the food safety requirements for food importers (“Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Foods” and “Standards for Growing, Harvesting, Packing, and Holding of Produce for Human Consumption”).
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,	x	Status is unknown.
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	FDA issued an interim final rule in May 2011 regarding its requirements for submitting prior notice of imported food, including food for animals. <sup>9</sup>
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	To date, FDA has not issued guidance under this section but has conducted outreach and public meetings, and released web videos and written materials.
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.	x	To date, 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, “Memoranda of Understanding and Other Cooperative Arrangements.” <sup>r</sup>

Section(s)	Timeline/Schedule in Law	Regulation Guidance Report	Available Information on Implementation Status
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	**Regulations under §307 are cited among other delayed regulations in the August 2012 Center for Food Safety complaint against FDA and OMB. Status of implementation is unknown.
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 <i>Report to Congress on the FDA Foreign Offices</i> . <sup>s</sup>
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. <sup>t</sup>

**Source:** Compiled by CRS, as of early January 2013, 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 press releases and publicly available progress reports (FDA, "Progress Reports," <http://www.fda.gov/Food/FoodSafety/FSMA/ucm255893.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.

- a. Interim final rule regarding FDA's access to records: <http://www.gpo.gov/fdsys/pkg/FR-2012-02-23/html/2012-4165.htm>. Draft industry guidance regarding FDA's access to records: <http://www.fda.gov/Information/GuidanceDocuments/FoodDefenseandEmergencyResponse/ucm292745.htm>. Guidance for industry regarding FDA's access to records: <http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodDefenseandEmergencyResponse/ucm292746.htm>.
- b. Draft industry guidance on facility registration: <http://www.fda.gov/downloads/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodDefenseandEmergencyResponse/UCM332460.pdf>. Guidance for industry on facility registration: <http://www.fda.gov/downloads/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/UCM324792.pdf>.
- c. See the list of reports and studies at <http://www.fda.gov/Food/FoodSafety/FSMA/ucm271961.htm>.
- d. Guidance and information regarding FSMA fees: <http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodSafety/ucm274176>; <http://www.fda.gov/Food/FoodSafety/FSMA/ucm257982.htm>; and <http://www.fda.gov/Food/FoodSafety/FSMA/ucm247559.htm#fees>. Fee rates: <http://www.regulations.gov/?source=govdelivery#!documentDetail;D=FDA-2012-N-0799-0001>.
- e. Request on whether the agency can safely establish threshold levels for major food allergens: [http://www.ofr.gov/OFRUpload/OFRData/2012-30123\\_PI.pdf?source=govdelivery](http://www.ofr.gov/OFRUpload/OFRData/2012-30123_PI.pdf?source=govdelivery).

- f. Draft guidance for the dietary supplement on the safety of new dietary ingredients: <http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/DietarySupplements/ucm257563.html>.
- g. For the *Seafood Hazard and Control Guidance*: <http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/Seafood/FishandFisheriesProductsHazardsandControlsGuide/default.htm>.
- h. Information describing how the agency identifies a high-risk facility: <http://www.fda.gov/Food/FoodSafety/FSMA/ucm295345.htm>.
- i. ICLN: <https://www.icln.org/>.
- j. IFT pilot projects: <http://www.fda.gov/Food/FoodSafety/FSMA/ucm270851.htm>. Types of foods for product tracing pilots: <http://www.fda.gov/Food/FoodSafety/FSMA/ucm247559.htm#ProductTracing>.
- k. Grants: <http://www.fda.gov/Training/ForStateLocalTribalRegulators/ucm274064.htm>. FSPCA: <http://www.fda.gov/Food/FoodSafety/FSMA/ucm284406>. *Federal Register* notice: <http://www.gpo.gov/fdsys/pkg/FR-2012-05-31/html/2012-13140.htm>.
- l. GAO report: <http://www.gao.gov/assets/600/593031.pdf>.
- m. Interim final rule: <http://www.regulations.gov/#!documentDetail;D=FDA-2011-N-0197-0001>.
- n. MOU on competitive grant program for food safety training and other projects: <http://www.fda.gov/AboutFDA/PartnershipsCollaborations/MemorandaofUnderstandingMOUs/DomesticMOUs/ucm261929.html>.
- o. CDC Integrated Food Safety Centers of Excellence: <http://www.cdc.gov/foodsafety/fsma.html#section399>.
- p. FDA's Reportable Food Registry (RFR) website: <http://www.fda.gov/Food/FoodSafety/FoodSafetyPrograms/RFR/default.htm>.
- q. Interim final rule regarding requirements for submitting prior notice of imported food, including food for animals: <http://www.regulations.gov/#!documentDetail;D=FDA-2011-N-0179-0001>.
- r. FDA, "Memoranda of Understanding and Other Cooperative Arrangements": <http://www.fda.gov/InternationalPrograms/Agreements/MemorandaofUnderstanding/default.htm?source=govdelivery>.
- s. FDA, *Report to Congress on the FDA Foreign Offices*: <http://www.fda.gov/Food/FoodSafety/FSMA/ucm291803.htm>.
- t. Joint anti-smuggling strategy: <http://www.fda.gov/downloads/ForIndustry/ImportProgram/UCM261739.pdf>.

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