



# The Federal Food Safety System: A Primer

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## Summary

Numerous federal, state, and local agencies share responsibilities for regulating the safety of the U.S. food supply. Federal responsibility for food safety rests primarily with the Food and Drug Administration (FDA) and the U.S. Department of Agriculture (USDA). FDA, an agency of the Department of Health and Human Services, is responsible for ensuring the safety of all domestic and imported food products (except for most meats and poultry). 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. State and local food safety authorities collaborate with federal agencies for inspection and other food safety functions, and they regulate retail food establishments.

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—as evidenced by a series of widely publicized food safety problems, including concerns about adulterated food and food ingredient imports, and illnesses linked to various types of fresh produce, to peanut products, and to some meat and poultry products. Some critics also note that the organizational complexity of the U.S. food safety system as well as trends in U.S. food markets—for example, increasing imports as a share of U.S. food consumptions, increasing consumption of fresh often unprocessed foods—pose ongoing challenges to ensuring food safety.

The 111<sup>th</sup> Congress passed comprehensive food safety legislation in December 2010 (FDA Food Safety Modernization Act, P.L. 111-353). Although numerous agencies share responsibility for regulating food safety, this newly enacted legislation focused on foods regulated by FDA 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.*). This newly enacted law is the largest expansion of FDA's food safety authorities since the 1930s; it does not directly address meat and poultry products under the jurisdiction of USDA. The 112<sup>th</sup> Congress will likely provide oversight and scrutiny over how the law is implemented, including FDA's coordination with other federal agencies such as USDA and the Department of Homeland Security (DHS).

In addition, 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. Food safety incidents and concerns regarding USDA-regulated meat and poultry products are similarly well-documented. A series of bills were introduced and debated in the previous few Congresses. These bills may be re-introduced and debated in the 112<sup>th</sup> Congress.

## **Contents**

Background .....	1
The Agencies and Their Roles .....	1
Food and Drug Administration .....	2
Food Safety and Inspection Service .....	3
Centers for Disease Control and Prevention.....	4
National Marine Fisheries Service .....	5
Environmental Protection Agency .....	5
Other Federal Agencies .....	5
Congressional Committees .....	5
Issues for Congress .....	6
Food Safety Incidents.....	6
Food Safety Legislation .....	7

## **Tables**

Table 1. Major Federal Food Safety Agencies.....	8
Table 2. Selected Comparison of FSIS and FDA Responsibilities .....	10

## **Contacts**

Author Contact Information .....	11
Acknowledgments .....	11

## Background

Americans spend more than \$1 trillion on food each year, nearly half of it in restaurants, schools, and other places outside the home.<sup>1</sup> Federal laws give food manufacturers, distributors, and retailers the basic responsibility for assuring that foods are wholesome, safe, and handled under sanitary conditions. A number of federal agencies, cooperating with state, local, and international entities, play a major role in regulating food quality and safety under these laws.

The combined efforts of the food industry and the regulatory agencies often are credited with making the U.S. food supply among the safest in the world. Nonetheless, 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 foodborne illnesses caused by contamination from any one of a number of microbial pathogens.<sup>2</sup> Of these, an estimated 128,000 cases require hospitalization and 3,000 cases result in death. In addition, experts have cited numerous other hazards to health, including the use of unapproved veterinary drugs, pesticides, and other dangerous substances in food commodities, of particular concern at a time when a growing share of the U.S. food supply is from overseas sources. These concerns, combined with the ongoing recurrence of major food safety-related incidents have heighten public and media scrutiny of the U.S. food safety system, and magnified congressional interest in the issue.

## The Agencies and Their Roles

The Government Accountability Office (GAO) has identified as many as 15 federal agencies collectively administering at least 30 laws related to food safety. The Food and Drug Administration (FDA), which is part of the U.S. Department of Health and Human Services (HHS), and the Food Safety and Inspection Service (FSIS), which is part of the U.S. Department of Agriculture (USDA), together comprise the majority of both the total funding and the total staffing of the government's food regulatory system. (See **Table 1** and **Table 2** for a brief comparative look at the agencies' responsibilities.)

FSIS's FY2010 budget was \$1.019 billion in appropriated funds plus another approximately \$130 million in industry-paid user fees.<sup>3</sup> FDA's budget for foods was \$784.1 million in FY2010,<sup>4</sup> virtually all of it appropriated with limited authorized user fees.<sup>5</sup> 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%-20% of

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<sup>1</sup> 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/>.

<sup>2</sup> U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, "Estimates of Foodborne Illness in the United States," <http://www.cdc.gov/foodborneburden/2011-foodborne-estimates.html>.

<sup>3</sup> 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](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.

<sup>4</sup> FDA data are from the President's Budget Request "All Purpose Table—Total Program Level."

<sup>5</sup> 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.

the U.S. food supply, while FDA is responsible for the remainder.<sup>6</sup> 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.

The comprehensive food safety legislation that passed in the 111<sup>th</sup> Congress (FDA Food Safety Modernization Act, P.L. 111-353) authorized additional appropriations and staff for FDA's future food safety activities. This newly enacted law is the largest expansion of FDA's food safety authorities since the 1930s; it does not directly address meat and poultry products under the jurisdiction of USDA. 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); collections from possible revenue and direct spending increases from new criminal penalties would be "insignificant, yielding a negligible net impact in each year."<sup>7</sup> The enacted bill authorizes an increase in FDA staff, reaching up to 5,000 staff members in FY2014.

## **Food and Drug Administration**

The FDA is responsible for ensuring that all domestic and imported food products—except for most meats and poultry—are safe, nutritious, wholesome, and accurately labeled. Examples of FDA-regulated foods are produce, dairy products, seafood, and processed foods. FDA has jurisdiction over meats from animals or birds that are not under the regulatory jurisdiction of FSIS. FDA shares responsibility for the safety of eggs with FSIS. FDA has jurisdiction over establishments that sell or serve eggs or use them as an ingredient in their products. FDA is also responsible for ensuring that most seafood products do not endanger public health (FSIS is to begin inspecting farmed catfish products under a 2008 farm bill provision). The primary statutes governing FDA's activities are the Federal Food, Drug, and Cosmetic Act, as amended (21 U.S.C. 301 *et seq.*); the Public Health Service Act, as amended (42 U.S.C. §§ 201 *et seq.*); and the Egg Products Inspection Act, as amended (21 U.S.C. §§ 1031 *et seq.*).

FDA's food inspection force numbers more than 1,900 in field offices throughout the United States, plus nearly 900 in the Washington, DC, area. FDA regulates food manufacturers' safety practices by relying on companies' self-interest in producing safe products, and by working with the industry to improve production practices. Overall, FDA has oversight of more than 44,000 U.S. food manufacturers, plus well over 100,000 additional registered food facilities such as warehouses and grain elevators. In addition, some 200,000 foreign food facilities are registered with the agency. Various estimates of unannounced compliance inspections of domestic establishments by FDA officials range from once every five years to once every 10 years, on average, although the agency claims to visit about 6,000 so-called high-risk facilities on an annual basis. FDA relies on notifications from within the industry or from other federal or state

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<sup>6</sup> The 20% estimate is based on information reported by the Government Accountability Office (GAO) in "Revamping Oversight of Food Safety," prepared for the 2009 Congressional and Presidential Transition, and appear to represent proportions of total spending for food consumed at home. The 10% estimate is based on data from USDA's Economic Research Service (ERS) on U.S. per capita food consumption at <http://www.ers.usda.gov/data/foodconsumption/>.

<sup>7</sup> CBO, Cost Estimate, "S. 510, Food Safety Modernization Act, as reported by the Senate Committee on Health, Education, Labor, and Pensions on December 18, 2009, incorporating a manager's amendment released on August 12, 2010," August 12, 2010. Reflecting the August 2010 Senate amendment to S. 510.

inspection personnel, as well as other sources, to alert it to situations calling for increased inspection.

A report by HHS's Office of Inspector General (OIG) provided additional insights into the FDA's inspections of domestic facilities. The OIG reported that the number of facilities subject to such inspections has risen from about 59,000 in 2004 to nearly 68,000 in 2008. However, the number of inspections conducted declined from about 17,000 in 2004 (29% of the total) to about 15,000 in 2008 (22%). During the five-year period examined by the OIG, 56% of food facilities were not inspected at all.<sup>8</sup>

In the Washington DC area, two FDA offices are the focal point for food safety-related activities. The Center for Food Safety and Applied Nutrition (CFSAN) is responsible for (1) conducting and supporting food safety research; (2) developing and overseeing enforcement of food safety and quality regulations; (3) coordinating and evaluating FDA's food surveillance and compliance programs; (4) coordinating and evaluating cooperating states' food safety activities; and (5) developing and disseminating food safety and regulatory information to consumers and industry. FDA's Center for Veterinary Medicine (CVM) is responsible for ensuring that all animal drugs, feeds (including pet foods), and veterinary devices are safe for animals, are properly labeled, and produce no human health hazards when used in food-producing animals.

The FDA also cooperates with over 400 state agencies across the nation that carry out a wide range of food safety regulatory activities. However, the state agencies are primarily responsible for actual inspection. FDA works with the states to set the safety standards for food establishments and commodities and evaluates the states' performance in upholding such standards as well as any federal standards that may apply. FDA also contracts with states to use their food safety agency personnel to carry out certain field inspections in support of FDA's own statutory responsibilities.

## **Food Safety and Inspection Service**

FSIS regulates the safety, wholesomeness, and proper labeling of most domestic and imported meat and poultry and their products sold for human consumption. Under the Federal Meat Inspection Act of 1906, as amended (21 U.S.C. §§ 601 *et seq.*), FSIS is required to inspect all cattle, sheep, swine, goats, and equines during slaughtering and processing. Under the Poultry Products Inspection Act of 1957, as amended (21 U.S.C. §§ 451 *et seq.*), FSIS is required to inspect "any domesticated bird" being processed for human consumption; however, USDA regulations implementing this law limit the definition of domesticated birds to chickens, turkeys, ducks, geese, ratites (emus, ostriches, and rheas), and guineas. FDA has jurisdiction over exotic and alternative meats not inspected by FSIS, and shares the responsibility for egg safety with FSIS.<sup>9</sup> The latter is responsible for the safety of liquid, frozen, and dried egg products, domestic and imported, and for the safe use or disposition of damaged and dirty eggs under the Egg Products Inspection Act, as amended (21 U.S.C. §§ 1031 *et seq.*).

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<sup>8</sup> HHS OIG, *FDA Inspections of Domestic Food Facilities* (OEI-02-08-00080), April 2010.

<sup>9</sup> USDA's Agricultural Marketing Service (AMS) also has responsibility for ensuring shell eggs for quality, but not safety, considerations (see **Table 1**).

FSIS staff numbers around 9,400; roughly 8,000 of them, including about 1,000 veterinarians, are in about 6,300 meat slaughtering and/or processing plants nationwide. FSIS personnel inspect all meat and poultry animals at slaughter on a continuous basis, and at least one federal inspector is on the line during all hours the plant is operating. Processing inspection does not require an FSIS inspector to remain constantly on the production line or to inspect every item. Instead, inspectors are on site daily to monitor the plant's adherence to the standards for sanitary conditions, ingredient levels, and packaging, and to conduct statistical sampling and testing of products. Because all plants are visited daily, processing inspection also is considered to be continuous.

FSIS also is responsible for certifying that foreign meat and poultry plants are operating under an inspection system equivalent to the U.S. system before they can export their product to the United States. FSIS inspectors located at U.S. ports of entry carry out a statistical sampling program to verify the safety of imported meats from cattle, sheep, swine, goats, and equines and imported poultry meat from chickens, turkeys, ducks, geese, quail, ratites, and guineas before they are released into domestic commerce. FDA is responsible for ensuring the safety of imported meat from any other species.

Twenty-seven states operate their own meat and/or poultry inspection programs. FSIS is statutorily responsible for ensuring that the states' programs are at least equal to the federal program. Plants processing meat and poultry under state inspection can market their products only within the state. If a state chooses to discontinue its own inspection program, or if FSIS determines that it does not meet the agency's equivalency standards, FSIS must assume the responsibility for inspection if the formerly state-inspected plants are to remain in operation. FSIS also has cooperative agreements with more than two dozen states under which state inspection personnel are authorized to carry out federal inspection in meat and/or poultry plants. Products from these plants may travel in interstate commerce.<sup>10</sup>

## **Centers for Disease Control and Prevention**

CDC is responsible for (1) monitoring, identifying, and investigating foodborne disease problems to determine the contributing factors; (2) working with FDA, FSIS, NMFS, state and local public health departments, universities, and industry to develop control methods; and (3) evaluating the effect of control methods. In 1995, CDC launched "FoodNet," a collaborative project with the FDA and USDA to improve data collection on foodborne illness outbreaks. FoodNet includes active surveillance of clinical microbiology laboratories to obtain a more accurate accounting of positive test results for foodborne illness; a physician survey to determine testing and laboratory practices; population surveys to identify illnesses not reported to doctors; and research studies to obtain new and more precise information about which food items or other exposures may cause diseases. FoodNet data allows CDC to have a clearer picture of the incidence and causes of foodborne illness and to establish baseline data against which to measure the success of changes in food safety programs. The Public Health Service Act provides legislative authority for CDC's food safety-related activities.

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<sup>10</sup> The 2008 farm bill (P.L. 110-246) contains new provisions intended to enable more interstate shipment of state-inspected products; USDA published proposed regulations to implement these provisions in the September 16, 2009, *Federal Register*.

## **National Marine Fisheries Service**

Although the FDA is the primary agency responsible for ensuring the safety, wholesomeness, and proper labeling of domestic and imported seafood products, the National Marine Fisheries Service (NMFS), which is part of the U.S. Department of Commerce, conducts, on a fee-for-service basis, a voluntary seafood inspection and grading program that focuses on marketing and quality attributes of U.S. fish and shellfish. The primary legislative authority for NMFS's inspection program is the Agricultural Marketing Act of 1946, as amended (7 U.S.C. §§ 1621 *et seq.*). NMFS has approximately 160 seafood safety and quality inspectors, and inspection services are funded with user fees.

## **Environmental Protection Agency**

EPA has the statutory responsibility for ensuring that the chemicals used on food crops do not endanger public health. EPA's Office of Pesticide Programs is the part of the agency that (1) registers new pesticides and determines residue levels for regulatory purposes; (2) performs special reviews of pesticides of concern; (3) reviews and evaluates all the health data on pesticides; (4) reviews data on pesticides' effects on the environment and on other species; (5) analyzes the costs and benefits of pesticide use; and (6) interacts with EPA regional offices, state regulatory counterparts, other federal agencies involved in food safety, the public, and others to keep them informed of EPA regulatory actions. The Federal Insecticide, Fungicide, and Rodenticide Act, as amended (7 U.S.C. 136 *et seq.*), and the Federal Food, Drug, and Cosmetic Act, as amended (21 U.S.C. 301 *et seq.*), are the primary authorities for EPA's activities in this area.

## **Other Federal Agencies**

Among the other agencies that play a role in food safety, USDA's Agricultural Research Service (ARS) performs food safety research in support of FSIS's inspection program. It has scientists working in animal disease bio-containment laboratories in Plum Island, NY, and Ames, IA. USDA's Animal and Plant Health Inspection Service (APHIS) indirectly protects the nation's food supply through programs to protect plant and animal resources from domestic and foreign pests and diseases, such as brucellosis and bovine spongiform encephalopathy (BSE, or "mad cow" disease). The Department of Homeland Security (DHS) is to coordinate many food security activities, including at U.S. borders.

## **Congressional Committees**

In the Senate, food safety issues are considered by the Committees on Agriculture, Nutrition, and Forestry; Homeland Security and Governmental Affairs; and Health, Education, Labor, and Pensions. In the House, various food safety activities fall under the jurisdiction of the Committees on Agriculture; Energy and Commerce; Oversight and Government Reform; and Science. Agriculture subcommittees of the House and Senate Appropriations Committees also serve oversight and funding roles in how the major agencies carry out food safety policies.



## Issues for Congress

### Food Safety Incidents

Food safety-related incidents have tended to heighten congressional scrutiny of the issue and to fuel interest in food safety reform, as a number of developments in recent years have illustrated. These incidents have included a major outbreak of *Salmonella* Typhimurium infections linked to the consumption of products containing peanut ingredients from a single firm, the Peanut Corporation of America. Between September 1, 2008, and mid-March 2009, the CDC identified nearly 700 cases in 46 states; the infection may have contributed to the deaths of nine people, according to the CDC. A series of expanding recalls was announced by FDA in early 2009, involving thousands of products from more than 200 companies (though not the major peanut butter brands). These developments unfolded two years after a different nationwide recall of peanut butter, in February 2007, due to *Salmonella* contamination, when hundreds of illnesses, dating back to August 2006, were linked to the bacterium.<sup>11</sup>

In April-July 2008, more than 1,300 persons in 43 states, the District of Columbia, and Canada were found to be infected with the same unusual strain of bacteria (*Salmonella* Saintpaul). Officials first suspected fresh tomatoes as the vehicle, but later genetic tests confirmed the pathogen on samples of a serrano pepper and irrigation water from a farm in Mexico. Throughout 2007 and 2008, USDA announced numerous recalls totaling many million pounds of ground beef products due to concerns about *E. coli* O157:H7 contamination.

In July 2010, CDC noticed a spike in cases of infection with *Salmonella* Enteritidis, a strain commonly associated with shell eggs, which are regulated by FDA.<sup>12</sup> In August, FDA found the same pathogen on two egg farms in Iowa, leading to the nationwide recall by the companies of more than 500 million eggs packaged under several brand names.<sup>13</sup> According to the CDC, this is the largest such outbreak reported since the start of its outbreak surveillance in the early 1970s.<sup>14</sup> This investigation is ongoing.

Attention also expanded to the safety of food imports in early 2007, when adulterated pet food ingredients imported from China sickened or killed numerous dogs and cats and subsequently were found in some hog, chicken, and fish feed.<sup>15</sup> In June 2007, FDA announced that it was detaining imports of certain types of farm-raised seafood from China (specifically, shrimp, catfish, basa, dace, and eel) until their shippers could confirm that they are free of unapproved drug residues. In late 2008, FDA announced that all Chinese dairy products and dairy ingredients were being detained until importers could prove they were free of melamine (the same adulterant found earlier in the pet food ingredients). The toxic chemical was being added to milk in China to

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<sup>11</sup> For sources and updates see the FDA website at <http://www.fda.gov/opacom/7/alerts.html>.

<sup>12</sup> USDA regulates processed eggs, and grades shell eggs for quality (such as grade and size), but does not oversee the safety of shell eggs.

<sup>13</sup> FDA, "Salmonella Enteritidis Outbreak in Shell Eggs," <http://www.fda.gov/Food/NewsEvents/WhatsNewinFood/ucm222684.htm>.

<sup>14</sup> FDA, "Frequently Asked Questions and Answers: FDA's Investigation into the Salmonella Enteritidis Outbreak Involving the Recall of Shell Eggs," <http://www.fda.gov/Food/NewsEvents/WhatsNewinFood/ucm223723.htm>.

<sup>15</sup> FDA has the same basic safety standards for human foods and animal feeds, including pet food.

boost protein readings; seven infants reportedly were killed and approximately 300,000 sickened there after consuming tainted infant formula.

These types of incidents have been cited repeatedly in a series of congressional and non-congressional hearings, reports, and studies, issued throughout the 110<sup>th</sup> Congress, as evidence of significant shortcomings in the federal food safety system. In the last Congress, a subcommittee of the House Energy and Commerce Committee alone held eight hearings on food safety problems, and various other Senate and House panels held similarly focused hearings. One topic of interest was the Bush Administration's Food Protection Plan, an "integrated strategy for protecting the nation's food supply" issued in late 2007 by FDA. The plan was simultaneously applauded for recommending a comprehensive three-pronged approach to food safety reform (prevention, intervention, and response) and criticized for offering too few implementing and funding details. The Obama Administration has proposed increases for food safety oversight in its FY2010 budget plan, and the President has charged an interagency Food Safety Working Group with developing more detailed recommendations for change.

## **Food Safety Legislation**

In the 110<sup>th</sup> Congress, several bills were introduced addressing one or more aspects of the issue. Provisions affecting food safety were included in 2007 in P.L. 110-85, the FDA amendments, including a requirement that FDA establish a registry to which companies must begin to report events involving potentially adulterated foods. Food safety provisions in the 2008 farm bill (P.L. 110-234) include subjecting farmed catfish products to FSIS mandatory inspections similar to those for red meat and poultry; creating an option for state-inspected meat and poultry plants to ship products across state lines; and requiring meat and poultry establishments to notify USDA about potentially adulterated or misbranded products. Congressional appropriators also have consistently increased funding for food safety activities in recent years. A number of more comprehensive food safety proposals were introduced, but not enacted.

In the 111<sup>th</sup> Congress, nearly a dozen food safety bills, several of them comprehensive, were introduced. The major vehicle in the House is H.R. 2749, introduced by Representative John Dingell. This bill passed the House, with a recorded vote of 283 to 142, on July 30, 2009. In the Senate, S. 510 was introduced by Senator Richard Durbin. During 2010, a series of substitute amendments to the bill were offered and debated, which included additional modifications to the proposal. On November 30, 2010, S. 510 passed the Senate with a recorded vote of 73-25. However, a procedural issue held up final action on the legislation, which was resolved when the Senate inserted its version of the bill into an earlier House bill (H.R. 2751) that was cleared by the House in December 2010. The FDA Food Safety Modernization Act (P.L. 111-353) was signed into law on January 4, 2011.<sup>16</sup>

The 112<sup>th</sup> Congress will likely provide oversight and scrutiny over how the law is implemented, including FDA's coordination with other federal agencies, such as USDA and DHS. Implementation of the law will depend largely on discretionary appropriations, and some have questioned whether funding is available in the current budgetary climate. The 112<sup>th</sup> Congress also

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<sup>16</sup> For more detailed information see CRS Report R40443, *Food Safety in the 111<sup>th</sup> Congress: H.R. 2749 and S. 510*, coordinated by Renée Johnson.

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.

The congressional appropriations process annually offers another potential venue for food safety changes. In addition to determining annual funding levels for FSIS, FDA, and other agencies with food safety responsibilities, the House and Senate Appropriations Committees frequently include directives in either the appropriation itself, or in accompanying report language, intended to instruct the Administration in how it is to use that money.

**Table 1. Major Federal Food Safety Agencies**

Agency	Major Responsibilities and Activities	Primary Authorities <sup>a</sup>
<i>Department of Health and Human Services</i>		
Food and Drug Administration <sup>b</sup>	Ensuring that all domestic and imported foods, except processed egg products and major types of meat and poultry, are safe, wholesome, and properly labeled, by setting safety and sanitation standards, periodically inspecting manufacturing facilities, reviewing records of and spot-checking imports. Also overseeing the safety of animal drugs and feeds including those used in food-producing animals	Federal Food, Drug, and Cosmetic Act (FFDCA; 21 USC 301), Public Health Service Act (42 USC 201), Egg Products Inspection Act (21 USC 1031), Public Health Security and Bioterrorism Preparedness and Response Act (21 USC 341). among others
Centers for Disease Control and Prevention	Monitoring, identifying, and investigating foodborne diseases; developing and evaluating improved epidemiological and laboratory methods	Public Health Service Act (42 USC 201)
<i>Department of Agriculture</i>		
Food Safety Inspection Service <sup>b</sup>	Regulating the safety, wholesomeness and proper labeling of most commercial types of both domestic and imported meat and poultry, catfish products, and processed egg products, by approving establishment designs, safety plans; inspecting every animal and carcass in slaughtering plants and daily inspecting all meat and poultry processing plants; determining the equivalency of importing countries' meat and poultry safety systems	Federal Meat Inspection Act (21 USC 601), Poultry Products Inspection Act (21 USC 451), Egg Products Inspection Act
Animal and Plant Health Inspection Service	Overseeing animal and plant health, including the prevention of foreign diseases and pests, eradication and containment of such problems domestically (including those that threaten public health)	Animal Health Protection Act (7 USC 8301), Plant Health Protection Act (7 USC 7701)
Agricultural Marketing Service	Establishing quality and marketing grades and standards for dairy products, fruits and vegetables, livestock, meat, poultry, seafoods, and shell eggs; certifying quality programs; conducting quality grading services, generally user fee-funded	Agricultural Marketing Act of 1946 (7 USC 1621), Egg Products Inspection Act (21 USC 1031), Agricultural Marketing Agreement Act (7 USC 601)
Food and Nutrition Service	Encouraging and coordinating efforts to ensure the safety of foods in school lunch and other domestic programs	Program subsidies authorized by Richard B. Russell National School Lunch Act (42 USC 1751), Child Nutrition Act (42 USC 1771).

<b>Agency</b>	<b>Major Responsibilities and Activities</b>	<b>Primary Authorities<sup>a</sup></b>
Grain Inspection, Packers and Stockyards Administration	Setting quality standards for, and testing, grains and related commodities, primarily for marketing purposes	U.S. Grain Standards Act (7 USC 71), Agricultural Marketing Act of 1946
Agricultural Research Service	Conducts in-house USDA research on agricultural and food topics, of which food safety is one of many	Numerous laws dating to the Department of Agriculture Organic Act of 1862 (7 USC 2201 note), up through and including recent omnibus farm laws
Cooperative State Research, Education, and Extension Service	Coordinates and administers federal funding of land grant and other institutions to conduct agricultural and food research, education and extension activities; food safety is one of many subject areas	Numerous laws dating to the Department of Agriculture Organic Act of 1862, up through and including recent omnibus farm laws
<i>Department of Commerce</i>		
National Oceanic and Atmospheric Administration	Offering a variety of voluntary seafood safety and quality inspection services on a fee-for-service basis	Agricultural Marketing Act of 1946, Fish and Wildlife Act of 1956 (16 USC 742)
Environmental Protection Agency	Regulating pesticide products; setting maximum allowable tolerances for residue levels on food commodities and animal feeds	Federal Insecticide, Fungicide, and Rodenticide Act (7 USC 136), FFDCA
Federal Trade Commission	Enforcing federal prohibitions against unfair or deceptive acts or practices in trade, including consumer deception regarding foods	Federal Trade Commission Act (15 USC 41)
<i>Department of the Treasury</i>		
Alcohol and Tobacco Tax and Trade Bureau	Administering and enforcing laws on the production, safety, distribution and use of alcoholic beverages	Federal Alcohol Administration Act (27 USC 201), Internal Revenue Code (26 USC Ch. 51)
<i>Department of Homeland Security</i>		
U.S. Customs and Border Protection	Coordinating many food security activities, including at the border; now conducting agricultural border inspection activities formerly done by APHIS	Homeland Security Act (6 USC 101)

**Source:** Prepared by CRS based in part on various reports by the Government Accountability Office.

- a. This table has not yet been updated to reflect changes that may have been authorized in the FDA Food Safety Modernization Act, P.L. 111-353.
- b. These agencies have the leading food safety regulatory authorities.

**Table 2. Selected Comparison of FSIS and FDA Responsibilities**

Activity <sup>a</sup>	Food Safety and Inspection Service	Food and Drug Administration (Foods Only)
Primary Authorizations	Federal Meat Inspection Act (21 USC 601), Poultry Products Inspection Act (21 USC 451), Egg Products Inspection Act (21 USC 1031)	Federal Food, Drug, and Cosmetic Act (FFDCA; 21 USC 301), Public Health Service Act (42 USC 201), Egg Products Inspection Act (21 USC 1031), Public Health Security and Bioterrorism Preparedness and Response Act (21 USC 341)
Foods Regulated	Major types of domestic and imported meat and poultry and their products; catfish products; processed (dried, frozen, liquid) egg products (20% of at-home U.S. food spending)	All other domestic and imported foods, also animal drugs and feeds including those used in food-producing animals (80% of at-home U.S. food spending)
Funding (FY2009)	Appropriated: \$972 million; user fees: \$140 million	Appropriation: \$649 million (plus \$137 million for animal drugs and feeds including \$20 million in user fees)
Staff (est. field only)	8,000	1,900
Domestic facilities	6,300 slaughter and/or processing establishments	68,000 subject to inspection
Inspection Approach	Ante- and post-mortem inspection of every animal, carcass and part; traditionally organoleptic (but see “Food safety plans” below); only USDA-inspected and passed products may enter commerce	Prohibits adulteration or misbranding; relies on facilities that manufacture, process, pack, or hold food for humans or animals to be meet prescribed standards (e.g., regarding additives, contaminants, etc.); all facilities must register, report changes in timely manner
Required inspection frequency	Slaughter plants: all times of operation; processing plants: at least once daily	Not explicitly required; annual for 6,000 high-risk facilities; once every 5-10 years for rest (ests. vary)
Food safety plans	Requires all establishment to prepare and have preapproved “HACCP” (hazard analysis and critical control point) plans determining risks, controlling them (with documentation)	Facilities must follow more general regulations on good manufacturing practices (GMPs) which address safe handling and plant sanitation—except a form of HACCP required for seafood, low-acid canned foods, juices
Imports	Specified products only from countries where FSIS has determined equivalence of foreign safety system, with annual verification; imports exempt from prior notice but subject to reinspection at 150 import establishments (est. 10% reinspected)	Equivalence not determined beforehand; reliance on inspections at 300 ports; all foreign facilities (like domestic) must register and report changes in timely manner; must provide prior notice for each food article imported (est. 1% of notified entries inspected)
Third party certification	Private labs accredited for chemical testing of meat and poultry (for imports, see above)	No accreditation for food testing labs or use of third parties for import oversight addressed in current law
On-farm oversight	FSIS inspection authority begins at slaughter plant	Those engaged solely in harvesting, storing or distributing raw agricultural commodities generally exempt from registration, GMP regulations, recordkeeping, although may have authority to regulate some on-farm activities

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<b>Activity<sup>a</sup></b>	<b>Food Safety and Inspection Service</b>	<b>Food and Drug Administration (Foods Only)</b>
Labeling	Review and preapproval required for all labels	All foods must adhere to food labeling requirements such as statement of identity, declaration of net contents, nutrition labeling; labels cannot be false or misleading
Notification Requirements	P.L. 110-246 requires an establishment to promptly notify USDA if it has reason to believe that an adulterated or misbranded product has entered commerce	P.L. 110-85 requires reportable food registry to report if an article of food poses a reasonable probability of causing serious adverse health consequences or death to humans or animals; not yet established by agency
Recall Authority	No authority to mandate recalls; relies on voluntary	No authority to mandate recalls (except infant formula); relies on voluntary

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**Source:** Prepared by CRS.

- a. This table has not yet been updated to reflect changes that may have been authorized in the FDA Food Safety Modernization Act, P.L. 111-353.

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## **Acknowledgments**

This report was originally written by Geoffrey S. Becker, Specialist in Agricultural Policy.