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Food Safety Issues for the 114th Congress

Renée Johnson

Specialist in Agricultural Policy

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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.

Congress will likely continue to monitor FDA's implementation of the law and provide oversight over how some provisions are carried out and enforced, as well as FDA's coordination with other federal agencies, such as those in USDA and the Department of Homeland Security. Under FSMA, FDA is responsible for more than 50 regulations, guidelines, and studies; however, some FDA rules under FSMA have been substantially delayed, and it is uncertain whether full implementation of some provisions in the law will meet their expected deadlines. Regulations were to have been proposed or, in some cases, finalized within one to two years of enactment (roughly January 2012 and January 2013). Given delays in the rulemaking process, the Center for Food Safety filed suit in federal court against FDA and the Office of Management and Budget (OMB), citing the government's failure to implement several food safety regulations required by FSMA. By early 2014, FDA had proposed a majority of the regulations that constitute the food safety framework under FSMA, but there are continued delays in some rules, industry guidance, and reports as required under the law. FDA also re-proposed some aspects of four major proposed rules in September 2014. FDA has agreed to a new court-ordered schedule for issuing final FSMA regulations for many of the major rules between 2015 and 2016.

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

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

Background

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

Estimates of the economic costs associated with foodborne illness vary. Researchers at FDA report that health costs associated with foodborne illness in the United States caused by known viruses, bacteria, parasites, allergens, and marine biotoxins, as well as unspecified agents total an estimated \$36 billion annually.² Researchers at USDA report individual cost estimates for 15 pathogens that account for most (95%) of the illnesses and deaths from foodborne illnesses in the United States for which a specific pathogen cause can be identified, which when combined total more than \$15 billion annually.³ Most of these costs are attributable to estimated losses from five pathogens: nontyphoidal *Salmonella enterica* (\$3.7 billion), *Toxoplasma gondii* (\$3.3 billion), *Listeria monocytogenes* (\$2.8 billion), *Campylobacter* spp. (\$1.9 billion), and norovirus (\$2.3 billion). The USDA estimates update previous studies that reported that foodborne illness from 14 pathogens caused an estimated \$14.0 billion in cost of illness.⁴ Another study looking at the 31 pathogens for which CDC can identify a specific pathogen cause as well as unspecified agents estimates that together they cause a total economic burden of \$77.7 billion from foodborne illness

¹ CDC, "Estimates of Foodborne Illness in the United States," December 2010.

² T. Minor, A. Lasher, K. Klontz, et al., "The Per Case and Total Annual Costs of Foodborne Illness in the United States," *Risk Analysis*, January 2015.

³ S. Hoffman, B. McCollough, M. Batz, "Economic Burden of Major Foodborne Illnesses Acquired in the United States," forthcoming. See also "Cost Estimates of Foodborne Illnesses Data," USDA, Economic Research Service, <http://www.ers.usda.gov/data-products/cost-estimates-of-foodborne-illnesses.aspx>. Estimated in 2013 dollars.

⁴ S. Hoffmann, M. B. Batz, J. G. Morris, Jr., "Annual Cost of Illness and Quality-Adjusted Life Year Losses in the United States due to 14 Foodborne Pathogens," *Journal of Food Protection*, vol. 75, no. 7 (July 2012), pp. 1292-1302.

in the United States each year.⁵ Differences between the studies may be explained by the number of identified pathogens included; whether or not unidentified agents causing foodborne illness are included; and differences in analytical methods.

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.⁶

Both the Obama and Bush Administrations addressed food safety concerns. In 2007, then President Bush released the *Food Protection Plan of 2007* and *Action Plan for Import Safety* to address changes in food sources, production, and consumption. In 2009, President Obama established a Food Safety Working Group (FSWG) of Cabinet Secretaries and senior officials to provide advice on how to upgrade U.S. food safety laws, foster coordination throughout government, and ensure that food safety laws are effective and enforced. In 2010, as part of the FSWG's annual progress report, the Administration announced that it had taken steps to reduce the prevalence of certain food risks and implemented new food safety standards, among other actions. The HHS released a draft of its plans regarding specific food safety goals, setting percentage reduction goals for major food contaminants as well as targeted reductions in the number of cases each year by 2020.⁷

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.⁸ CDC reports that more than 1,000 foodborne outbreaks are investigated by local and state health departments each year.⁹ Overall, from available outbreak data, CDC reports that roughly one-half of all outbreaks involved meat, dairy, fish/seafood, 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,

⁵ R. Scharff, "Economic Burden from Health Losses due to Foodborne Illness in the United States," *Journal of Food Protection*, vol. 75, no. 1 (January 2012), pp. 123-131.

⁶ GAO, *High Risk Series: An Update* (GAO-15-290), February 2015.

⁷ FDA, "Strategic Priorities 2011–2015: Responding to the Public Health Challenges of the 21st Century," draft, September 29, 2010. Part of the broader Healthy People 2020 initiative at <http://www.healthypeople.gov/2020>.

⁸ A foodborne outbreak is when two or more people get the same illness from the same contaminated food or drink. See CDC, "Multistate Foodborne Outbreak Investigations" (<http://www.cdc.gov/foodsafety/outbreaks/>); FDA, "Outbreak Investigations" (<http://www.fda.gov/food/recallsoutbreaksemergencies/outbreaks/ucm272351.htm>); and FDA, "Recalls, Market Withdrawals, and Safety Alerts" (<http://www.fda.gov/Safety/Recalls/default.htm>).

⁹ CDC, "Food Safety," <http://www.cdc.gov/foodsafety/facts.html>.

or through cross-contamination. Other foods associated with foodborne illness include shellfish eaten raw and also fresh produce, including unpasteurized juices.¹⁰

Some foodborne outbreaks affect multiple states, depending on how widely the food associated with the outbreak is distributed. CDC reports that 103 multi-state foodborne outbreaks occurred during the five-year period from 2008 to 2012, an increase from previous years (**Figure 2**), thus continuing to raise questions about the adequacy of the U.S. food system's safeguards for ensuring the safety of both domestically produced foods and imported foods.

Examples of foodborne outbreaks involving FDA-regulated foods include multi-state outbreaks in 2012 of *Salmonella* infections, involving peanut butter and cantaloupe, and *E. coli* infections linked to raw clover sprouts; multi-state outbreaks in 2011 of listeriosis linked to cantaloupe; the 2010-2011 multi-state recall of *Salmonella*-contaminated sprouts; and a 2010 nationwide recall of more than 500 million eggs associated with increased cases of *Salmonella* infection, among other outbreaks.¹¹

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.¹²

CDC regularly tracks national foodborne outbreak data from local and state public health departments and makes these data publically available online.¹³ 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.¹⁴

¹⁰ 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>.

¹¹ FDA, "Outbreak Investigations," <http://www.fda.gov/food/recallsoutbreaksemergencies/outbreaks/ucm272351.htm>. See also CRS Report R43794, *Food Recalls and Other FDA Administrative Enforcement Actions*, and CRS Report R40916, *Food Safety: Foodborne Illness and Selected Recalls of FDA-Regulated Foods*.

¹² FSIS, "FSIS Recalls," http://www.fsis.usda.gov/FSIS_Recalls/index.asp. See also CRS Report RL34313, *The USDA's Authority to Recall Meat and Poultry Products*.

¹³ CDC, Foodborne Outbreak Tracking and Reporting, <http://www.cdc.gov/foodsafety/fdoss/index.html>.

¹⁴ CDC, "Foodborne Outbreak Online Database (FOOD)," <http://wwwn.cdc.gov/foodborneoutbreaks/>.

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

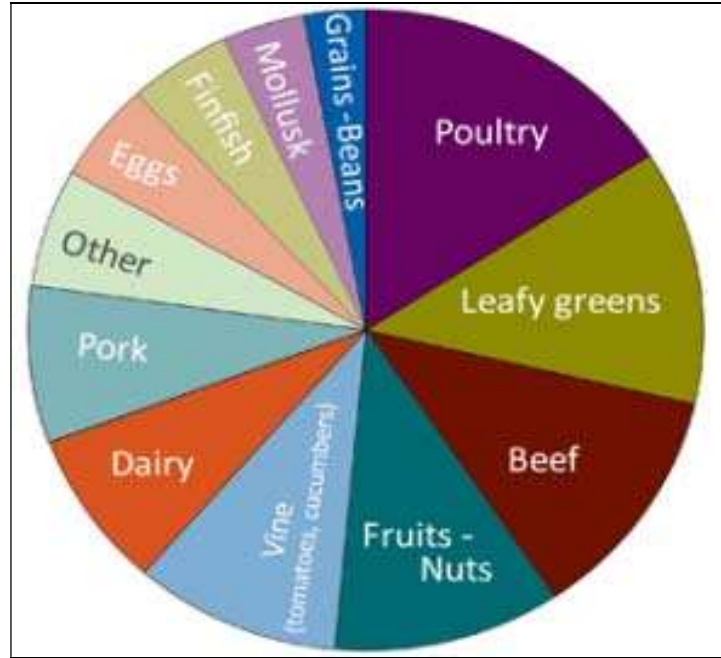
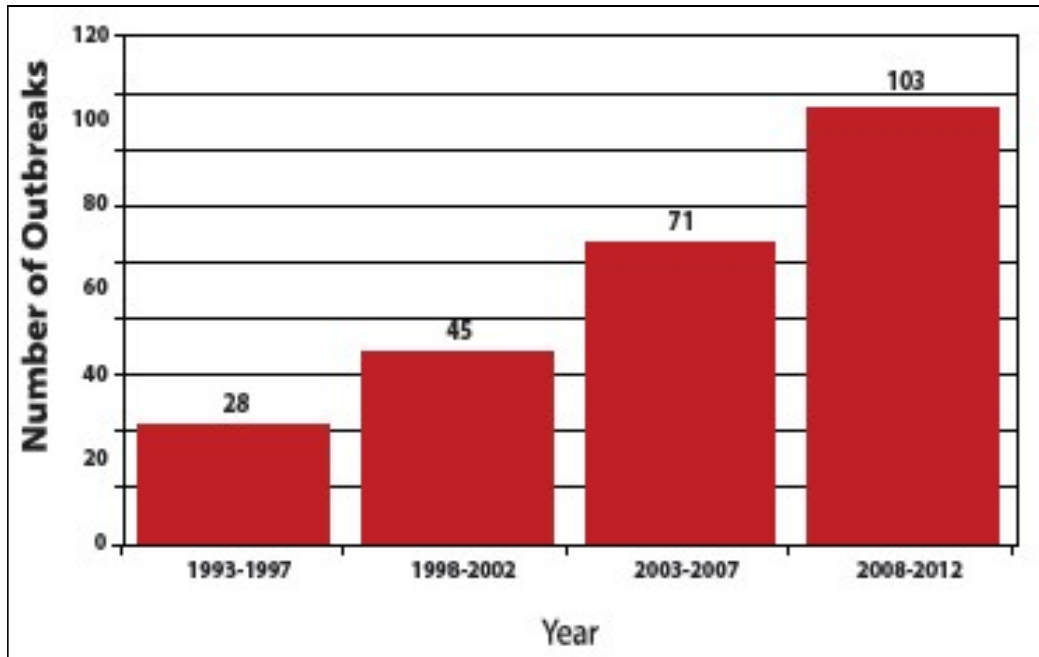


Figure 2. Multistate Foodborne Outbreaks, 1989-2008



Source: CDC, *CDC and Food Safety*, March 2014, <http://www.cdc.gov/foodborneburden/PDFs/CDC-and-Food-Safety.pdf>.

Notes: Data in **Figure 1** and **Figure 2** are based on a total of 81,757 foodborne outbreak-associated illnesses, 2008–2012, as reported by the CDC’s National Outbreak Reporting System.

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:¹⁵

- 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)¹⁶ O157 (4%). The top five pathogens contributing to annual foodborne illnesses resulting in death are *Salmonella*, nontyphoidal (28% of deaths), *Toxoplasma gondii* (24%), *Listeria monocytogenes* (19%), norovirus (11%), and *Campylobacter* spp. (6%).¹⁷

Table 1. Number of Foodborne Illnesses, Hospitalizations, and Deaths
(United States, estimated annual)

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

Source: CDC, “Estimates of Foodborne Illness in the United States,” December 2010, <http://www.cdc.gov/foodborneburden/>. See also CDC’s fact sheet dated February 2011, Table I, http://www.cdc.gov/foodborneburden/PDFs/FACTSHEET_A_FINDINGS.pdf.

¹⁵ CDC, “Estimates of Foodborne Illness in the United States,” December 2010, <http://www.cdc.gov/foodborneburden/>. See also CDC’s fact sheet dated February 2011.

¹⁶ 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.

¹⁷ CDC, “Estimates of Foodborne Illness in the United States,” December 2010.

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

Other CDC reports indicate that there were 831 foodborne disease outbreaks in 2012.¹⁸ These outbreaks resulted in 14,972 illnesses, 794 hospitalizations, and 23 deaths.

Norovirus was the most common disease, accounting for 41% of outbreaks and 45% of illnesses. *Salmonella* was the second-most common, accounting for 25% of outbreaks and 33% of illnesses. Beef, poultry, and finfish were the commodities associated with the largest number of foodborne outbreaks. Fish, vegetable row crops, and dairy were the most commonly implicated single food categories in outbreaks in which a single food category could be implicated.

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 (see **Figure 3**). CDC reports:¹⁹ "The incidence of laboratory-confirmed *Salmonella* infections was lower in 2013 than 2010-2012, whereas the incidence of *Vibrio* infections increased. No changes were observed for infection with *Campylobacter*, *Listeria*, STEC O157, or *Yersinia*, the other pathogens transmitted commonly through food."

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.²⁰ State and local food safety authorities collaborate with federal agencies for inspection and other food safety functions, and they regulate retail food establishments. This organizational complexity, coupled with trends in U.S. food markets—for example, increasing imports as a share of U.S. food consumption and increasing consumption of fresh, often unprocessed, foods—pose ongoing challenges to ensuring food safety.

Although numerous federal agencies have some responsibility, primary responsibility for food safety rests with the FDA and the USDA. FDA at the U.S. Department of Health and Human Services (HHS) is responsible for ensuring that all domestic and imported food products—except for most meats and poultry—are safe, nutritious, wholesome, and accurately labeled. FDA also has oversight of all seafood, fish, and shellfish products.²¹ USDA's Food Safety and Inspection Service (FSIS) regulates most meat and poultry and some egg and fish products. The division of

¹⁸ CDC, "Surveillance for Foodborne Disease Outbreaks—United States, 2012 Annual Report," May 30, 2014, <http://www.cdc.gov/foodsafety/pdfs/foodborne-disease-outbreaks-annual-report-2012-508c.pdf>.

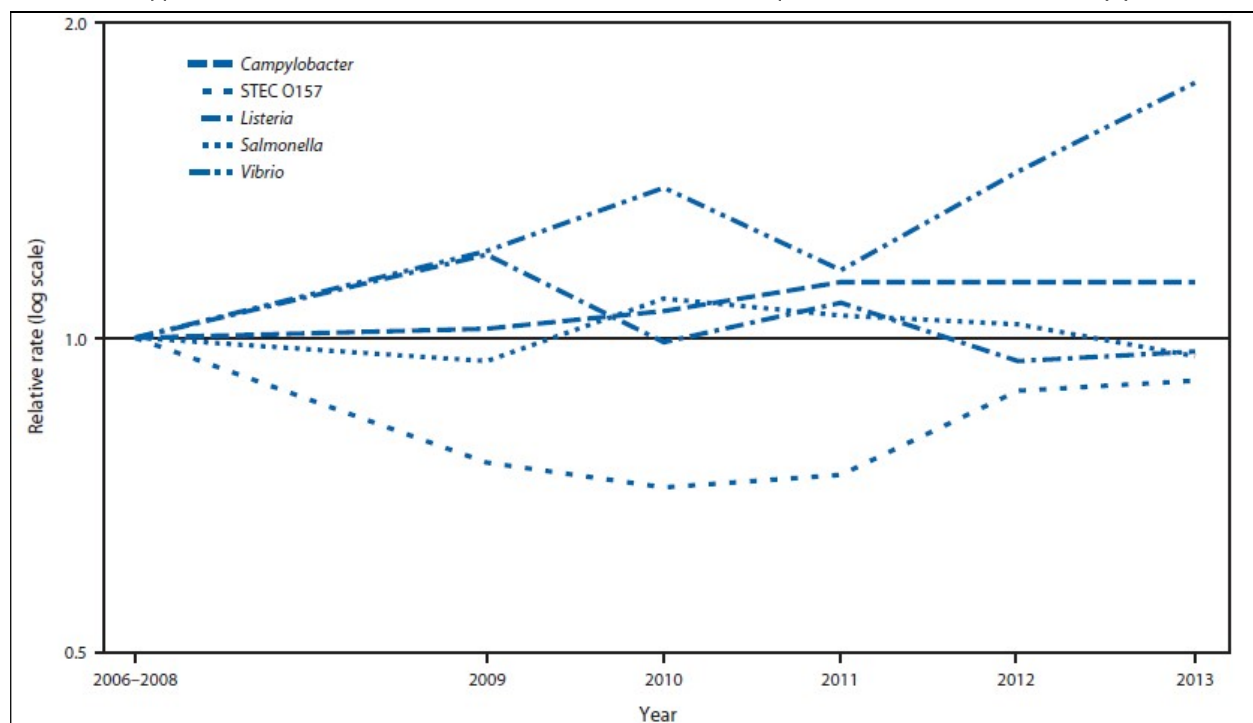
¹⁹ CDC, "Incidence and Trends of Infection with Pathogens Transmitted Commonly Through Food—Foodborne Diseases Active Surveillance Network, 10 U.S. Sites, 2006–2013," *Morbidity and Mortality Weekly Report* (MMWR), vol. 63, no. 15 (April 2014), pp. 328-332.

²⁰ GAO, *Food Safety Working Group Is a Positive First Step but Governmentwide Planning Is Needed to Address Fragmentation*, GAO-11-289, March 2011. Also see Institute of Medicine, National Research Council (IOM/NRC), *Enhancing Food Safety: The Role of the Food and Drug Administration*, 2010.

²¹ 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), which was reconfirmed in the 2014 farm bill (P.L. 113-79, §12106). FSIS has not yet fully implemented the catfish program.

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

Figure 3. Relative Rates of Laboratory-Confirmed Infections, Selected Pathogens
Campylobacter, E. coli O157, Listeria, Salmonella, and Vibrio, compared with 2006–2008 rates, by year



Source: CDC, “Incidence and Trends of Infection with Pathogens Transmitted Commonly Through Food—Foodborne Diseases Active Surveillance Network, 10 U.S. Sites, 2006–2013,” *Morbidity and Mortality Weekly Report* (MMWR), vol. 63, no. 15 (April 2014), pp. 328-332, http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6315a3.htm?s_cid=mm6315a3_w.

Notes: Data are from CDC’s Foodborne Diseases Active Surveillance Network (“FoodNet”). For 2013, based on FoodNet-identified 19,056 cases of infection, 4,200 hospitalizations, and 80 deaths.

In addition, the majority of both total federal funding and total staffing is with FSIS and FDA. FSIS’s FY2015 budget is about \$1.0 billion in appropriated funds plus another roughly \$160 million in industry-paid user fees annually.²² In recent years, the balance of funding for food safety activities between FDA and USDA has started to shift. Congressional appropriations for FDA have increased, more than doubling from \$435.5 million in FY2005 to \$903.4 million in FY2015, with another roughly \$17 million authorized user fees.²³ Thus, FSIS receives a larger share of the two agencies’ combined food safety budget, although FSIS is responsible for between 10% and 20% of the U.S. food supply, while FDA is responsible for the remainder.²⁴ Staffing

²² USDA, FSIS Explanatory Notes, http://www.obpa.usda.gov/explan_notes.html.

²³ HHS, FDA Budget Justifications, <http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/BudgetReports/default.htm>.

²⁴ 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 (continued...)

levels also vary among the two agencies: FSIS staff number around 9,400 full-time equivalents (FTEs), while FDA staff working on food-related activities number about 3,800 FTEs (FY2014 estimates).²⁵

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

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 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 regarding foreign companies that supply food imports to the United States. FSMA does not directly address meat and poultry products under the jurisdiction of USDA.

FDA has identified five key elements of FSMA:²⁶

- **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);²⁷ giving FDA access to industry records and food safety plans; and requiring certain testing be conducted by accredited labs.
- **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;²⁸ establishing pilot projects so FDA can enhance its product

(...continued)

Research Service (ERS) on U.S. per capita food consumption at <http://www.ers.usda.gov/data/foodconsumption/>.

²⁵ FSMA, P.L. 111-353, §401. By fiscal year, staff level increases were authorized to a total of not fewer than 4,000 staff members (FY2011); 4,200 staff (FY2012); 4,600 staff (FY2013); and 5,000 staff (FY2014).

²⁶ 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)."

²⁷ 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).

²⁸ If a facility's food is found to have a "reasonable probability of causing serious adverse health consequences or (continued...)

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 help ensure that food imports meet U.S. food safety standards. Examples include requiring 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 authority to improve training of state, local, territorial, and tribal food safety officials. Examples include requiring FDA to develop and implement strategies to enhance the food safety capacities of state and local agencies through multi-year grants, as well as strategies to enhance the capacities of foreign governments and their industries; and giving FDA the authority to rely on inspections of other federal, state, and local agencies in meeting its increased inspection mandate for domestic facilities.

FSMA authorized additional appropriations and staff for FDA’s future food safety activities. The Congressional Budget Office (CBO) estimated that implementing the newly enacted law could increase net federal spending subject to appropriations by \$1.4 billion over a five-year period (FY2011-FY2015).²⁹ FSMA also authorized an increase in FDA staff, reaching 5,000 in FY2014.

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

Key Issues for the 114th Congress

The 114th 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 114th 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-therapeutic 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.

(...continued)

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.

²⁹ 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.

FSMA Oversight and Implementation

FSMA is the largest expansion of FDA's food safety authorities since the 1930s, and includes provisions requiring the agency to establish and enforce new preventive controls and food safety plans at some food processing facilities and farms, among numerous other oversight capabilities of both domestic and foreign food and feed companies.

Along with general oversight of FSMA's key provisions, many in Congress have actively followed 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.³⁰ These provisions will exempt from federal regulation some small-sized farms and food processors that sell directly to consumers (FSMA, §103 and §105). These exemptions require additional rulemaking by FDA to determine what constitutes a "small" and "very small" business under the new law. Some public health groups may remain vigilant of how these exemptions are implemented, particularly for growers and processors of certain perceived "high-risk" foods (to be determined by the HHS Secretary), although these operations would be subject to oversight by state and local authorities and their exemption can be withdrawn by the FDA in the event of a foodborne illness. Some agribusiness groups also remain opposed to these exemptions because of broader industry concerns about the need to preserve consumer confidence in the safety of all marketed produce; another industry concern is whether small foreign producers might also be exempt, if small U.S. producers are exempt (given prevailing U.S. equivalency standards).

Under FSMA, FDA is responsible for more than 50 regulations, guidelines, and studies.³¹ However, FDA action on some major FSMA provisions—including rules specifying the requirements and conditions for establishing preventive controls in food facilities, food safety standards for produce growers, and requirements for food importers, among other provisions—have yet to be finalized, and most rules have been 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 have been submitted within 18 months of enactment (mid-2012). (FSMA was signed into law on January 4, 2011.)

Several factors appear to have contributed to the delay in implementing FSMA. Substantial delays in publication of several FSMA proposed rules were reportedly due to rules being held up, often for months, by the Office of Management and Budget's (OMB's) review process. Delays in the rulemaking process also resulted from FDA granting a number of extensions in the public comment and response period for many of the major FSMA proposed rules. These extensions were requested by a wide range of stakeholders, given the complexity of the regulations as well as FDA's delayed release of other related FSMA rules that some groups argued needed to be

³⁰ For more information, see CRS Report RL34612, *Food Safety on the Farm*.

³¹ For information on the agency's activities and progress, see FDA's FSMA rules and guidance web page, <http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm359436.htm>.

considered together as a full regulatory package. Implementation of some provisions has also required coordination with other federal agencies, including Department of Homeland Security, USDA, and EPA. Further implementation delays have resulted from FDA's decision to re-propose some key provisions of four major FSMA regulations,³² which many Members of Congress and some key industry stakeholders have broadly supported. Finally, resources and the availability of discretionary appropriations might also have affected FDA's rollout and implementation of FSMA.

Given delays in the rulemaking process, the Center for Food Safety filed suit in federal court against FDA and OMB, citing the government's failure to implement several food safety regulations required by FSMA. FDA filed a motion to dismiss the complaint against the agency, which was denied by the court in April 2013. FDA also filed a motion to reconsider, asking the court to extend the implementation timeline for two FSMA-required rules, which was also denied. Under a February 2014 agreement between FDA and the Center for Food Safety, the agency must issue the regulations under a court-order schedule, as follows:³³

- preventative controls for both human food and animal food (FSMA §103(a) and (c)): August 30, 2015;
- imported food and foreign suppliers, including the Foreign Supplier Verification Program (FSMA §301(a)) and Accreditation of Third Party Auditors (FSMA §307): October 31, 2015;
- produce safety (FSMA §105(a)): October 31, 2015;
- sanitary transportation practices for food and feed (FSMA §111): March 31, 2016;
- intentional adulteration of food (FSMA §106(b)): May 31, 2016.

This schedule further pushes back the implementation dates for final FSMA regulations beyond the dates originally mandated by Congress in the enacted law (P.L. 111-353). Reportedly, an FDA official indicated in September 2014 that full implementation of FSMA would likely take another 10 years, the amount of time needed to “reasonably expect all the rules to be working.”³⁴

To date, FDA has not yet issued final rules and guidance for many of the regulations required under certain key sections of FSMA. For more detailed information on implementation of specific law provisions and FDA-reported actions taken to date, see CRS Report R43724, *Implementation of the FDA Food Safety Modernization Act (FSMA, P.L. 111-353)*.

Funding FSMA Implementation

Food safety issues and FDA's implementation of FSMA also continue to be an ongoing issue for both House and Senate appropriators within the annual Agriculture appropriations process, given current budgetary constraints. Such 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

³² Includes regulations covering preventative controls for both human food and animal food; producer safety standards; and foreign supplier verification program.

³³ The joint consent decree is available at <http://www.centerforfoodsafety.org/>.

³⁴ “Food Safety Law to Take a Decade to Implement, FDA Says,” *CQ News*, September 9, 2014.

and imported foods.³⁵ Among the many provisions of FSMA is the expansion of FDA's authority to increase inspection of domestic and foreign food facilities, to increase surveillance of foodborne illness and outbreak response, to conduct mandatory recall of contaminated foods, and to enforce new requirements at food facilities and produce operations. FSMA states a "goal of not fewer than ... 5,000 staff members in fiscal year 2014" (FSMA, §401), an increase from estimated FDA field staff of about 3,400 FTEs (full-time equivalents) in 2011. CBO estimated that implementing the law could increase net federal spending subject to appropriation by about \$1.4 billion over a five-year period (FY2011-FY2015); collections from possible revenue and direct spending increases from new criminal penalties would be "insignificant, yielding a negligible net impact in each year."³⁶ Given the current budgetary climate, funding to undertake many federal activities in FSMA is uncertain. Although the law authorized appropriations when it enacted FSMA, it did not provide the actual funding needed for FDA to perform these activities. These funding decisions are guided by the House and Senate Appropriations Committees, which annually fund FDA's activities in the Agriculture appropriations bill. FDA officials have indicated funding remains a concern, and ongoing efforts to implement FSMA will likely need to rely on state regulators to help enforce some of the major rules under the law.³⁷

In recent years, the Administration's budget requests have projected the need for additional funds for FDA, anticipating a total need of about \$1.1 billion, consisting of approximately \$0.9 billion in appropriations for FDA's food program and another more than \$0.2 billion in requested new user fees for the year.³⁸ Appropriated funding for FDA's food program in the FY2015 Consolidated Appropriations Act (P.L. 113-235) totaled \$903.4 million, along with another \$17 million in FSMA-mandated user fees.³⁹ Congressional appropriators have not approved the Administration's request to implement additional new user fees to fund FDA's food program, including a proposed new food establishment registration and inspection fee. Other proposed or expected fees in addition to appropriated funds in the Administration's budget request include food import, international courier, and food contact notification fees. FDA justified its requested increase based on the need to implement the various elements of FSMA.⁴⁰

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.⁴¹ The need for new user fees to provide additional resources to support FDA's food safety mission has been raised by the Obama Administration in

³⁵ See for example Robert Wood Johnson Foundation, *Ready or Not? Protecting the Public's Health from Diseases, Disasters, and Bioterrorism*, December 2012.

³⁶ 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.

³⁷ H. Bottenmiller, "Sweeping Food Safety Rules Raise More Concerns About FDA Funding," *Food Safety News*, January 8, 2013.

³⁸ Data from annual FDA Budget Explanatory Notes for Committee on Appropriations, various years, <http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/BudgetReports/default.htm>.

³⁹ Fees authorized under FSMA include food export certification, food reinspection, food recall, and other user fees.

⁴⁰ See, for example, HHS, "FY2013 FDA: Justification of Estimates for Appropriations Committees," p. 30; "Hamburg Defends Request for Food Registration Fee Facing Lawmakers' Criticism," *InsideHealthPolicy.com*, February 29, 2012; and "Hamburg: Slow Going on FDA User Fees for Food Companies," *Hagstrom Report*, April 19, 2012.

⁴¹ See, for example, Robert Wood Johnson Foundation, *Ready or Not? Protecting the Public's Health from Diseases, Disasters, and Bioterrorism*, December 2012.

consecutive statements of administration policy (SAPs) regarding annual appropriations.⁴² Although Congress has added to FDA's budget for its Foods Program in the past few years, agency officials claim it will need an additional \$400 million to \$450 million more per year above its FY2012 base to fully implement FSMA.⁴³ 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.

Other budgetary concerns regarding FSMA implementation continue to be regularly noted by congressional appropriators, along with recommendations for FDA. Examples are provided in CRS Report R43669, *Agriculture and Related Agencies: FY2015 Appropriations*, and CRS Report R43110, *Agriculture and Related Agencies: FY2014 and FY2013 (Post-Sequestration) Appropriations*.

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 (FSMA §105(a)). 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.

In January 2013, FDA proposed its produce rule.⁴⁴ 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.”⁴⁵ Not covered by the proposed rule are foods that are rarely consumed raw, 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.⁴⁶

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.⁴⁷ The rule addresses five identified routes of potential contamination: (1) agricultural water used

⁴² Executive Office of the President, “Statement of Administration Policy,” Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act for FY2013 and FY2014.

⁴³ FDA, *Building Domestic Capacity to Implement the FDA Food Safety Modernization Act (FSMA)*, May 2013. FY2012 appropriations totaled \$866.1 million, not including revenue from user fees.

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

⁴⁵ *Ibid.*

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

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

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

Since the produce rule was proposed, FDA has extended the public comment period numerous times. FDA has also conducted outreach and public meetings and released web videos and written materials. In March 2013, FDA corrected technical errors to the proposed rule. In August 2013, FDA announced it would prepare an environmental impact statement (EIS) to evaluate the potential environmental effects of the proposed rule for produce safety. Also, in December 2013, FDA announced it would re-propose some key provisions of the produce rule, as well as the regulations regarding preventive controls affecting food facilities (FSMA §103).⁴⁸ Provisions that FDA plans to change “include water quality standards and testing, standards for using raw manure and compost, certain provisions affecting mixed-use facilities, and procedures for withdrawing the qualified exemption for certain farms.”⁴⁹ FDA published its re-proposal in September 2014.⁵⁰ In addition, FDA entered into a cooperative agreement with the National Association of State Departments of Agriculture (NASDA) to provide information to help plan and carry out implementation of FSMA's national produce safety rule, in partnership with state regulatory agencies.⁵¹ The court-ordered deadline for final regulations regarding produce safety (FSMA §105(c)) is October 31, 2015.

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

⁴⁹ *Ibid.*

⁵⁰ FSMA rules are at <http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm359436.htm>.

⁵¹ FDA, “FDA Announces Cooperative Agreement to Implement National Produce Safety Rule,” September 16, 2014.

USDA’s “National Leafy Green Marketing Agreement” Proposal

USDA had been considering a separate proposal for selected produce growers to develop and implement USDA-administered requirements, reflecting FDA- and USDA-recommended food safety practices for leafy greens. This proposal was published in April 2011 by USDA’s Agricultural Marketing Service (AMS) as part of its “National Marketing Agreement Regulating Leafy Green Vegetables” (76 *Federal Register* 24292, April 29, 2011).

USDA’s proposed rule covered the handling of fresh leafy green vegetables—spinach, lettuce, cabbage—only. The AMS proposal had been under consideration at USDA for the past few years and reflected an industry-led effort to establish a voluntary program requiring compliance of its signatories (marketing agreement), including importers, in meeting certain commercial food quality and safety requirements. Following the enactment of FSMA, it was unclear how USDA’s proposed voluntary efforts for leafy greens would interact with FDA’s rulemaking process to develop mandatory safety standards for a wider range of fruits and vegetables subject to FSMA.

In December 2013, AMS announced it was terminating the rulemaking to establish a marketing agreement for leafy green vegetables, in part because FDA had published and was moving forward on its proposed produce rule (78 *Federal Register* 73111, December 5, 2013).

Meat and Poultry Inspection⁵²

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 egg products, excluding shell eggs. 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.⁵³ Food safety incidents and concerns regarding USDA-regulated meat and poultry products are similarly well documented. In addition, a series of bills were introduced and debated in the 111th and 112th Congress regarding the safety of meat and poultry products, some of which were reintroduced in the 113th Congress (including S. 1502 and H.R. 4966). Congress may consider reintroducing these bills in the 114th Congress.

In August 2014, USDA finalized its proposed rule to modernize the poultry inspection system, as part of the New Poultry Inspection System (NPIS).⁵⁴ Under NPIS, poultry plant personnel will be responsible for carcass sorting, and federal inspectors will be stationed further down the line. FSIS inspectors will focus on pathogen reduction and offline food safety inspection activities. NPIS is voluntary, and implementation will be phased in. Poultry slaughter plants may opt to continue to operate under current inspection systems; however, all poultry plants are required to expand pathogen control and testing. The proposed rule allowed for increases in line speeds in poultry plants, but the final rule left speeds unchanged. Unchanged line speeds could potentially sway some poultry plants to stay with their current inspection system.⁵⁵ Throughout the 113th Congress, there has been debate about USDA’s rule, with some Members of Congress and food safety advocates opposing USDA’s proposed changes as compromising food safety.⁵⁶ Other Members of Congress have supported USDA’s push to modernize poultry inspection.⁵⁷ On

⁵² For more direct assistance, contact CRS Analyst Joel L. Greene (jgreene@crs.loc.gov, 7-9877).

⁵³ See, for example, Statement by Representative Rosa DeLauro, *Congressional Record*, December 21, 2010, p. H8887.

⁵⁴ 79 *Federal Register* 49566, August 21, 2014. The proposed rule was published in January 27, 2012 (77 *Federal Register* 4408).

⁵⁵ G. Thornton, “Incentives Missing in New Poultry Inspection System, Says NCC’s Peterson,” *WATTAgNet.com*, August 21, 2014.

⁵⁶ Letter from several Members of Congress to USDA Secretary Tom Vilsack, March 17, 2014.

⁵⁷ Letter from several U.S. Senators to USDA Secretary Tom Vilsack, December 12, 2013.

September 11, 2014, Food and Water Watch filed suit in federal court to stop USDA from implementing NPIS.⁵⁸

Other food safety issues regarding meat and poultry products include the safety of the meat and poultry supplied to school feeding programs; FSIS protocols for handling food recalls and related enforcement issues; improved meat traceability capabilities; FSIS budgetary and staffing constraints; humane slaughter and animal welfare concerns; and the continued implementation of state meat inspection rules.⁵⁹ In May 2013, USDA's Office of the Inspector General released a report critical of USDA's existing enforcement policies, including those under the HACCP-based Inspection Models Project (HIMP), the basis for NPIS.⁶⁰ In August 2013, GAO released a study recommending that USDA collect and analyze information to determine if the agency's young hog pilot project is meeting its purpose, and to clearly disclose to the public limitations in the information used for the proposed rule to modernize poultry slaughter inspections.⁶¹ In November 2014, FSIS released its final evaluation of market hog HIMP plants. FSIS found that HIMP plants are performing as well as comparable large non-HIMP market hog establishments.⁶²

Antibiotic Use in Animal Agriculture⁶³

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-therapeutic purposes in food animals. Antibiotics are added to feed for some types of food-producing animals not only to treat and prevent diseases, but also to improve growth and efficient use of feed rations. Some public health advocates argue that non-medical uses in food animals should be limited to drugs that are not useful in human medicine. Others oppose this approach, arguing that animal production may not be commercially viable without the drugs' routine use, and that the linkage between such use and antimicrobial resistance in humans lacks a strong scientific basis. In the past several Congresses, bills have been introduced that would curtail the non-medical use of antibiotics in animal feeds, including the Preservation of Antibiotics for Medical Treatment Act (PAMTA) introduced in both the House and Senate. These bills were offered again in the 112th Congress (H.R. 965; S. 1211) and in the 113th Congress (H.R. 1150; S. 1256). Congress may consider reintroducing these bills in the 114th Congress.

In 2013, the Food and Drug Administration (FDA) issued guidance for industry that defines judicious use of antibiotics, asks animal drug companies voluntarily to stop labeling antibiotics for production uses within three years, and calls for more veterinary oversight.⁶⁴ FDA claims a

⁵⁸ M. Fielding, "Group Sues to Halt New Poultry Rules," *Meatingplace*, September 12, 2014.

⁵⁹ For more information, see CRS Report RL32922, *Meat and Poultry Inspection: Background and Selected Issues*.

⁶⁰ USDA, OIG, *Food Safety and Inspection Service—Inspection and Enforcement Activities at Swine Slaughter Plants*, Audit Report 24601-0001-41, May 2013.

⁶¹ GAO, *More Disclosure and Data Needed to Clarify Impact of Changes to Poultry and Hog Inspections*, GAO-13-775, August 22, 2013.

⁶² FSIS, "Evaluation of HACCP Inspection Models Project (HIMP) for Market Hogs," final report, November 2014.

⁶³ For more direct assistance, contact CRS Analysts Joel L. Greene (jgreene@crs.loc.gov, 7-9877) and Sarah A. Lister (slister@crs.loc.gov, 7-7320).

⁶⁴ FDA, Guidance for Industry #209, *The Judicious Use of Medically Important Antimicrobial Drugs in Food-Producing Animals*, April 2012; and FDA, Guidance for Industry #213, *New Animal Drugs and New Animal Drug* (continued...)

voluntary approach is the fastest and most efficient way to tighten control over the use of medically important antibiotics. Regulatory action may require FDA to conduct product-by-product evaluations that could require more time and resources. While some stakeholders remain skeptical of FDA's voluntary approach, the livestock and poultry industry have been supportive.

In September 2014, the President's Council of Advisors on Science and Technology released a report on antibiotic resistance and the Administration created through executive order an Interagency Task Force for Combating Antibiotic-Resistant Bacteria.⁶⁵ In a letter to the task force, some Members of Congress raised questions about how the Administration will address concerns that FDA does not have the authority or means to properly address antibiotic use in food producing animals through its voluntary guidance.⁶⁶

Seafood and Fisheries Products⁶⁷

Many food safety changes enacted in FSMA did not specifically address seafood and fisheries products.⁶⁸ Prior to FSMA, domestic and imported fish and shellfish were already regulated under a system of risk prevention controls known as HACCP (for "Hazard Analysis and Critical Control Points"). However, FSMA did include some provisions affecting domestic and imported seafood products. These include interagency agreements to improve seafood safety by examining and testing seafood, coordinating inspections, standardizing data, modifying existing processes, sharing enforcement and compliance information, and conducting joint training and outreach (FSMA, §201); requirements for guidance related to post-harvest processing of raw oysters (FSMA, §114); and inspections of foreign processing facilities by the Secretary of Commerce to assess practices and processes used in connection with seafood production (FSMA, §306). In addition, a number of issues related to seafood continue to be debated in Congress. These include further strengthening of federal coordination among programs concerned with seafood safety, preventing seafood fraud, using third parties to certify the safety of imported seafood, and developing a system to trace domestic and imported seafood from producer to consumer. (For more information on efforts to address seafood fraud, see the following section, "Fraud Concerning Food and Food Ingredients.")

Fraud Concerning Food and Food Ingredients

Food fraud (also referred to as "economically motivated adulteration," or EMA) refers to the act of defrauding buyers of food and food ingredients for economic gain—whether they be consumers or food manufacturers, retailers, and importers—and has vexed the food industry throughout history. Foods and food ingredients commonly associated with food fraud include

(...continued)

Combination Products Administered in or on Medicated Feed or Drinking Water of Food-Producing Animals: Recommendations for Drug Sponsors for Voluntarily Aligning Product Use Conditions with GFI #209, December 2013. For information, see CRS Report IF00017, *Antibiotic Use in Food Animals: FDA's Current Activities (In Focus)*.

⁶⁵ For details, see White House Blog, "New Executive Actions to Combat Antibiotic Resistance and Protect Public Health," September 18, 2014, <http://www.whitehouse.gov/blog/2014/09/18/new-executive-actions-combat-antibiotic-resistance-and-protect-public-health>.

⁶⁶ "Three Senators Have Questions for Interagency Antibiotics Task Force," *Food Safety News*, December 17, 2014.

⁶⁷ For more direct assistance, contact CRS Analyst Harold F. Upton (hupton@crs.loc.gov, 7-2264).

⁶⁸ For more information see CRS Report RS22797, *Seafood Safety: Background and Issues*.

olive oil, fish and seafood, honey, milk and dairy products, meat products, grain-based foods, fruit juices, wine and alcoholic beverages, organic foods, spices, coffee, and tea, and some highly processed foods.

Although the vast majority of food fraud incidents do not pose a public health risk, a few fraud cases have resulted in actual or potential public health risks. Perhaps the most widely cited, high-profile cases have involved the addition of melamine to high-protein feed and milk-based products to artificially inflate protein values in products that may have been diluted. For example, in 2007, evidence emerged that adulterated pet food ingredients from China had caused the deaths of a large number of dogs and cats in the United States. This was followed by reports that melamine-contaminated baby formula had sickened an estimated 300,000 Chinese children, killing a reported 6 infants. Other reports indicate that fish and seafood fraud may be widespread in some markets, consisting mostly of the mislabeling or substitution of a higher-valued species with something different from and inferior to the expected species, possibly with a fish species that could be associated with some types of food poisoning or exposure to certain allergens. Substitution of olive oil with other types of seed, legume, or nut oils could have unintended consequences if consumed by those with certain food allergies. Other fraud cases might not initially appear to involve intentional adulteration but may do so on closer examination. Charges of fraud were part of the federal criminal indictment charging former officials of the Peanut Corporation of America with numerous offenses in connection with the *Salmonella* outbreak in 2009—which killed 9 people and sickened 700—since company officials were found to have sold and distributed products known to be contaminated.

FSMA does not directly address food fraud or EMA; however, some of its provisions may have application to EMA even though these provisions may have originated as part of an overall food defense strategy.⁶⁹ These include provisions regarding “Protection Against Intentional Adulteration” (FSMA §106) and provisions regarding preventive controls (FSMA §103), among other provisions. FSMA Section 106 requires FDA to issue regulations to protect against the intentional adulteration of food, such as “specifying appropriate science-based mitigation strategies or measures to prepare and protect the food supply chain from intentional adulteration at specific vulnerable points.”⁷⁰ FDA’s proposed regulations covering intentional adulteration (FSMA §106) were published in December 2013 and represent the first time FDA has proposed a regulatory approach for preventing intentional adulteration of food.⁷¹ Other changes were published in FDA’s re-proposal of key regulations in September 2014.⁷² The court-ordered deadline for final regulations regarding the intentional adulteration (FSMA §106(b)) is May 31, 2016.

Other ongoing efforts are intended to address fish and seafood fraud. In June 2014, the Obama Administration initiated a presidential task force on seafood fraud, calling for the establishment of a “comprehensive framework to combat illegal, unreported, and unregulated fishing [IUU] and

⁶⁹ Food defense also refers to intentional contamination, but is generally motivated by the desire to cause harm or damage (e.g., agro-terrorism) and might not be economically motivated. For additional information, see section titled “Food Defense” in CRS Report R42985, *Issues in Homeland Security Policy for the 113th Congress*, and CRS Report RL34160, *The National Bio- and Agro-Defense Facility: Issues for Congress*. For more direct assistance, contact CRS Analysts Sarah A. Lister (slister@crs.loc.gov, 7-7320) or Jim Monke (jmonke@crs.loc.gov, 7-9664).

⁷⁰ FDA, “Frequently Asked Questions,” <http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm247559.htm>.

⁷¹ For more information, see FDA, “Focused Mitigation Strategies to Protect Food Against Intentional Adulteration,” December 2013, <http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm378628.htm>.

⁷² FSMA rules are at <http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm359436.htm>.

seafood fraud,”⁷³ co-chaired by the Departments of State and Commerce. Other ongoing efforts exist at the National Marine Fisheries Service (NMFS) at the National Oceanic and Atmospheric Administration (NOAA) in the Department of Commerce. NMFS also administers a number of seafood and fisheries safety and sanitation programs. NMFS’s voluntary seafood and fisheries safety inspection program focuses on marketing and product quality.⁷⁴

Over the years, Congress has introduced a number of bills intended to address concerns about food fraud for a particular food or food ingredient. Such legislation has not addressed food fraud in a comprehensive manner. However, although no single federal agency or U.S. law directly addresses food fraud, a number of existing laws and statutes already provide the authority for various federal agencies to address fraud. Currently, food fraud is broadly addressed through various food safety, food defense, and food quality authorities as well as border protection and import authorities across a number of federal agencies. FDA and USDA are the principle agencies working to protect the food supply from food safety risks—both unintentionally and intentionally introduced contamination—in conjunction with border protection and enforcement activities by the U.S. Department of Homeland Security. Other agencies also play a role.

For more background information, see CRS Report R43358, *Food Fraud and “Economically Motivated Adulteration” of Food and Food Ingredients*, and also CRS Report RL34124, *Seafood Fraud*.

Omnibus Farm Bill

Some food safety reforms enacted under FSMA included provisions that involve coordination with other federal agencies. Some provisions have implications for certain farm bill programs administered by USDA. For example, FSMA required 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, with authorized funds to be appropriated through FY2015 (FSMA, §209).

The 2014 farm bill (Agriculture Act of 2014, P.L. 113-79) contained a number of provisions that address food safety.⁷⁵ First, it required FDA, when publishing its final regulations establishing new produce standards (FSMA §105) to publish an analysis of the scientific information used to

⁷³ 79 *Federal Register* 147: 44404-44405, July 31, 2014. See also “Presidential Memorandum—Comprehensive Framework to Combat Illegal, Unreported, and Unregulated Fishing and Seafood Fraud,” June 17, 2014, <http://www.whitehouse.gov/the-press-office/2014/06/17/presidential-memorandum-comprehensive-framework-combat-illegal-unreported>. NOAA’s website: http://www.fishwatch.gov/buying_seafood/identifying_seafood_fraud.htm.

⁷⁴ NOAA Seafood Inspection Program, http://www.seafood.nmfs.noaa.gov/program_services/Program_Services.html. See also CRS Report RS22797, *Seafood Safety: Background and Issues*. For more direct assistance, contact CRS Analyst Harold F. Upton (hupton@crs.loc.gov, 7-2264).

⁷⁵ For more information about the farm bill, see CRS Report RS22131, *What Is the Farm Bill?* and CRS Report R43076, *The 2014 Farm Bill (P.L. 113-79): Summary and Side-by-Side*. A provision that was in the House-passed version of the farm bill (H.R. 2642) but not included in the final agreement would have prohibited any state or local government from “setting standards or conditions on the production or manufacture of agricultural products,” including food safety requirements, among other types of standards, that might “prevent interstate sales” of the agricultural products. H.R. 2642, §12312.

promulgate the final rule, as well as an economic impact analysis of the rule focusing on a variety of business sizes, and small and mid-sized value-added food processors. It also required the U.S. Comptroller General to submit a report to certain House and Senate congressional committees within one year after FDA promulgates the final produce rule, and further required an updated report to the committees within one year after that report.⁷⁶ The 2014 farm bill also established training coordination for food and agriculture protection as a “high-priority” research and extension activity within USDA, and provided for competitive grants to establish a “Comprehensive Food Safety Training Network.” Eligible recipients would include nonprofit institutions that provide food safety protection training, and training centers in institutions of higher education. It further authorized \$20 million in appropriations annually (FY2014-FY2018) to remain available until expended.⁷⁷

The 2014 farm bill also directed the Federal Crop Insurance Corporation (FCIC) to conduct a “food safety insurance” study (to be submitted to Congress within one year of enactment) to determine whether policies that provide coverage for specialty crops from food safety and contamination issues benefit producers. The study shall evaluate insurance policies and plans that provide protection for production or revenue impacted by “food safety concerns including, at a minimum, government, retail, or national consumer group announcements of a health advisory, removal, or recall related to a contamination concern.”⁷⁸ Finally, the 2014 farm bill required USDA to finalize regulations for food safety inspections of catfish no later than 60 days after the date of enactment of the law.⁷⁹ FSIS has not yet implemented the catfish program. It also mandated that USDA and FDA enter into an agreement to improve interagency cooperation and prevent inspection duplication. This agreement was signed in April 2014.⁸⁰

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.⁸¹ Each year, FDA physically examines about 2% of the total number of food import lines imported during the year.⁸² 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.⁸³ FSMA included several

⁷⁶ P.L. 113-79, §12311.

⁷⁷ P.L. 113-79, §7209(f).

⁷⁸ P.L. 113-79, §11022(a)(23).

⁷⁹ FSIS was authorized to inspect farmed catfish products under a 2008 farm bill provision (P.L. 110-246, §11016). The 2014 farm bill (P.L. 113-79, §12106) reconfirmed this provision.

⁸⁰ MOU 225-14-0009 (between USDA’s FSIS and FDA), <http://www.fda.gov/aboutfda/partnershipcollaborations/memorandaofunderstandingmous/domesticmous/ucm396294.htm>.

⁸¹ 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.

⁸² FDA’s Annual Report on Food Facilities, Food Imports, and FDA Foreign Offices. Among the cited reasons for this low incidence of inspections are limited and declining resources, including too few inspectors to cover the more than 360 U.S. ports of entry despite ever-increasing import volumes.

⁸³ 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>.

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.⁸⁴

FDA has issued a series of proposed regulations to address FSMA's import provisions. In July 2013, FDA released two primary rules—namely, the Foreign Supplier Verification Program (§301) and a program establishing a certification system or verification systems involving so-called third parties (§307). FDA re-proposed aspects of the Foreign Supplier Verification Program in September 2014.⁸⁵ FDA issued final regulations in May 2013 regarding prior notice of imported food shipments (§304). FDA has entered discussions with several foreign countries to facilitate inspection of foreign facilities (§306).⁸⁶ Also, in early 2013, FDA released its plans for international food safety capacity-building and its report identifying programs and practices intended to promote the safety of the U.S. food supply. Some FSMA provisions have been largely addressed, including one for developing a strategy for addressing smuggled foods (§309) and another reporting on FDA foreign offices (§308). Other FSMA provisions have not yet been fully addressed, including FDA's plans for its "Voluntary Qualified Importer Program" (§302) and other FSMA import provisions authorize FDA to require food imports to be accompanied by certification (§303). The court-ordered deadline for final regulations regarding imported food and foreign suppliers is October 31, 2015. Other FSMA regulations also require that food importers address certain food safety requirements, including preventive controls for (human) food facilities (FSMA §103) and also requirements for produce growers (FSMA §105).

Outside of FSMA, federal efforts and oversight have focused on changes to China's food safety laws made in 2013. Changes to China's legal and regulatory framework highlight ongoing efforts there to address food safety concerns and also to enhance enforcement efforts to punish violations.⁸⁷ The 114th Congress may monitor implementation of these changes as part of ongoing U.S. concerns about the safety of imported foods from China.

Dietary Supplements⁸⁸

FSMA provisions apply to most foods, including dietary supplements.⁸⁹ FSMA also granted FDA the authority to enforce the adulteration and misbranding provisions of the FFDCA. Prior to FSMA, FDA could only issue voluntary recalls or request the responsible party to cease distribution of the violative product (food or dietary supplement). FSMA further granted FDA the

⁸⁴ See, for example, C. Smith DeWaal, "FSMA: Import Rules May Foster Global Food Safety," *Food Safety News*, February 14, 2011.

⁸⁵ FSMA rules are at <http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm359436.htm>.

⁸⁶ FDA's website, "Memoranda of Understanding and Other Cooperative Arrangements," <http://www.fda.gov/InternationalPrograms/Agreements/MemorandaofUnderstanding/default.htm>.

⁸⁷ See USDA/FAS, "The Food Safety Management System in China," GAIN Report# CH13020, April 26, 2013; and USDA/FAS, "China's General Hygiene Regulation for Food Production," GAIN Report# CH15003, January 12, 2015.

⁸⁸ For direct assistance contact CRS Analyst Agata Dabrowska (adabrowska@crs.loc.gov; 7-9455).

⁸⁹ Section 201(ff) of the FFDCA (21 U.S.C. §321(ff)) states dietary supplements are deemed to be foods, aside from a few exceptions. For more information, see CRS Report R43062, *Regulation of Dietary Supplements*.

authority to issue mandatory recalls if the responsible party does not cease distribution of the adulterated or misbranded article of food/dietary supplement.⁹⁰

FDA must 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. FSMA further 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 2011,⁹¹ 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, Senator Orrin Hatch and former Senator Tom Harkin asked FDA to withdraw its draft NDI guidance, but this request was rejected by FDA.⁹²

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.⁹³ In December 2014, the offices of Senators Edward J. Markey, Richard J. Durbin, and Richard Blumenthal released a report with recommendations "to ensure that information about adverse events associated with the consumption of energy drinks is disclosed, to further improve transparency and representation of energy drink products in the marketplace, and ensure that children and teens are adequately protected from deceptive and potentially harmful advertising practices."⁹⁴ The Institute of Medicine (IOM) published a summary report in January 2014 of a 2013 workshop on caffeine in food and dietary supplements, which was requested by FDA. The report presents recommendations and opinions of individual participants, but does not reflect the consensus of the IOM, nor is it intended to constitute a comprehensive review of the subject.⁹⁵

Criminal Penalties and Enforcement

FSMA did not substantially alter the criminal penalties provisions within existing FDA laws. However, such provisions were actively considered as part of the broader food safety debate. For example, the House-passed food safety bill (H.R. 2749, 111th Congress) would have amended the penalties provisions of FFDCFA 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

⁹⁰ For more information, see CRS Report R43794, *Food Recalls and Other FDA Administrative Enforcement Actions*.

⁹¹ 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>.

⁹² 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.

⁹³ R. Cox, "Durbin, Blumenthal Ask FDA to Review Energy Drinks Quickly," *The Hill*, November 27, 2012.

⁹⁴ See "Buzzkill: A Survey of Popular Energy Drinks Finds Majority of the Market Unwilling to Make Commitments to Protect Adolescents," written by staff of Senators Markey, Durbin, and Blumenthal was released back in December 2014, http://www.markey.senate.gov/imo/media/doc/2014-12-30-Report_BuzzKill_EnergyDrinks_ScreenV.pdf.

⁹⁵ IOM, *Caffeine in Food and Dietary Supplements: Examining Safety: Workshop Summary* (National Academies Press).

the food safety bill and not enacted as part of FSMA. Although these provisions were ultimately not adopted in the enacted law, some Members of Congress are concerned about the need to modify existing laws to institute stricter criminal fines and penalties as part of the U.S. food safety system. In the 112th Congress, such legislation was reintroduced and passed in the Senate (S. 216). During the farm bill debate in the 112th Congress, Senator Leahy proposed an amendment that would have increased criminal penalties for those who knowingly violate food safety laws, but it was not included in Senate-passed farm bill (S. 3240). Such provisions were not considered in the farm bill debated and ultimately enacted in the 113th Congress.

Bisphenol A (BPA)⁹⁶

There continues to be controversy over whether the levels of bisphenol A (BPA) in food containers and packaging are “safe.” BPA is a component of certain plastics that is commonly used in food containers, such as plastic bottles or metal can liners. FDA is authorized to regulate BPA as an indirect food additive when the chemical is used in food containers and packaging. Some scientific studies have suggested BPA exposure may lead to certain developmental effects in laboratory animals, but there still remains no definitive scientific consensus regarding the risk of BPA exposure to humans, in particular to children, from the leaching of the chemical from food containers and packaging.⁹⁷ In June 2014, FDA issued its most recent safety assessment of BPA exposure from food packaging. The agency concluded that “BPA is safe at the current levels occurring in foods,” and the “available information continues to support the safety of BPA for the currently approved uses in food containers and packaging.”⁹⁸

In 2012 and 2013, FDA granted two petitions to amend its food additive regulations to no longer allow certain uses of BPA after the petitioners showed that those uses were “abandoned.”⁹⁹ The two uses that had been abandoned were BPA-based polycarbonate resins in baby bottles and “sippy” cups, and BPA-based epoxy resins as coatings of infant formula packaging. FDA notes that the regulations were not amended based on a determination of safety. Although these petitions were granted, FDA had also denied a petition in 2012 to ban all uses of BPA in food containers and packaging, arguing that the petitioner had “failed to provide sufficient data and information to persuade FDA” to take the requested regulatory action.¹⁰⁰

The 111th Congress considered various proposals to reduce or eliminate the use of BPA in food containers as part of the FSMA debate, but the final bill did not include a provision to alter FDA’s existing regulation of BPA.¹⁰¹ Congress has continued to introduce various proposals to reduce or

⁹⁶ For direct assistance, contact CRS Analysts Jerry Yen (jyen@crs.loc.gov; 7-9113) and Sarah A. Lister (slister@crs.loc.gov, 7-7320).

⁹⁷ For more information, see CRS Report RS22869, *Bisphenol A (BPA) in Plastics and Possible Human Health Effects*.

⁹⁸ FDA, “Bisphenol A (BPA): Use in Food Contact Application,” updated November 2014, available at <http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm064437.htm>.

⁹⁹ FDA, “Indirect Food Additives: Polymers,” 77 *Federal Register* 41899-41902, July 17, 2012, and FDA, “Indirect Food Additives: Adhesives and Components of Coatings,” 78 *Federal Register* 41840-41843, July 12, 2013.

¹⁰⁰ FDA, “FDA/OC Letter to Natural Resources Defense Council – Petition Denial,” March 30, 2012, available at <http://www.regulations.gov/#!documentDetail;D=FDA-2008-P-0577-0007>.

¹⁰¹ During the FSMA debate, the House-passed food safety bill (H.R. 2749, 111th Congress) 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. 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. The Senate provision introduced by Senator Dianne (continued...)

eliminate the use of BPA in food containers and packaging.¹⁰² Several bills were introduced in the 113th Congress to address risks of BPA exposure from food containers and packaging (H.R. 2248, H.R. 5033, S. 1124, and S. 2572). Additionally, several states and other countries have adopted or considered adopting measures to restrict certain uses of BPA.¹⁰³

Pesticide Residues¹⁰⁴

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. Pesticides are used in agricultural food production to control unwanted pests—such as insects, rodents, weeds, bacteria, mold, and fungus—that may affect crop yields and food quality, but pesticide application may leave residues in or on foods that might present risks to the general public. When Congress enacted the Food Quality Protection Act of 1996 (FQPA), it established maximum allowable levels of pesticide residues (i.e., tolerances) for domestically produced and imported food that ensure with “reasonable certainty that no harm will result from aggregate exposure.”¹⁰⁵ EPA was directed to reassess all existing tolerances by 2006 to ensure that tolerances met this standard. Additionally, FQPA amended the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) to direct EPA to approve (i.e., register) pesticides for use in food production only if tolerances were set beforehand by the agency.¹⁰⁶ Under FIFRA, EPA is authorized to regulate the labeling, sale, and use of pesticides to prevent unreasonable adverse effects on the environment, which includes human dietary risk from levels of pesticide residue that exceed the tolerance.

There have been ongoing concerns regarding whether EPA has set tolerances for pesticide residues at a sufficiently protective level and whether foods are adequately being inspected or monitored to ensure that these tolerances are not exceeded.¹⁰⁷ EPA completed its reassessment of existing tolerances in 2007 and continues to review tolerance decisions based on residue data the agency collects.¹⁰⁸ FIFRA also directs EPA to review pesticide registrations periodically, which may involve reviewing tolerances if new information suggests the need for reexamination.¹⁰⁹

(...continued)

Feinstein (S. 593, 111th Congress) would have banned BPA in all FDA-regulated food containers.

¹⁰² S. 593 (111th Congress) and H.R. 432 and S. 136 (112th Congress).

¹⁰³ See, for example, Minnesota Statutes §§ 325F.173-175 and also California’s Health and Safety Code §§ 108940-108941. Also, under the Canada Consumer Product Safety Act (CPSIA) it is illegal to manufacture, import, advertise, or sell polycarbonate baby bottles that contain BPA (see <http://healthycanadians.gc.ca/index-eng.php>).

¹⁰⁴ For direct assistance contact CRS Analyst Jerry Yen (jen@crs.loc.gov; 7-9113).

¹⁰⁵ 21 U.S.C. 346a; 40 CFR Part 180. See also CRS Report RL31921, *Pesticide Law: A Summary of the Statutes*.

¹⁰⁶ 7 U.S.C. 136 et seq. 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, 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 (“tolerance”) can be established under the FFDCA.

¹⁰⁷ See, for example, GAO, *Food Safety: FDA and USDA Should Strengthen Pesticide Residue Monitoring Programs and Further Disclose Monitoring Limitations*, GAO-15-38, October 2014; and L. Zuraw, “USDA Says Pesticide Data Show No Food Safety Concerns,” *Food Safety News*, March 10, 2014.

¹⁰⁸ See EPA’s website: <http://www.epa.gov/pesticides/tolerance/reassessment.htm>.

¹⁰⁹ Although EPA is responsible for setting tolerances for pesticide residues, FDA and USDA are authorized to enforce those tolerances through inspection and monitoring of food. USDA also measures residue levels for pesticides in both domestically produced and imported fruit, vegetables, grain, meat, and dairy products under its Pesticide Data Program.

Congress oversees EPA implementation of the FQPA and has raised concerns about the agency's implementation of the statute regarding restrictions (or lack thereof) for some pesticides. In 2012, Congress enacted the Pesticide Registration Improvement Extension Act of 2012 (P.L. 112-177), amending FIFRA and FFDCFA to reauthorize and revise, through FY2017, the collection and use of fees to enhance and accelerate EPA's pesticide registration activities. In addition, previous Congresses have introduced legislation to improve scrutiny of endocrine-disrupting chemicals, which are usually pesticides.¹¹⁰

Agricultural Biotechnology¹¹¹

Opinions differ on whether or not agricultural biotechnology should be considered a food safety issue.¹¹² Genetically engineered (GE, sometimes called genetically modified, or GM) crop varieties first became commercially available in the mid-1990s.¹¹³ 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 deregulatory review process, as well as the continuing effectiveness of the 1986 General Framework that underlies the U.S. biotechnology regulatory structure. Concern about increased herbicide-resistant weeds associated with the widespread use of genetically engineered crop varieties was the subject of hearings in recent years. Other concerns involve the possibility of cross-contamination by GE crops with other traditional and organically grown crops.¹¹⁴ 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.¹¹⁵ Various product labeling options for the salmon have also been debated. In the 113th Congress, proposed legislation would amend FFDCFA to require labeling of GE fish (H.R. 584, S. 248). In addition, GE food "right-to-know" bills were proposed in the 113th Congress (H.R. 1699, S. 809). Many of these bills were reintroduced from previous Congresses. Another bill, introduced in the 113th Congress, would establish a federal labeling standard for foods with genetically modified ingredients, giving sole authority to FDA to require mandatory labeling if such foods are found to be unsafe or materially different from foods produced without GE ingredients (H.R. 4432). Congress may consider re-introducing these bills in the 114th Congress.

¹¹⁰ See CRS Report R40177, *Environmental Exposure to Endocrine Disruptors: What Are the Human Health Risks?*

¹¹¹ For more direct assistance, contact CRS Analyst Tadlock Cowan (tcowan@crs.loc.gov, 7-7600).

¹¹² 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 R43450, *Sanitary and Phytosanitary (SPS) and Related Non-Tariff Barriers to Agricultural Trade*, or contact CRS Analyst Renée Johnson (7-9588).

¹¹³ CRS Report RL32809, *Agricultural Biotechnology: Background, Regulation, and Policy Issues*, and CRS Report RL33334, *Biotechnology in Animal Agriculture: Status and Current Issues*.

¹¹⁴ See, for example, Organic Trade Association (OTA) press release, "OTA Deeply Disappointed with Failure to Protect Farmer and Consumer Choice," January 27, 2011.

¹¹⁵ For more information, see CRS Report R43518, *Genetically Engineered Salmon*. For direct assistance, contact CRS Analysts Tadlock Cowan (tcowan@crs.loc.gov, 7-7600) and Harold F. Upton (hupton@crs.loc.gov, 7-2264). See also FDA's website, "Genetically Engineered Salmon," <http://www.fda.gov/animalveterinary/developmentapprovalprocess/geneticengineering/geneticallyengineeredanimals/ucm280853.htm>.

In both the 113th and 112th Congresses, there were a series of attempts to alter U.S. policies regarding bioengineered crops, as part of the periodic farm bill debate. These included proposed 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.¹¹⁶ These provisions were not part of the enacted 2014 farm bill (P.L. 113-79). A provision debated as part of recent House Agriculture appropriations would have required USDA to grant temporary permits to producers to continue planting or cultivating a bioengineered crops while USDA reexamines possible petitions regarding “non-regulated status” or other deregulatory actions. This provision was not enacted.

Single Food Agency

Some in Congress may continue to advocate for additional reforms to the nation’s food safety system, particularly with respect to coordination and organization among federal agencies. Efforts to establish a single federal food safety agency were introduced and debated in the 103rd Congress.¹¹⁷ The organization of the U.S. food safety system has been debated ever since FDA was removed from USDA in 1940. Years later, the final report from a 1969 White House Conference on Food, Nutrition and Health report highlighted the divergence in food safety policy between USDA and the Department of Health, Education, and Welfare (HEW), where FDA resided at that time.¹¹⁸ In the years following the conference, there were a series of reports and hearings adding to the debate over a single food safety agency.¹¹⁹ Although the idea of a single food agency has the support of GAO,¹²⁰ the National Research Council (NRC), and the Institute of Medicine (IOM),¹²¹ 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.

FSMA did not alter the existing food safety jurisdiction between FDA and USDA, yet the issue has remained of interest to Congress. Press reports had suggested that Representative Rosa DeLauro intended to reintroduce legislation to create a single food safety agency in the 113th Congress,¹²² although such legislation was not reintroduced until the 114th Congress. The Safe

¹¹⁶ 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 C.F.R. part 340, see USDA, “Biotechnology,” <http://www.aphis.usda.gov/wps/portal/aphis/ourfocus/biotechnology>.

¹¹⁷ H.R. 3751/S. 2350 and S. 1349 (103rd Congress); H.R. 2801/S. 1465 (105th Congress); H.R. 2345/S. 1281 (106th Congress); H.R. 1671/S. 1501 (107th Congress); H.R. 5259/S. 2910 (108th Congress); H.R. 1507/S. 729 (109th Congress); H.R. 1148/S. 654 (110th Congress); and H.R. 6552 (111th Congress).

¹¹⁸ *White House Conference on Food, Nutrition and Health, Final Report*, 1969, pp. 118-119, http://www.nns.nih.gov/1969/full_report/PDFcontents.htm. Conference experts recommended that HEW establish an interdepartmental coordinating committee on federal food regulatory policy and create a single regulatory food agency; whether or not USDA’s meat and poultry inspection should be transferred to HEW was also discussed.

¹¹⁹ CRS Report 98-400 STM, *Food Safety: Recommendations for Changes in the Organization of Federal Food Safety Responsibilities, 1949-1997*, April 21, 1998. Available upon request from CRS.

¹²⁰ 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). The Government Accountability Office’s (GAO) reports on food safety have regularly highlighted that the U.S. food safety system is fragmented across different departments and agencies that have overlapping food safety responsibilities. GAO has noted in reports that a single food safety agency would be one way to address the fragmented system, improving effectiveness and efficiency.

¹²¹ NRC/IOM, *Enhancing Food Safety: The Role of the Food and Drug Administration*, 2010.

¹²² S. Armour, “Rep. DeLauro Will Introduce Single Food Safety Agency Bill, Slams Self-Regulation,” *Bloomberg* (continued...)

Food Act of 2015 (H.R. 609/DeLauro; S. 287/Durbin) would create a single independent Food Safety Administration (FSA) by transferring and consolidating the food safety authorities at FDA¹²³ and USDA¹²⁴ as well as portions of the National Marine Fisheries Service at the National Oceanic and Atmospheric Administration. FSA would be responsible for regulating food safety and related labeling, inspection, enforcement, and research functions of both domestically produced and imported foods. According to the bill authors, the new independent FSA would provide a more integrated approach, eliminate duplication, and result in efficient use of available resources and overall cost savings.¹²⁵ Among those supporting the H.R. 609 and S. 287 are the Consumer Federation of America and the Center for Science in the Public Interest.¹²⁶

As part of the FY2016 budget request, the Obama Administration also proposed to establish a single food agency. According to the Administration, a single food safety agency would “provide focused, centralized leadership, a primary voice on food safety standards, and clear lines of responsibility and accountability that will enhance both prevention of and responses to outbreaks of foodborne illnesses.”¹²⁷ Unlike the legislative proposals, the Administration’s proposal would not create a new independent agency but would instead transfer existing food safety functions into a new agency within the U.S. Department of Health and Human Services (HHS). Consumer advocate groups such as the Consumer Federation of America (CFA) and the Center for Science in the Public Interest have been supportive of the Durbin/DeLauro legislation as a means to address concerns about the U.S. food safety system.¹²⁸

However, some public health groups who have traditionally favored the creation of a single food safety agency oppose the Administration’s plan since it calls for consolidation of food safety operations within HHS. Some contend HHS does not have the necessary expertise or adequate resources to manage an expanded food safety function; others claim USDA has a better record regarding food safety inspection and enforcement and worry that transferring these functions to HHS will lower standards for meat and poultry inspection.¹²⁹ CFA opposes the Administration’s proposal because of concern that the new agency would reside in HHS and be overwhelmed by HHS’s large areas of responsibility and priorities beyond food safety.¹³⁰ Another advocacy group, Food and Water Watch, sees the Administration’s budget proposal as a step backward in that the different inspection cultures between FSIS and FDA could end up weakening FSIS standards.¹³¹

(...continued)

News, December 18, 2012. The 111th Congress version of this bill was H.R. 6552, Single Food Safety Agency Act of 2010.

¹²³ FDA’s food programs, including Center for Food Safety and Applied Nutrition (CFSAN) and FDA’s Center for Veterinary Medicine (CVM), as well as the FDA Office of Regulatory Affairs and other administrative offices.

¹²⁴ FSIS as well as portions of Animal and Plant Health Inspection Service (APHIS), Agricultural Marketing Service (AMS), and its research program areas within USDA’s Research, Education, and Economics.

¹²⁵ Senator Durbin and Representative DeLauro, “Food Safety Is a Matter of National Security,” *The Hill*, January 20, 2015.

¹²⁶ CFA, “Consumer Federation of America Supports the Safe Food Act of 2015,” January 28, 2015 press release; and J. Whitworth, “Single Food Safety Agency Aim for Legislation,” *Food Quality*, January 29, 2015.

¹²⁷ Office of Management and Budget, *Fiscal Year 2016 Budget of the U.S. Government*, p. 82.

¹²⁸ L. Zuraw, “Lawmakers Introduce Bills to Create Single Food Safety Agency,” *Food Safety News*, January 28, 2015.

¹²⁹ “Obama Proposes Single Food Agency, But Consumer Groups Oppose It,” *Hagstrom Report*, February 2, 2015.

¹³⁰ “President’s Plan for Single Food Safety Agency Faces NGO Criticism,” *Inside U.S. Trade*, February 6, 2015.

¹³¹ Food and Water Watch, “Food and Water Protections Weakened Under President’s 2016 Budget,” press release, February 2, 2015.

The livestock industry has expressed opposition to a single food safety agency. The National Cattleman’s Beef Association has an organization resolution opposing a single food agency.¹³² The National Milk Producers Federation notes that FDA is in the middle of implementing FSMA.

Author Contact Information

Renée Johnson
Specialist in Agricultural Policy
rjohnson@crs.loc.gov, 7-9588

¹³² J. Marsden, “Are We Ready for a Single Food Safety Agency?—Part II,” *Meatingplace Safety Zone Blog*, February 23, 2015.