



# The Federal Food Safety System: A Primer

**Renée Johnson**

Specialist in Agricultural Policy

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## Summary

Numerous federal, state, and local agencies share responsibilities for regulating the safety of the U.S. food supply, which many experts say is among the safest in the world. Nevertheless, 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.

A number of comprehensive food safety proposals aimed at addressing perceived shortcomings in the U.S. food safety system were introduced but not enacted by the 110<sup>th</sup> Congress. These included measures to reform the Food and Drug Administration's (FDA's) oversight of food and other imports, to create a new independent food safety agency, and to impose a variety of new requirements on food manufacturers, handlers, and producers (including farms), such as mandated risk-based safety plans, recordkeeping for product tracing purposes, more rigorous registration requirements, and performance standards. The adequacy of inspection resources also has been at issue, and appropriators have been ramping up funding for the major agencies, particularly FDA.

Bills with similarly broad goals (such as H.R. 759, which was revised and reintroduced in June 2009 as H.R. 2749; H.R. 875; H.R. 1332; and S. 510) re-emerged in the 111<sup>th</sup> Congress. On the one hand, food safety reform is a relatively complex, controversial matter competing for attention with a long list of domestic priorities. On the other hand, there has been a growing consensus that changes are needed.

Lawmakers took the first step toward new legislation on June 10, 2009, when the House Energy and Commerce Subcommittee on Health approved an amended version of H.R. 2749. The full committee approved the bill, with additional changes, on June 17, 2009, and the full House passed a further-modified H.R. 2749 on July 30, 2009. The Senate also has reported a comprehensive bill (S. 510).

The Senate Health, Education, Labor, and Pensions Committee amended and approved S. 510, and later reported it in December 2009. In mid-July 2010, potential amendments to the bill were being discussed, aimed at addressing issues of continued interest to various Senators. In August 2010, a group of Senate leaders released a manager's amendment to S. 510. However, Senate floor action continued to be held up by objections about the projected cost of the bill, as well as continued attempts to further amend it. In November 2010, the Senate resumed consideration of its bill and a second substitute amendment to S. 510 (S.Amdt. 4715) was offered. This substitute amendment to S. 510 passed the Senate on November 30, 2010. Following passage of the Senate bill, however, it was reported that the House may block the Senate bill using a procedure known as "blue-slipping," because the bill contains fees that might be subject to certain tax origination provisions. (For more details see CRS Report R40443, *Food Safety in the 111<sup>th</sup> Congress: H.R. 2749 and S. 510*.)

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## Background<sup>1</sup>

Americans spend more than \$1 trillion on food each year, nearly half of it in restaurants, schools, and other places outside the home.<sup>2</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, public health officials estimate that each year 76 million people become sick, 325,000 are hospitalized, and 5,000 die from foodborne illnesses caused by contamination from any one of a number of microbial pathogens.<sup>3</sup> 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.

At issue is whether the current U.S. regulatory system has the resources and structural organization to protect consumers from these dangers. Also at issue is whether the federal food safety laws themselves, first enacted in the early 1900s, have kept pace with the significant changes that have occurred in the food production, processing, and marketing sectors since then.

## 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.)<sup>4</sup>

FSIS's FY2009 budget was approximately \$972 million in appropriated funds plus another estimated \$140 million in industry-paid user fees. FDA's budget for foods was \$649 million in FY2009, virtually all of it appropriated (plus an additional \$137 million for regulation of animal drugs and feeds, which includes \$20 million in user fees). Thus, FSIS had approximately 65% of

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<sup>1</sup> Background on the agencies is updated information that first appeared in CRS Report 98-91, *Food Safety Agencies and Authorities: A Primer* (out of print). Primary sources for that report included various documents and materials provided by federal food safety agencies and by the U.S. Government Accountability Office.

<sup>2</sup> Roughly two-thirds of the \$1 trillion is for domestically produced farm foods; imports and seafood account for the balance. Source: USDA, Economic Research Service data, at <http://www.ers.usda.gov/Browse/FoodSector/>.

<sup>3</sup> U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, "Foodborne Illness: Frequently Asked Questions," <http://www.cdc.gov/foodsafety/>. However, this estimate appears to be based primarily on 1997 and earlier data in a report by Paul S. Mead et al., "Food-related Illness and Death in the United States," *Emerging Infectious Diseases*, vol. 5, pp. 607-625, 1999.

<sup>4</sup> *High Risk Series: An Update* (GAO-07-310), January 2007.

the two agencies' combined food safety budget, and FDA had the other approximately 35%.<sup>5</sup> Conversely, FSIS is responsible for approximately 20% of the U.S. food supply, but FDA is responsible for 80%.<sup>6</sup>

Among other agencies with smaller but still significant shares of the food safety portfolio are the National Marine Fisheries Service (NMFS), which is part of the U.S. Department of Commerce, the Environmental Protection Agency (EPA), and the Centers for Disease Control and Prevention (CDC) in HHS.

## **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 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

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<sup>5</sup> Data source: various documents of the Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Subcommittee of the House Committee on Appropriations.

<sup>6</sup> Source for the food supply proportions is GAO, "Revamping Oversight of Food Safety," urgent issues prepared for the 2009 Congressional and Presidential Transition, [http://www.gao.gov/transition\\_2009/urgent/food-safety.php](http://www.gao.gov/transition_2009/urgent/food-safety.php). GAO here does not provide a basis for its calculations, although they appear to represent proportions of total spending for food consumed at home. Examined another way, meat and poultry could account for as little as 10% of U.S. per capita food consumption, according to data maintained by USDA's Economic Research Service (ERS); these per capita data adjust food availability for spoilage, plate waste, and other losses. See ERS Food Availability (Per Capita) Data System, at <http://www.ers.usda.gov/data/foodconsumption/>.

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>7</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>8</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.).

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

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<sup>7</sup> HHS OIG, *FDA Inspections of Domestic Food Facilities* (OEI-02-08-00080), April 2010.

<sup>8</sup> USDA's Agricultural Marketing Service (AMS) also has responsibility for ensuring shell eggs for quality, but not safety, considerations (see **Table 1**).

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>9</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.

## **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

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<sup>9</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*.

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 with Food Safety Responsibilities**

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.



## Selected Issues

### 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>10</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>11</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>12</sup> According to the CDC, this is the largest such outbreak reported since the start of its outbreak surveillance in the early 1970s.<sup>13</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>14</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>10</sup> For sources and updates see the FDA website at <http://www.fda.gov/opacom/7/alerts.html>.

<sup>11</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>12</sup> FDA, "Salmonella Enteritidis Outbreak in Shell Eggs," <http://www.fda.gov/Food/NewsEvents/WhatsNewinFood/ucm222684.htm>.

<sup>13</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>14</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**

Several dozen bills were introduced in 2007 and 2008 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 increased funding for food safety activities for FY2008 and FY2009. However, a number of more comprehensive food safety proposals were not enacted by the 110<sup>th</sup> Congress.

Similar comprehensive food safety measures emerged in the 111<sup>th</sup> Congress. Lawmakers took the first step toward new legislation on June 10, 2009, when the House Energy and Commerce Subcommittee on Health amended and approved a bill (H.R. 2749) introduced by Representative Dingell. The bill is a revised version, focusing on FDA-regulated foods, of a more wide-ranging FDA reform bill (H.R. 759) introduced earlier by Representative Dingell. The full committee approved the bill, with additional changes, on June 17, 2009. A further-amended bill was adopted by the full House on July 30, 2009.

On the Senate side, a comprehensive but differing bill (S. 510 by Senator Durbin) was modified and approved by the Senate Health, Education, Labor, and Pensions Committee, and later reported in December 2009. In mid-July 2010, potential amendments to the bill were being discussed, aimed at addressing issues of continued interest to various Senators. In August 2010, a group of Senate leaders released a manager's amendment to S. 510. However, Senate floor action continued to be held up by objections about the projected cost of the bill, as well as continued attempts to further amend it. In November 2010, the Senate resumed consideration of its bill and a second substitute amendment to S. 510 (S.Amdt. 4715) was offered, which passed the Senate on November 30, 2010. Following passage of S. 510, however, it was reported that the House may block the Senate bill using a procedure known as "blue-slipping," because the bill contains fees that might be subject to certain tax origination provisions. (For more details see CRS Report R40443, *Food Safety in the 111<sup>th</sup> Congress: H.R. 2749 and S. 510.*)

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 I. Major Federal Food Safety Agencies**

Agency	Major Responsibilities and Activities	Primary Authorities
<i>Department of Health and Human Services</i>		
Food and Drug Administration <sup>a</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>a</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).
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

<b>Agency</b>	<b>Major Responsibilities and Activities</b>	<b>Primary Authorities</b>
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. These agencies have the leading food safety regulatory authorities.

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

Activity	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

<b>Activity</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

**Source:** Prepared by CRS.

## **Author Contact Information**

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

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