



Food Safety Issues for the 112th Congress

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Summary

The 111th Congress passed comprehensive food safety legislation in December 2010 (FDA Food Safety Modernization Act (FSMA), P.L. 111-353). 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). FSMA does not apply to the federal food safety system as a whole, and did not alter oversight authorities within other federal agencies responsible for food safety, such as the U.S. Department of Agriculture (USDA).

Although numerous agencies share responsibility for regulating food safety, 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 expands FDA's authority to conduct a mandatory recall of contaminated food products, enhances surveillance systems for foodborne illness outbreaks, establishes preventive 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. Since the law was signed in January 2011, FDA has been actively engaged in developing new regulations to implement FSMA.

The 112th Congress may provide oversight over how the law is implemented, including FDA's coordination with other federal agencies, such as those in 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. Several bills debated in the 110th and 111th Congress have been reintroduced.

Some in Congress also may continue to push 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, including concerns about the adequacy of resources and regulatory tools to combat foodborne illness, as well as concerns about coordination and organization among federal agencies.

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FSMA is focused on FDA-regulated foods and is the largest expansion of FDA's food safety authorities since the 1930s. Among its key elements, FSMA 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 about one in six Americans—a total of 48 million people—become sick from contaminated food.¹ Of these, an estimated 128,000 cases require hospitalization and 3,000 cases result in death. It is reported that foodborne illness is associated with an estimated economic burden of \$77.7 billion in the United States each year.²

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

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

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

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

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

other actions.⁴ 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 2020.⁵

Since the law was signed in January 2011, FDA has been actively engaged in developing new regulations to implement FSMA, including a preventive controls rule in food facilities, a foreign supplier verification rule, and a produce safety rule. FDA also hosted a series of public meetings during 2011 to provide interested parties with an opportunity to participate and comment prior to the proposal of a rule.⁶

Food Safety Incidents

Food safety incidents frequently heighten public and media scrutiny of the U.S. food safety system.⁷ 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 foods, such as the 2011 multi-state outbreak of listeriosis linked to whole cantaloupes; the 2010-2011 multistate recall of *Salmonella*-contaminated sprouts; and a 2010 nationwide recall of more than 500 million eggs associated with increased cases of infection with *Salmonella* Enteritidis. 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. 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 reports that in 2008 there were 1,034 foodborne disease outbreaks.⁸ Norovirus was the most common disease, accounting for 49% of outbreaks and 46% of illnesses. *Salmonella* was the second most common, accounting for 23% of outbreaks and 31% of illnesses. As in previous years, beef, poultry, and finfish were the commodities associated with the largest number of foodborne outbreaks. Among most large multistate outbreaks, vine-stalk vegetables, fruits-nuts, and beef were the commodities with the most outbreak-associated illnesses.

⁴ FSWG, "Food Safety Working Group: Progress at 1 Year," July 9, 2010, <http://www.foodsafetyworkinggroup.gov/>.

⁵ 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>.

⁶ For more information, see FDA, "The New FDA Food Safety Modernization Act (FSMA)," <http://www.fda.gov/Food/FoodSafety/FSMA/default.htm>.

⁷ 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*.

⁸ CDC, "Surveillance for Foodborne Disease Outbreaks—United States, 2008," *Morbidity and Mortality Weekly Report* (MMWR), vol. 60, no. 35, September 9, 2011, <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6035a3.htm>. These outbreaks resulted in about 23,152 cases of illness, 1,276 hospitalizations, and 22 deaths in 2008 (the most recent year for which data are available).

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 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

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

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.

(28% of deaths), *Toxoplasma gondii* (24%), *Listeria monocytogenes* (19%), norovirus (11%), and *Campylobacter* spp. (6%).¹²

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 and fish 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

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

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*.

responsibilities has been problematic, or whether a reorganization would divert time and attention from other fundamental problems in the system.¹⁴

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 FY2011 budget was \$1.007 billion in appropriated funds plus another approximately \$150 million in industry-paid user fees.¹⁵ FDA's budget for foods was \$835.7 million, virtually all of it appropriated with limited authorized user fees.¹⁶ 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.¹⁷ Staffing levels also vary considerably among the two agencies: FSIS staff number around 9,600 FTEs, while FDA staff working on food-related activities number about 3,400 FTEs (FY2011 estimates).

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 law:¹⁸

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

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 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 USDA, 2012 Explanatory Notes, Food Safety and Inspection Service, February 12, 2011, <http://www.obpa.usda.gov/21fsis2012notes.pdf>.

¹⁶ FDA "Operating Plan for FY 2011 and Comparisons to FY 2010," http://www.hhs.gov/asfr/ob/docbudget/2011operatingplan_fda.pdf.

¹⁷ 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/>.

¹⁸ FDA, "Questions and Answers on the Food Safety Modernization Act," <http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm238506.htm>.

The law specifies how often FDA should inspect food producers. FDA has said that it is “committed to applying its inspection resources in a risk-based manner and adopting innovative inspection approaches.”

- **Imported Food Safety**—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**—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.

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).¹⁹ FSMA 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. 111-353)*.

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 the agency’s authority to conduct a mandatory recall of contaminated food products; enhance surveillance systems to investigate foodborne illness outbreaks; establish and

¹⁹ 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.

enforce new preventive controls and food safety plans at some food processing facilities and farms; enhance traceability capacity within the nation's food distribution channels; increase inspection frequencies of high-risk food facilities (both domestic and foreign facilities); and expand FDA's authority and oversight capabilities of foreign companies that supply food imports to the United States. FDA has been actively engaged in developing new regulations to implement the FSMA.²⁰ Implementation of a number of provisions requires 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. FSMA 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 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."²²

Given the current budgetary climate, funding to undertake many federal activities in FSMA 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 budget request

²⁰ See, for example, FDA, "Implementation and Progress," <http://www.fda.gov/Food/FoodSafety/FSMA/ucm250568.htm> and FDA's FSMA "Progress Reports," <http://www.fda.gov/Food/FoodSafety/FSMA/ucm255893.htm>. FDA's one year progress report is at <http://www.fda.gov/Food/FoodSafety/FSMA/ucm285773.htm>.

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

²² 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.

projected the need for additional funds for FDA, anticipating a total need of \$1.035 billion for FDA's food program for FY2012, not including expected fees. FDA justified its requested increase based on the need to implement the various elements of FSMA. The enacted FY2012 appropriation provides \$866.1 million for FDA's Foods Program, which is \$30.4 million above FY2011 levels (+4%), not including funding from expected user fees. The enacted amount is almost \$90 million less than the Administration's FY2012 request.²³ This discrepancy has raised questions about how FDA will be able to implement food safety reforms authorized in the 111th Congress, 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.

The Next Omnibus Farm Bill

The 112th Congress has started to consider reauthorization of the 2008 farm bill (Food, Conservation, and Energy Act of 2008, P.L. 110-246), given that much of the current law expires in 2012.²⁴ Although many of the food safety reforms enacted under FSMA were 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. Possible farm bill programs that could be affected include provisions within the research and the horticulture and organic titles of the 2008 bill. 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.

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. Some in 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. Such programs could be funded in the farm bill with mandatory funding. Competition for limited mandatory funds is expected to be fierce in the farm bill among existing mandatory programs.

Food Safety Regulations for Produce Growers

Under FSMA, FDA is developing mandatory food safety regulations and traceability requirements affecting farmers, packers, and processors of both domestically produced and

²³ For more information, see CRS Report R41964, *Agriculture and Related Agencies: FY2012 Appropriations*.

²⁴ 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*.

imported products. At the farm production level, these requirements will mostly affect produce growers. Most other types of food producers—such as meat, poultry and dairy farms; fisheries; and producers of raw, bulk grains—will likely not be subject to FSMA’s farm-level requirements. FSMA also exempted from regulation most small grower and processing operations that sell products locally. Requirements for produce growers under FSMA, which must be established within two years of enactment, are to include science-based, minimum standards for the safe production and harvesting of fruits and vegetables. These standards could address certain farm practices at produce operations, including the use of soil amendments, hygiene, packaging, temperature controls, animals in the growing area and water. Congress will likely monitor development and implementation of these regulations as they are announced.

In addition, in April 2011, USDA’s Agricultural Marketing Service (AMS) published a proposed rule to develop and implement USDA-administered requirements, reflecting FDA and USDA recommended food safety practices for leafy greens (“National Marketing Agreement Regulating Leafy Green Vegetables”).²⁵ This proposed rule covers the handling of fresh leafy green vegetables—spinach, lettuce, cabbage—only. The AMS proposal has been under consideration at USDA for the past few years and reflects an industry-led effort to establish a voluntary program requiring compliance of its signatories (marketing agreement), including importers, in meeting certain commercial food quality and safety requirements. It remains unclear how USDA’s proposed voluntary efforts for leafy greens will interact with FDA’s rulemaking process to develop mandatory safety standards for a wider range of fruits and vegetables subject to FSMA.

Meat and Poultry Inspection

FSMA focused on FDA-regulated foods and did not directly address foods under the jurisdiction of USDA. USDA’s FSIS regulates most meat and poultry and some egg products. Some Members of Congress have long claimed that once FDA’s food safety laws were amended and updated, it would be expected that Congress would next turn to amending laws and regulations governing USDA’s meat and poultry products.²⁶ 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. Some of these bills were re-introduced in the 112th Congress (for example, S. 1529). Among food safety issues regarding meat and poultry products are the safety of the meat and poultry being supplied to school feeding programs; FSIS protocols for handling food recalls and related enforcement issues; improved meat traceability capabilities and animal identification systems; FSIS budgetary and staffing constraints; animal diseases and other related sanitary issues; and humane slaughter and animal welfare concerns.²⁷

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

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

²⁶ See, for example, Statement by Representative Rosa DeLauro, Congressional Record, December 21, 2010, p. H8887.

²⁷ For more information, see CRS Report RL32922, *Meat and Poultry Inspection: Background and Selected Issues*.

state-inspected plants.²⁸ 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.

Antibiotic Use in Animal Agriculture

Public health experts have expressed concern about growing resistance of infectious diseases to antibiotics, and about patients whose infections were difficult or impossible to treat as a result. Antibiotic resistance has been linked to a number of causes, including the overuse of antibiotics by medical professionals, and the use of antibiotics for non-medical purposes in food animals. Antibiotics are added to feed for some types of food-producing animals not only to treat and prevent diseases, but also to improve growth and efficient use of feed rations. Some public health advocates argue that non-medical uses in food animals should be limited to drugs that are not useful in human medicine. Others oppose this approach, arguing that animal production may not be commercially viable without the drugs' routine use, and that the linkage between such use and antimicrobial resistance in humans lacks a strong scientific basis. In the past several Congresses, bills have been introduced that would curtail the non-medical use of antibiotics in animal feeds. In the 111th Congress, these bills included the Preservation of Antibiotics for Medical Treatment Act of 2009 (PAMTA) introduced in both the House and Senate. These bills did not advance, but were offered again in the 112th Congress (H.R. 965; S. 1211).

Seafood and Fisheries Products

Many food safety changes enacted in FSMA did not specifically address seafood and fisheries products.²⁹ 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, other food safety reforms enacted in the 111th Congress 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 food safety issues regarding seafood were considered by the 111th Congress and continue to be debated in the 112th Congress. These include a bill that would strengthen federal consumer product safety programs and activities for commercial marketed seafood (S. 50), a bill that would repeal inspection and grading requirements for catfish (S. 496), and a bill that would strengthen research on food safety of Gulf of Mexico seafood (H.R. 832), following the 2010 oil spill.

²⁸ See CRS Report RL34202, *State-Inspected Meat and Poultry: Issues for Congress*.

²⁹ For more information see CRS Report RS22797, *Seafood Safety: Background and Issues*.

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 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).

Bisphenol A (BPA)

FSMA did not alter FDA's existing requirements regarding bisphenol A (BPA), a component of certain plastics that is commonly used in food containers, such as plastic bottles or metal can liners.³⁰ 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.³¹ The Senate provision introduced by Senator Dianne Feinstein, Ban Poisonous Additives Act of 2009 (S. 593, 111th Congress), would have banned BPA in all FDA-regulated food containers. These proposals were not enacted, and were reintroduced in the 112th Congress (S. 136; H.R. 432). Also, a court ruling in response to a citizen suit requires FDA to respond to a petition seeking a ban on BPA in food containers, and the agency reports that it plans to do so.

Dietary Supplements

FSMA provisions apply to most foods, including dietary supplements. The law includes two provisions specifically affecting supplements. The first requires FDA to notify the Drug Enforcement Administration (DEA) if, when reviewing the safety 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. The second provision required FDA to publish guidelines to clarify the information manufacturers must provide when notifying the agency of the use of a new dietary ingredient in a supplement. The guidelines (published in July 2011) have generated controversy,

³⁰ See CRS Report RS22869, *Bisphenol A (BPA) in Plastics and Possible Human Health Effects*.

³¹ See, for example, Julian Pecquet, "Democrats quarrel over food safety legislation," *The Hill*, July 19, 2010.

with some manufacturers claiming them to be burdensome and not in keeping with the Dietary Supplement Health and Education Act (DSHEA).

Pesticide Residues

The Environmental Protection Agency (EPA) is responsible for regulating pesticide use on food and determining whether and under what conditions the proposed pesticide use would present an unreasonable risk to human health or the environment. In addition, when Congress enacted the Food Quality Protection Act of 1996 (FQPA), it established a new standard of safety for pesticide residues on food. Maximum pesticide residue levels (known as “tolerances”) must be set by EPA to ensure with “a reasonable certainty” that “no harm” will come to children as a result of pesticide exposure.³² EPA regulates the labeling, sale, and use of pesticides on domestically produced and imported food toward that safety goal. FDA is responsible for ensuring that tolerance levels for food are not exceeded. Based on the data submitted by pesticide manufacturers when they apply to register a pesticide active ingredient, pesticide product, or a new use of a registered pesticide under FIFRA (Section 3), EPA determines whether and under what conditions the proposed pesticide use would present an unreasonable risk to human health or the environment. If the pesticide is proposed for use on a food crop, EPA also determines whether a “safe” level of pesticide residue, called a “tolerance,” can be established under the FFDCA. Congress oversees EPA implementation of the FQPA and often questions EPA’s statutory authority and regulatory decisions regarding restrictions (or lack thereof) for popular pesticides. In addition, legislation has also been introduced to improve scrutiny of endocrine-disrupting chemicals, which are usually pesticides (H.R. 2521 and S. 1361).

Agricultural Biotechnology

Genetically engineered (GE, sometimes called genetically modified, or GM) crop varieties first became commercially available in the mid-1990s.³³ In recent years, the introduction and proposed deregulation of several new GE crops (e.g., alfalfa, sugar beets), and subsequent legal challenges to that introduction and deregulation, have raised important issues regarding the effectiveness of the USDA’s environmental review process, as well as the continuing effectiveness of the 1986 General Framework that underlies the U.S. biotechnology regulatory structure. Concern about increased herbicide-resistant weeds associated with the widespread use of genetically engineered crop varieties was the subject of hearings in the 111th Congress. Other concerns involve the possibility of cross-contamination by GE crops with other traditional and organically grown crops.³⁴ FDA is also nearing completion of its review to approve a genetically engineered salmon, which could be the first GE animal approved for human consumption. Various product labeling options for the salmon have also been debated. In the 112th Congress, two bills would, respectively, amend FFDCA to require labeling of GE fish (H.R. 520) and prevent the approval of GE fish (H.R. 521). Two additional bills would require labeling of foods that contain GE material (H.R. 3553), and regulate genetically engineered pharmaceutical and industrial crops (H.R.

³² For more information see CRS Report RL31921, *Pesticide Law: A Summary of the Statutes*.

³³ 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*

³⁴ See, for example, Organic Trade Association (OTA) press release, “OTA Deeply Disappointed with Failure to Protect Farmer and Consumer Choice,” January 27, 2011.

3554), among other purposes. Given these impending regulatory actions and concerns, Congress may closely monitor the situation.

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.

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