



Food Safety Issues for the 112th Congress

Renée Johnson

Specialist in Agricultural Policy

February 10, 2011

Congressional Research Service

7-5700

www.crs.gov

R41629

CRS Report for Congress

Prepared for Members and Committees of Congress

Summary

The 111th Congress passed comprehensive food safety legislation in December 2010 (FDA Food Safety Modernization Act (FSMA), P.L. 111-353). Although numerous agencies share responsibility for regulating food safety, this newly enacted legislation focuses on foods regulated by the Food and Drug Administration (FDA) and amends 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, the new law expands FDA's authority to conduct a mandatory recall of contaminated food products, enhances surveillance systems for foodborne illness outbreaks, establishes preventative controls at some food processing facilities and farms, enhances FDA's traceability capacity within the nation's food distribution channels, increases the number of FDA inspections at domestic and foreign food facilities, and expands FDA's authority and oversight of foreign companies that supply food imports to the United States.

The 112th Congress may provide oversight over how the law is implemented, including FDA's coordination with other federal agencies, such as those in the U.S. Department of Agriculture (USDA) and the Department of Homeland Security (DHS). Implementation of the law will depend largely on the availability of discretionary appropriations, and some have questioned whether additional funding is available in the current budgetary climate.

In addition, the 112th Congress may continue to consider changes to other food safety laws and policies that are being actively debated in Congress. Among these are food safety initiatives covering meat, poultry, and seafood products; legislation intended to curtail the non-medical use of antibiotics in animal feeds and to ban the use of certain plastic components commonly used in food containers; food labeling; and the use of plant and animal biotechnology. Several of these issues were actively debated in the 111th Congress during the food safety debate leading up to passage of the FSMA.

Some in Congress also may continue to push for additional policy reforms either to existing FDA or USDA food safety laws to address other perceived concerns regarding the safety of the U.S. food supply, including resources and regulatory tools to adequately combat foodborne illness, as well as coordination and organization among federal agencies.

Contents

Background	1
Food Safety Incidents.....	2
Existing Food Safety Legal and Regulatory Landscape.....	4
FDA Food Safety Modernization Act (P.L. 111-353).....	5
Key Issues for the 112 th Congress.....	6
Oversight and Implementation of the New Law.....	6
Funding the New Law.....	7
The Next Omnibus Farm Bill.....	8
Meat and Poultry Inspection.....	9
Antibiotic Use in Animal Agriculture.....	10
Seafood and Fisheries Products.....	10
Criminal Penalties and Enforcement.....	11
Bisphenol A (BPA).....	11
Dietary Supplements.....	12
Agricultural Biotechnology.....	12
Single Food Agency.....	13

Tables

Table 1. Number of Foodborne Illnesses, Hospitalizations, and Deaths.....	3
---------------------------------------------------------------------------	---

Contacts

Author Contact Information.....	13
---------------------------------	----

The 111th Congress passed comprehensive food safety legislation in December 2010 (FDA Food Safety Modernization Act (FSMA), P.L. 111-353). The FSMA is focused on foods regulated by the Food and Drug Administration (FDA), within the U.S. Department of Health and Human Services (HHS), and is the largest expansion of FDA's food safety authorities since the 1930s. Among its key elements, the new law requires FDA to establish comprehensive, prevention-based controls across the food supply; specifies how often FDA should inspect food producers; provides FDA with new tools to ensure that food imports meet U.S. food safety standards; gives FDA mandatory recall authority for food products; and directs FDA to improve training of state, local, territorial, and tribal food safety officials.

The 112th Congress may provide oversight over how the law is implemented, but it may also continue to consider additional changes to other food safety laws and policies that have been actively debated in Congress.

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 an estimated one in six Americans—a total of 48 million people—become sick from contaminated food.¹ In 2007 and again in 2009, the Government Accountability Office (GAO) placed food safety on its biennially published list of high risk areas, one of 30 needing concerted attention by Congress and the Administration.²

The Obama Administration has taken certain actions to address food safety concerns. 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.³ 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 2020.⁴

At issue is whether the current food safety system has the resources, authority, and structural organization to safeguard the health of American consumers, who spend more than \$1 trillion on food each year.⁵ Also at issue are whether federal food safety laws have kept pace with the

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

² GAO, *High Risk Series: An Update* (GAO-09-271), January 2009.

³ FSWG, "Food Safety Working Group: Progress at 1 Year," July 9, 2010, <http://www.foodsafetyworkinggroup.gov/>.

⁴ FDA, "Strategic Priorities 2011–2015: Responding to the Public Health Challenges of the 21st Century," Draft, September 29, 2010 (part of the broader Healthy People 2020 initiative at <http://www.healthypeople.gov/2020>), <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/StrategicActionPlan/UCM226907.pdf>.

⁵ Roughly two-thirds of the \$1 trillion is for domestically produced farm foods; imports and seafood account for the balance. USDA, Economic Research Service (ERS) data, at <http://www.ers.usda.gov/Browse/FoodSector/>.

significant changes that have occurred in the food production, processing, and marketing sectors; whether food safety agencies have the resources, authority, and structural organization to safeguard the public; and whether they use resources effectively.

Food Safety Incidents

Food safety incidents frequently heighten public and media scrutiny of the U.S. food safety system.⁶ These outbreaks have raised questions about the adequacy of FDA's and FSIS's safeguards for ensuring the safety of both domestically produced foods and imported foods. These include major incidents involving FDA-regulated food such as the 2010-2011 multistate recall of *Salmonella*-contaminated sprouts that sickened more than 100 people in 16 states and Washington, DC, linked to an Illinois organic farm.⁷ This followed a nationwide recall of more than 500 million eggs in the summer of 2010, associated with increased cases of infection with *Salmonella* Enteritidis, a strain commonly associated with shell eggs. Another multi-state outbreak of *Salmonella* Typhimurium in late 2008 and early 2009 was linked to an institutional brand of peanut butter and other peanut-based ingredients from a single company. That outbreak sickened more than 700 people in 46 states, and may have contributed to the deaths of nine people. A series of expanding recalls was announced by FDA in early 2009, involving thousands of peanut-containing products from more than 200 companies. Other widespread illness outbreaks have been linked to the consumption of bagged fresh spinach grown in California that carried *E. coli* O157:H7 and, later, to Mexican produce that carried *Salmonella*. There have also been large recalls of FSIS-regulated meat and poultry products due to findings of *E. coli* O157:H7, *Listeria*, and other problems.

CDC reported that in 2007 there were 18 multistate foodborne illness outbreaks.⁸ Of these, 10 were attributed to *Salmonella*, six to *E. coli* O157:H7, one to *Clostridium botulinum*, and one to norovirus. Among the foods associated with multistate *Salmonella* outbreaks were commercially processed frozen pot pies (401 illnesses, three deaths), commercially processed vegetable snacks (87 illnesses), eggs (81 illnesses), spinach/lettuce (76 illnesses), beefsteak tomatoes (65 illnesses), raw tuna (44 illnesses), ground beef (43 illnesses), cheese (20 illnesses), alfalfa sprouts (15 illnesses), and raw fresh basil (11 illnesses). Most of the six multistate outbreaks of *E. coli* O157:H7 infection were for ground beef (117 illnesses), with one due to commercially processed frozen pepperoni pizzas (27 illnesses). *Clostridium botulinum* toxin resulted in eight illnesses from commercially canned hotdog chili sauce. The one multistate outbreak caused by norovirus was associated with raw oysters (40 illnesses).

CDC reports that each year an estimated total of 48 million people become sick from contaminated food.⁹ Of these an estimated 128,000 cases require hospitalization and 3,000 cases

⁶ Foodborne outbreaks and their implications for the nation's food safety system are discussed in more depth in CRS Report R40916, *Food Safety: Foodborne Illness and Selected Recalls of FDA-Regulated Foods*, by Sarah A. Lister and Geoffrey S. Becker, and CRS Report RL34313, *The USDA's Authority to Recall Meat and Poultry Products*.

⁷ FDA press release, "FDA: Don't Eat Certain Lots of Tiny Greens Brand Alfalfa Sprouts or Spicy Sprouts," December 27, 2010.; and M. Rothschild, "Sprouts Outbreak Toll Now at 112 in 18 States," *Food Safety News*, January 7, 2011.

⁸ CDC, "Surveillance for Foodborne Disease Outbreaks—United States, 2007," *Morbidity and Mortality Weekly Report (MMWR)*, Vol. 59, No. 31, August 13, 2010, <http://www.cdc.gov/mmwr/pdf/wk/mm5931.pdf>. Also based on summary findings posted in Suzanne Schreck, "CDC Releases 2007 Foodborne Illness Numbers," *Food Safety News*, August 13, 2010. 2007 is the most year that data are available.

⁹ CDC, "Estimates of Foodborne Illness in the United States," December 2010.

result in death. These estimates are for two major groups of foodborne illnesses: (1) known foodborne pathogens (31 pathogens, many of them tracked by public health systems that track diseases and outbreaks); and (2) “unspecified agents” where insufficient data does not allow for the estimation of agent-specific burden.¹⁰ 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.”

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/2011-foodborne-estimates.html>; also http://www.cdc.gov/foodborneburden/PDFs/FACTSHEET_A_FINDINGS.pdf (Table 1, Estimated annual number of domestically acquired, foodborne illnesses, hospitalizations, and deaths due to 31 pathogens and unspecified agents transmitted through food, United States).

- a. The credible interval (or Bayesian probability interval) refers to the point estimates obtained by CDC using posterior distributions to generate a posterior mean and an upper and lower 5% limits for a 90% credible interval (such that the estimated posterior probability is that 90% of that population is between the interval). See E. Scallan, R. M. Hoekstra, F. J. Angulo, R. V. Tauxe, M. Widdowson, S. L. Roy, J. L. Jones, and P. M. Griffin, “Foodborne Illness Acquired in the United States—Major Pathogens,” *Emerging Infectious Diseases*, Vol. 17, No. 1, January 2011, <http://www.cdc.gov/eid/content/17/1/pdfs/7.pdf>.

The top five pathogens contributing to foodborne illnesses are norovirus (58% of illnesses), *Salmonella*, nontyphoidal (11%), *Clostridium perfringens* (10%), *Campylobacter* spp. (9%), and *Staphylococcus aureus* (3%). The top five pathogens contributing to foodborne illnesses resulting in hospitalization are *Salmonella*, nontyphoidal (35% of illnesses), norovirus (26%), *Campylobacter* spp. (15%), *Toxoplasma gondii* (8%), and *E. coli* (STEC¹¹) O157 (4%). The top five pathogens contributing to foodborne illnesses resulting in death are *Salmonella*, nontyphoidal (28% of deaths), *Toxoplasma gondii* (24%), *Listeria monocytogenes* (19%), norovirus (11%), and *Campylobacter* spp. (6%).¹²

¹⁰ Ibid; also http://www.cdc.gov/foodborneburden/PDFs/FACTSHEET_A_FINDINGS.pdf.

¹¹ 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.

¹² CDC, “Estimates of Foodborne Illness in the United States,” December 2010.

Throughout the 110th and 111th Congress, hearings and government reports cited problems with food imports from China and other countries, at a time when Americans receive an increasing portion of their food supply from foreign sources. That prompted consideration of additional actions—beyond the infrequent sampling and testing now done at the border to detect problems among the millions of food import shipments annually—that FDA could take to ensure the safety of foreign foods. USDA’s FSIS, for example, allows foreign meat and poultry imports to enter the United States only from countries that it has determined have equivalent safety standards. This prompted consideration about whether FDA should adopt a similar approach for the significantly larger portion of the food supply it regulates, or at least for certain higher-risk foods. Other related issues included how such risks should be determined; the extent to which private importers should be responsible for assuring food safety; and the best approach for government to certify the adequacy of importer food safety efforts.

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.¹³ Federal responsibility for food safety rests primarily 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. USDA’s Food Safety and Inspection Service (FSIS) regulates most meat and poultry and some egg products. GAO has identified 15 federal agencies collectively administering at least 30 laws related to food safety. 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, and 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.

The division of food safety responsibility between FDA and USDA is rooted in the early history of U.S. food regulation. Congress created separate statutory frameworks when it enacted, in 1906, both the Pure Food and Drugs Act and the Meat Inspection Act. The former addressed the widespread marketing of intentionally adulterated foods, and its implementation was assigned to USDA’s Bureau of Chemistry. The latter law addressed unsafe and unsanitary conditions in meat packing plants, and implementation was assigned to the USDA’s Bureau of Animal Industry. This bifurcated system has been perpetuated and split further into additional food safety activities under additional agencies (for example, the Environmental Protection Agency, the National Marine Fisheries Service, and others) by a succession of statutes and executive directives. The separation of the two major food safety agencies was further reinforced when, in 1940, the President moved responsibilities for safe foods and drugs, other than meat and poultry, from USDA to the progenitor of HHS, the Federal Security Agency. Meat inspection remained in USDA. There has been discussion over time regarding whether this dispersal of food safety responsibilities has been problematic, or whether a reorganization would divert time and attention from other fundamental problems in the system.¹⁴

¹³ For other background information, see CRS Report RS22600, *The Federal Food Safety System: A Primer* and CRS Report RS22946, *Food and Drug Administration (FDA): Overview and Issues*.

¹⁴ For a discussion of the history of federal food safety organization and of efforts to change it, see Merrill, Richard A. and Jeffrey K. Francer, “Organizing Federal Food Safety Regulation,” *Seton Hall Law Review*, vol. 31:61, 2000. See (continued...)

The majority of both total funding and total staffing, however, is with FSIS at USDA, and FDA, which regulates virtually all other foods. FSIS's FY2010 budget was \$1.019 billion in appropriated funds plus another approximately \$130 million in industry-paid user fees.¹⁵ FDA's budget for foods was \$784.1 million in FY2010,¹⁶ virtually all of it appropriated with limited authorized user fees.¹⁷ Thus, FSIS had approximately 60% of the two agencies' combined food safety budget, and FDA had the other approximately 40%. This discrepancy in funding exists although FSIS is responsible for between 10% and 20% of the U.S. food supply, while FDA is responsible for the remainder.¹⁸ Staffing levels also vary considerably among the two agencies: FSIS staff numbers around 9,400, while FDA staff working on food-related activities numbers 2,800 full-time employees.

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

The FDA Food Safety Modernization Act (FSMA, P.L. 111-353) focused on FDA-regulated foods and amended FDA's existing structure and authorities, in particular the FFDCA (21 U.S.C. §§ 301 *et seq.*). FSMA does not directly address meat and poultry products under the jurisdiction of USDA. Among its many provisions, FSMA expands FDA's authority to conduct a mandatory recall of contaminated food products; enhancing surveillance systems to investigate foodborne illness outbreaks; establishing and enforcing new preventive controls and food safety plans at some food processing facilities and farms; enhancing FDA's traceability capacity within the nation's food distribution channels; increasing inspection frequencies of high-risk food facilities (both domestic and foreign facilities); and expanding FDA's authority and oversight capabilities of foreign companies that supply food imports to the United States.

FDA has identified five key elements to the new law:¹⁹

- **Preventive controls**—For the first time, FDA has a legislative mandate to require comprehensive, prevention-based controls across the food supply.
- **Inspection and Compliance**—The FSMA recognizes that inspection is an important means of holding industry accountable for its responsibility to produce safe food. The law specifies how often FDA should inspect food producers. FDA

(...continued)

also GAO, *High Risk Series: An Update* (GAO-07-310), January 31, 2007; and *Ensuring Safe Food From Production to Consumption*, Committee to Ensure Safe Food from Production to Consumption, Institute of Medicine, National Research Council, National Academy Press, 1998.

¹⁵ CRS Report R41475, *Agriculture and Related Agencies: FY2011 Appropriations*. Fees are from the explanatory notes of the President's Budget request: http://www.obpa.usda.gov/explan_notes.html. FSIS collects user fees to cover overtime and other services, including inspection and laboratory costs, and also trust fund activities.

¹⁶ FDA data are from the President's Budget Request "All Purpose Table—Total Program Level."

¹⁷ CRS Report R41288, *Food and Drug Administration FY2011 Budget and Appropriations*, by Susan Thaul. User fees related to foods have been proposed in legislation and in budget requests over time. The FY2011 President's budget request has proposed user fees for reinspection, export certification, inspection and registration.

¹⁸ The 20% estimate is based on information reported by the Government Accountability Office (GAO) in "Revamping Oversight of Food Safety," prepared for the 2009 Congressional and Presidential Transition, and appear to represent proportions of total spending for food consumed at home. The 10% estimate is based on data from USDA's Economic Research Service (ERS) on U.S. per capita food consumption at <http://www.ers.usda.gov/data/foodconsumption/>.

¹⁹ FDA, "Questions and Answers on the Food Safety Modernization Act," <http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm238506.htm>.

has said that it is “committed to applying its inspection resources in a risk-based manner and adopting innovative inspection approaches.”

- **Imported Food Safety**—The FSMA provides FDA with new tools to ensure that food imports meet U.S. food safety standards. For example, for the first time, importers must verify that their foreign suppliers have adequate preventive controls in place to ensure safety, and FDA will be able to accredit qualified third party auditors to certify that foreign food facilities are complying with U.S. food safety standards.
- **Response**—For the first time, FDA will have mandatory recall authority for all food products. FDA has said that it expects that “it will only need to invoke this authority infrequently since the food industry largely honors our requests for voluntary recalls.”
- **Enhanced Partnerships**—The FSMA directs FDA to improve training of state, local, territorial and tribal food safety officials. The law strengthens existing collaboration among all food safety agencies—U.S. federal, state, local, territorial, tribal, and foreign—to achieve its public health goals.

The FSMA also 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 appropriation by about \$1.4 billion over a five-year period (FY2011-FY2015).²⁰ The enacted bill authorizes an increase in FDA staff, reaching up to 5,000 in FY2014.

For more detailed information, see CRS Report R40443, *The FDA Food Safety Modernization Act (P.L. 111-53)*.

Key Issues for the 112th Congress

The 112th Congress may provide oversight and scrutiny of food safety changes enacted in the previous Congress as they are implemented. In addition, the 112th Congress also may continue to consider changes to other food safety laws and policies that continue to be actively debated in Congress. Among these are food safety initiatives covering meat, poultry, and seafood products; legislation intended to curtail the non-medical use of antibiotics in animal feeds and to ban the use of certain plastic components commonly used in food containers; food labeling; and the use of plant and animal biotechnology, among other issues.

Oversight and Implementation of the New Law

FSMA is the largest expansion of FDA’s food safety authorities since the 1930s. It includes provisions that expand FDA’s authority to conduct a mandatory recall of contaminated food products; enhance surveillance systems to investigate foodborne illness outbreaks; establish and enforce new preventive controls and food safety plans at some food processing facilities and

²⁰ 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.

farms; enhance FDA's traceability capacity within the nation's food distribution channels; increase inspection frequencies of high-risk food facilities (both domestic and foreign facilities); and expand FDA's authority and oversight capabilities of foreign companies that supply food imports to the United States. The 112th Congress may actively oversee implementation of the law, including associated rulemaking. Implementation of a number of provisions will require coordination with other federal agencies such as USDA and the Department of Homeland Security (DHS).

Some in Congress may actively follow the implementation of certain exclusions in the new food safety law intended to mitigate the economic effects on small, organic, direct-to-market, and sustainable farming operations.²¹ These provisions will exempt from the new federal regulations some small-sized farms and food processors that sell directly to consumers (FSMA, sections 103 and 105). These exemptions require additional rulemaking by FDA to determine what constitutes a "small" and "very small" business under the new law. Some public health groups may remain vigilant of how these exemptions are implemented, particularly for growers and processors of certain perceived "high-risk" foods (to be determined by the HHS Secretary), although these operations would be subject to oversight by state and local authorities and their exemption can be withdrawn by the FDA in the event of a foodborne illness. Some agribusiness groups also remain opposed to these exemptions because of broader industry concerns about the need to preserve consumer confidence in the safety of all marketed produce; another industry concern is whether small foreign producers might also be exempt, if small U.S. producers are exempt (given prevailing U.S. equivalency standards).

Funding the New Law

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. Given the current budgetary climate, funding to undertake many of these new or enhanced federal activities is uncertain. Although the law authorized appropriations when it established the new food safety system, it did not provide the actual funding needed for FDA to perform these activities. These funding decisions rest with the House and Senate Appropriations Committees, which annually fund FDA's activities in the Agriculture appropriations bill. The Administration requested additional funds for FDA in its budget request to fund additional food safety activities, but Congress has yet to act on a full-year appropriation to fund FDA for FY2011.²² FDA and the activities of the new food safety law will be competing for a limited amount of discretionary funds along with the other agencies funded in the annual appropriations bill. If sufficient funds are not forthcoming in the annual appropriations bill, then implementation of the food safety law may be difficult or delayed.

CBO estimated that implementing the newly enacted 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."²³ FDA's annual budget for

²¹ For more information, see CRS Report RL34612, *Food Safety on the Farm*.

²² See CRS Report R41475, *Agriculture and Related Agencies: FY2011 Appropriations*.

²³ 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, (continued...)

its human foods program was \$784 million for FY2010. Other industry experts have stated that FDA needs substantially more resources to effectively monitor the U.S. food supply.²⁴ FDA's deputy commissioner for foods, Michael Taylor, has indicated that FDA has "already done a lot of work in anticipation of the new law," but that funding will continue to be an issue and that building a new preventive system will require new resources and investment.²⁵

Given existing budgetary constraints, some have questioned whether the 112th Congress will fund the increased staff and regulatory activities authorized by the bill. FDA Commissioner Margaret Hamburg has stated that there are some steps the agency can take without the increased funding and said she remains "optimistic" that FDA will be able to move forward and implement the bill.²⁶ The expanded federal authorities in the new food safety bill—covering increased inspections, surveillance and enforcement—would likely require an increase in FDA field staff. The newly enacted law states a "goal of not fewer than ... 5,000 staff members in fiscal year 2014" (FSMA, section 401), an increase above estimated current FDA field staff of about 2,800 FTEs (full-time equivalents) in 2010.

The new chairman of the appropriations subcommittee overseeing FDA's and USDA's budgets, Representative Jack Kingston, has questioned the need for increased funding for FDA under the newly enacted law, considering the current budgetary environment.²⁷

The Next Omnibus Farm Bill

The 112th Congress could consider reauthorization of the 2008 farm bill (Food, Conservation, and Energy Act of 2008, P.L. 110-246) because much of the current law expires in 2012.²⁸ Although many of the enhancements enacted in FSMA focused on FDA-regulated foods and programs, the new law did include provisions that involve coordination with USDA and could have implications for some farm bill programs. For example, FSMA requires that FDA coordinate with the extension activities of USDA's National Institute of Food and Agriculture (NIFA) in advising producers and small processors of new food safety requirements through competitive training and technical assistance grants (FSMA, section 209). The new law also creates a new program, "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 new law. Funding for these programs is authorized to be appropriated through FY2015. These new programs may be considered in the context of the next farm bill. Similarly, the new food safety law also specifies that "in the case of production that is certified organic," the food safety requirements should not "conflict with or duplicate the requirements of the national organic program" under the Organic Foods Production Act of 1990 (P.L. 101-624), which was last amended by the 2008 farm bill.

(...continued)

2010," August 12, 2010. Reflecting the August 2010 Senate amendment to S. 510.

²⁴ Helena Bottemiller, "Acheson: FDA Needs \$5 Billion for Food Safety," *Food Safety News*, October 28, 2010.

²⁵ Helena Bottemiller, "FDA's Taylor: 'We'll Hit the Ground Running'," *Food Safety News*, January 28, 2011.

²⁶ Helena Bottemiller, "Food Safety Bill Advocates Expect Funding Fight," *Food Safety News*, January 4, 2011.

²⁷ Helena Bottemiller, "FDA Food Safety Funding Still on Chopping Block," *Food Safety News*, January 13, 2011.

²⁸ For more information, see CRS Report RS22131, *What Is the "Farm Bill"?* and CRS Report RL34696, *The 2008 Farm Bill: Major Provisions and Legislative Action*.

Alternatively, the next farm bill (possibly in 2012) could contain provisions in response to the new food safety law. For example, the new food safety law requires new safety standards for produce growers (FSMA, section 105), as well as new requirements that growers and food facilities have food safety plans. During the farm bill debate, the agricultural community may want USDA to deliver additional training programs, technical assistance, or research programs for produce growers who are affected by the law. If new USDA discretionary programs are developed in the farm bill, they might also face the same funding uncertainty as FDA for the new food safety law. If authorizers choose, such programs could be funded in the farm bill with mandatory funding. However, competition for limited mandatory funds is expected to be fierce in the farm bill among existing mandatory programs.

Meat and Poultry Inspection

The food safety changes enacted in the 111th Congress focused on FDA-regulated foods and did not address foods under the jurisdiction of USDA. USDA's FSIS regulates most meat and poultry and some egg products. Some in 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.²⁹ Food safety incidents and concerns regarding USDA-regulated meat and poultry products are similarly well documented. In addition, a series of bills were introduced and debated in the 111th Congress regarding the safety of meat and poultry products, which may be re-introduced in the 112th Congress. Among food safety issues regarding meat and poultry products are the safety of the meat and poultry being supplied to school meals programs; FSIS protocols for handling food recalls and related enforcement issues; improved meat traceability capabilities and animal identification systems; FSIS budgetary and staffing constraints; animal diseases and other related sanitary issues; and humane slaughter and animal welfare concerns.³⁰

A related issue involves allowing state-inspected meat and poultry products into interstate commerce. Federal law long prohibited state-inspected meat and poultry plants from shipping their products across state lines, a ban that many states and small plants sought to overturn. In the 110th Congress, the 2008 farm bill (Food, Conservation, and Energy Act of 2008, P.L. 110-246, section 11015) amended current meat and poultry laws to authorize a new opt-in program for state-inspected plants.³¹ This program was intended to supplement rather than replace the existing federal-state cooperative inspection programs, and reportedly was developed as a compromise in the 2008 farm bill. Some proponents of ending the interstate ban on state-inspected meat contended that the new language is overly restrictive, while those who supported the change countered that it provides appropriate safeguards. This issue could get renewed interest if Congress decides to actively review existing meat and poultry food safety laws at USDA; also, issues may arise as USDA finalizes and implements rules for an opt-in program for state-inspected plants.

²⁹ See, for example, Statement by Representative Rosa DeLauro, Congressional Record, December 21, 2010, p. H8887.

³⁰ For more information, see CRS Report RL32922, *Meat and Poultry Inspection: Background and Selected Issues*.

³¹ See CRS Report RL34202, *State-Inspected Meat and Poultry: Issues for Congress*.

Antibiotic Use in Animal Agriculture

Public health experts have expressed concern about growing resistance of infectious diseases to antibiotics, and about patients whose infections are difficult or impossible to treat as a result.³² Antibiotic resistance has been linked to a number of causes, including the overuse of antibiotics by medical professionals, and the use of antibiotics for non-medical purposes in food animals. (Antibiotics are added to feed for some types of food-producing animals not only to treat and prevent diseases, but also to improve growth and efficient use of feed rations.) Some 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. In the 111th Congress, these bills included the Preservation of Antibiotics for Medical Treatment Act of 2009 (PAMTA) introduced in the House and Senate by Representative Slaughter (H.R. 1549) and by Senator Reid (S. 619), respectively. These bills did not advance, and might be offered again in the 112th Congress.

Seafood and Fisheries Products

Many food safety changes enacted in FSMA did not specifically address seafood and fisheries products.³³ Domestic and imported fish and shellfish are already regulated under a system of risk prevention controls known as HACCP (for "Hazard Analysis and Critical Control Points"). However, FSMA contains various provisions that could affect domestic and imported seafood products and may generate congressional oversight. 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, section 201); requirements for guidance related to post harvest processing of raw oysters (FSMA, section 114); and inspections of foreign processing facilities by the Secretary of Commerce to assess practices and processes used in connection with seafood production (FSMA, section 306). In addition, a number of seafood safety issues were considered by the 111th Congress and may be of continued interest to the 112th Congress. These issues include regulation of Gulf oyster fisheries, catfish inspection, and the safety of Gulf of Mexico seafood following the 2010 oil spill.

In the wake of the Gulf of Mexico oil spill, large areas of federal and state waters were closed to fishing as a precautionary measure to ensure the safety of seafood.³⁴ Crude oil contains a mixture of chemicals including polycyclic aromatic hydrocarbons (PAHs) that may accumulate in the tissues of marine organisms. Petroleum products may also taint seafood with an oily smell and taste. FDA considers tainted fish to be adulterated and does not permit the sale of adulterated foods.³⁵ For Gulf waters that have re-opened, sensory analyses have found no detectable oil or

³² For more information see CRS Report R40739, *Antibiotic Use in Agriculture: Background and Legislation* and CRS Report R41047, *Potential Trade Implications of Restrictions on Antimicrobial Use in Animal Production*.

³³ For more information see CRS Report RS22797, *Seafood Safety: Background and Issues*.

³⁴ For more information contact Harry Upton at 7-2264.

³⁵ 21 U.S.C. § 331 and 21 U.S.C. § 342(a).

dispersant odors or flavors, and results of chemical analyses have been well below levels of concern.³⁶ Some have criticized these efforts because they believe seafood sampling coverage is insufficient, levels of concern should have considered additional factors, and the list of toxic substances being tested is too narrow.³⁷ Nearly all Gulf federal waters except for 1,041 square miles immediately surrounding the well-head, and all state waters except for some areas in Louisiana, have been reopened to commercial and recreational fishing.³⁸

Criminal Penalties and Enforcement

The food safety changes enacted in FSMA did not substantially alter the criminal penalties provisions within existing FDA laws. However, such provisions were actively considered as part of the broader food safety debate. For example, the House-passed food safety bill (H.R. 2749, 111th Congress) would have amended the penalties provisions of FFDCA to provide for fines and for 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 also was debated as part of the Senate food safety bill, but not included in the Senate version of the bill. A separate Senate bill, introduced by Senator Patrick Leahy (Food Safety Accountability Act of 2010, S. 3767) and approved and reported out of the Senate Judiciary Committee, also would have amended the penalty provisions of FFDCA to provide for fines and a maximum prison sentence for certain violations. Although these provisions ultimately were not included in the enacted food safety legislation, some may continue to be concerned about the need to modify existing laws to institute stricter criminal fines and penalties as part of the U.S. food safety system. Such legislation might be re-introduced and debated again in the 112th Congress.

Bisphenol A (BPA)

The food safety changes enacted in the 111th Congress did not alter existing requirements regarding Bisphenol A (BPA), a component of certain plastics that is commonly used in food containers, such as plastic bottles or metal can liners.³⁹ Food containers made with BPA are regulated by the FDA. BPA exposure has been linked to certain developmental problems in animals, and proposals to reduce or eliminate the amount of the chemical in food containers were actively considered as part of the food safety debate in the 111th Congress. For example, the House-passed food safety bill would have required FDA to determine whether there was “a reasonable certainty of no harm for infants, young children, pregnant women, and adults” for approved uses of polycarbonate plastic and epoxy resin made with BPA in food and beverage containers, among other provisions. A similar provision was debated as part of the Senate version of the bill, and it was thought by some to be the reason that earlier Senate passage of the food safety legislation was delayed.⁴⁰ The Senate provision introduced by Senator Dianne Feinstein,

³⁶ National Oceanic and Atmospheric Administration, “NOAA Reopens More Than 8,000 square miles of the Gulf of Mexico to Fishing,” press release, November 15, 2010, http://www.noaanews.noaa.gov/stories2010/20101115_reopening.html.

³⁷ Bob Marshall, “Safety of Gulf Seafood Debated 8 Months After BP Oil Spill,” *The Times-Picayune*, December 19, 2010, http://www.nola.com/news/gulf-oil-spill/index.ssf/2010/12/safety_of_gulf_seafood.html.

³⁸ For the FDA’s oil spill website see, <http://www.fda.gov/Food/FoodSafety/Product-SpecificInformation/Seafood/ucm210970.htm> and for NOAA’s website see, http://sero.nmfs.noaa.gov/deepwater_Horizon_oil_spill.htm.

³⁹ See CRS Report RS22869, *Bisphenol A (BPA) in Plastics and Possible Human Health Effects*.

⁴⁰ See, for example, Julian Pecquet, “Democrats quarrel over food safety legislation,” *The Hill*, July 19, 2010.

Ban Poisonous Additives Act of 2009 (S. 593, 111th Congress), would have banned BPA in all FDA-regulated food containers. These proposals were not enacted, and there may be continued interest in BPA regulation in the 112th Congress.

Dietary Supplements

The provisions of FSMA apply to most foods, including dietary supplements. FSMA includes two provisions specifically focused on supplements (FSMA, section 113). The first provision requires FDA to notify the Drug Enforcement Administration (DEA) if, when reviewing the safety of a new dietary ingredient, the agency determines the information to be inadequate because the ingredient contains an anabolic steroid or an analogue of one. Following notification, DEA can take action on the dietary ingredient as a controlled substance. The second provision requires that FDA publish guidelines, within 180 days of enactment, to clarify the definition of a new dietary ingredient and how a product so categorized is to be evaluated for safety. During the food safety debate, several other provisions were considered that would have addressed supplements issues, including product safety, increasing penalties for unsafe products, mandatory reporting for all adverse effects, and expanding allowable health claims. Such provisions were not included in FSMA, but could be addressed again in the 112th Congress.

Agricultural Biotechnology

Genetically engineered (GE, sometimes called genetically modified, or GM) crop varieties first became commercially available in the mid-1990s.⁴¹ Since then U.S. soybean, cotton, and corn farmers have rapidly adopted them to reduce production costs and raise crop yields. A number of animal biotechnologies (including cloning) also are becoming available. Some Members of Congress, particularly from agricultural areas, generally favor the adoption of such technologies, along with publicly supported research and other activities aimed at gaining their acceptance in foreign and domestic markets. Others question the food safety impacts of GE crops and animals, and whether the current U.S. regulatory framework, which is based primarily upon statutory authorities enacted before the rise of agricultural biotechnology, is still adequate.

In recent years, the introduction and pending efforts to deregulate several new genetically engineered crops (e.g., alfalfa, sugar beets), and subsequent legal challenges to that introduction and deregulation, have raised important issues regarding the effectiveness of the USDA's environmental review process, conducted through the agency's Animal and Plant Health Inspection Service (APHIS). Concern about increased herbicide resistant weeds associated with the widespread use of genetically engineered crop varieties was also the subject of hearings in the 111th Congress. Other concerns involve the possibility of cross-contamination by GE crops of other traditional crops and organically grown crops.⁴² FDA is also nearing completion of its review to approve a genetically engineered salmon for human consumption. Labeling issues have also been debated. Given these concerns and upcoming USDA regulations, Congress may closely monitor the situation.

⁴¹ For more information see CRS Report RL32809, *Agricultural Biotechnology: Background and Recent Issues* and CRS Report RL33334, *Biotechnology in Animal Agriculture: Status and Current Issues*

⁴² See, for example, Organic Trade Association (OTA) press release, "OTA Deeply Disappointed with Failure to Protect Farmer and Consumer Choice," January 27, 2011.

Single Food Agency

Some in Congress may continue to push for additional reforms to the nation's food safety system, particularly with respect to coordination and organization among federal agencies. Efforts to establish a single federal food safety agency were introduced and debated in the 105th and each subsequent Congress. Although the idea has the support of the Government Accountability Office, it also has its detractors. While some see consolidation as an opportunity for improvement in the efficiency and effectiveness of food safety regulation, others worry that it could unnecessarily compromise day-to-day food safety efforts. The food safety changes enacted in the 111th Congress did not alter the existing food safety jurisdiction between FDA and USDA, so the issue may remain of interest to the Congress.

Author Contact Information

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