



# 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 and 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 with the FDA Food Safety Modernization Act (FSMA, P.L. 111-353). FSMA is the largest expansion of FDA's food safety authorities since the 1930s. Although numerous agencies share responsibility for regulating food safety, FSMA focused on foods regulated by FDA and amended FDA's existing structure and authorities, and did not directly address meat and poultry products under USDA's jurisdiction. Beyond these changes, some in Congress continue to push for additional policy reforms to address other perceived concerns about the safety of the U.S. food supply.

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## 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—becomes 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 heightened 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.)

## Food and Drug Administration

Excluding the roughly 10%-20% of the U.S. food supply that is estimated to be under the jurisdiction of FSIS, it may be argued that the safety of the majority of all foods—about 80%-90%—falls under FDA's responsibility.<sup>3</sup> 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

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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> 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 appears 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/>.

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 (FFDCA), 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.*). The 111<sup>th</sup> Congress passed comprehensive food safety legislation with the FDA Food Safety Modernization Act (FSMA, P.L. 111-353). FSMA is the largest expansion of FDA's food safety authorities since the 1930s. Although numerous agencies share responsibility for regulating food safety, FSMA focused on foods regulated by FDA and amended FDA's existing structure and authorities, in particular FFDCA.<sup>4</sup> The Congressional Budget Office (CBO) estimated that implementing FSMA 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>5</sup> FSMA authorizes an increase in FDA staff to up to 5,000 staff members in FY2014. Given the current budgetary climate, funding to undertake many federal activities in FSMA is uncertain.<sup>6</sup>

FDA's FY2011 budget for its foods program was \$835.7 million, virtually all of it appropriated with limited authorized user fees.<sup>7</sup> FSMA also authorized additional user fees that provide limited funds to assist with implementation of the new law. FDA staff working on food-related activities in FY2011 were estimated at about 3,400 FTEs.

The number of food facilities subject to FDA inspection has been increasing sharply in the past few years. 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 had 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> Of these inspections, an increasing number of inspections have been conducted by states under contract with FDA, rather than by FDA.<sup>9</sup>

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<sup>4</sup> For more information, see CRS Report R40443, *The FDA Food Safety Modernization Act (P.L. 111-353)*. FSMA does not directly address meat and poultry products under USDA's jurisdiction.

<sup>5</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.

<sup>6</sup> For more information, see CRS Report R41964, *Agriculture and Related Agencies: FY2012 Appropriations*.

<sup>7</sup> FDA "Operating Plan for FY 2011 and Comparisons to FY 2010," [http://www.hhs.gov/asfr/ob/docbudget/2011operatingplan\\_fda.pdf](http://www.hhs.gov/asfr/ob/docbudget/2011operatingplan_fda.pdf).

<sup>8</sup> HHS OIG, *FDA Inspections of Domestic Food Facilities* (OEI-02-08-00080), Table 1, April 2010, <http://oig.hhs.gov/oei/reports/oei-02-08-00080.pdf>.

<sup>9</sup> HHS, OIG, *Vulnerabilities in FDA's Oversight of State Food Facility Inspections* (OEI-02-09-00430), December 2011, <http://oig.hhs.gov/oei/reports/oei-02-09-00430.pdf>.

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. GAO reported that, in 2000, FDA inspections covered only about 1% of the food imported under its jurisdiction.<sup>10</sup> Changes to FDA's import regime now being implemented under FSMA are expected to address some of these concerns.

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

Available USDA data indicate that FSIS is roughly responsible for 10%-20% of the U.S. food supply, while FDA is responsible for the remainder.<sup>11</sup> 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>12</sup> The latter is responsible for the safety of liquid, frozen, and dried egg products,

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<sup>10</sup> GAO, *Fundamental Changes Needed to Ensure Safe Food* (GAO-02-47T), October 10, 2001, <http://www.gao.gov/new.items/d0247t.pdf>.

<sup>11</sup> See footnote 3.

<sup>12</sup> USDA's Agricultural Marketing Service (AMS) also has responsibility for ensuring shell eggs for quality, but not safety, considerations (see **Table 1**).

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's FY2011 budget was \$1.007 billion in appropriated funds, plus another approximately \$150 million in industry-paid user fees.<sup>13</sup> FSIS staff numbers around 9,600; 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.<sup>14</sup> 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>15</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

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<sup>13</sup> USDA, 2012 Explanatory Notes, Food Safety and Inspection Service, February 12, 2011, <http://www.obpa.usda.gov/21fsis2012notes.pdf>.

<sup>14</sup> USDA, "Listing of Participating States," [http://www.fsis.usda.gov/regulations\\_&\\_policies/Listing\\_of\\_participating\\_states/index.asp](http://www.fsis.usda.gov/regulations_&_policies/Listing_of_participating_states/index.asp)

<sup>15</sup> The 2008 farm bill (P.L. 110-246, § 11017) contained new provisions intended to enable more interstate shipment of state-inspected products.

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 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.

USDA's Agricultural Marketing Service (AMS) is responsible for establishing quality and marketing grades and standards for many foods (including dairy products, fruits and vegetables, livestock, meat, poultry, seafoods, and shell eggs), and for certifying quality programs and conducting quality grading services. Accordingly, AMS is primarily responsible for ensuring *product quality* and not *food safety*.



## 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.

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

Agency	Major Responsibilities and Activities	Primary Authorities
<b>Department of Health and Human Services</b>		
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	As may be amended by the FDA Food Safety Modernization Act (FSMA): Federal Food, Drug, and Cosmetic Act (FFDCA; 21 U.S.C. 301), Public Health Service Act (42 U.S.C. 201), Egg Products Inspection Act (21 U.S.C. 1031), Public Health Security and Bioterrorism Preparedness and Response Act (21 U.S.C. 341), 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 U.S.C. 201)
<b>Department of Agriculture</b>		
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 U.S.C. 601), Poultry Products Inspection Act (21 U.S.C. 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 U.S.C. 8301), Plant Health Protection Act (7 U.S.C. 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 U.S.C. 1621), Egg Products Inspection Act (21 U.S.C. 1031), Agricultural Marketing Agreement Act (7 U.S.C. 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 U.S.C. 1751), Child Nutrition Act (42 U.S.C. 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 U.S.C. 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 U.S.C. 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
<b>Department of Commerce</b>		
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 U.S.C. 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 U.S.C. 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 U.S.C. 41)
<b>Department of the Treasury</b>		
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 U.S.C. 201), Internal Revenue Code (26 U.S.C. Ch. 51)
<b>Department of Homeland Security</b>		
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 U.S.C. 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 Program only)
Primary Authorizations	Federal Meat Inspection Act (21 U.S.C. 601), Poultry Products Inspection Act (21 U.S.C. 451), Egg Products Inspection Act (21 U.S.C. 1031)	As may be amended by the FDA Food Safety Modernization Act (FSMA); Federal Food, Drug, and Cosmetic Act (FFDCA; 21 U.S.C. 301; Public Health Service Act (42 U.S.C. 201); Egg Products Inspection Act (21 U.S.C. 1031); Public Health Security and Bioterrorism Preparedness and Response Act (21 U.S.C. 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 (enacted FY2012)	Appropriated: \$1.004 billion for FY2012. Expected user fees are estimated to include another \$150 million.	Appropriated: \$866.1 million for FDA’s Foods Program, not including funding from expected user fees. Expected user fees are estimated to include another \$79 million.
Staff (2011)	9,600 FTEs	3,400 FTEs
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	FSMA requires increased inspection rates for any registered facility, particularly those identified as “high-risk.” Domestic high-risk facilities are to be inspected not less than once in the five-year period after enactment, and not less than once every three years thereafter. Domestic non-high-risk facilities are to be inspected not less than once in the seven-year period after enactment, and not less than once every five years thereafter.
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)	Prior to FSMA, facilities followed general regulations on good manufacturing practices (GMPs) to address safe handling and plant sanitation—except a form of HACCP required for seafood, low-acid canned foods, juices. FSMA §103 created new requirements for facilities to evaluate hazards, implement preventive controls, monitor controls, and maintain records. FDA rulemaking is clarifying requirements under new written HACCP-type and/or broader written food safety plans as part of its so-called Hazard Analysis and Risk-Based Preventive Controls.

Activity	Food Safety and Inspection Service	Food and Drug Administration (Foods Program only)
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)	Prior to FSMA, food safety system equivalence was not determined beforehand; reliance on inspections was at 300 ports (est. 1% of notified entries inspected). FSMA provides for tighter controls and use certification or verification systems for imported foods(to be determined by FDA rulemaking). At least 600 foreign facilities must be inspected the year following enactment, and in each of the subsequent five years the number of foreign facilities inspected is to double.
Third party certification	Private labs accredited for chemical testing of meat and poultry (for imports, see above)	Prior to FSMA, there was no accreditation for food testing labs or use of third parties for import oversight. FSMA §202 requires FDA to establish a program for testing of food by accredited labs and to recognize accreditation bodies to accredit labs. FSMA §303 creates a system of accreditation of third-party auditors and audit agents to certify importing entities. FDA’s rulemaking is ongoing.
On-farm oversight	FSIS inspection authority begins at slaughter plant	Prior to FSMA, those engaged solely in harvesting, storing or distributing raw agricultural commodities were generally exempt from registration, GMP regulations, and record-keeping. FSMA §105 created new farm-level requirements, particularly for fresh produce determined to be higher-risk (FDA rulemaking is ongoing). Some small farm businesses are exempt from regulation.
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 §11017 amended meat and poultry laws to require an establishment to notify USDA if it has reason to believe that an adulterated or misbranded product has entered commerce	P.L. 110-85 (amended by FSMA) requires FDA to maintain a reportable food registry for industry to report food safety cases in order to help FDA better track patterns and target inspections. FSMA §204 provided for an enhanced tracing system for foods that FDA determines to pose a higher food safety risk. As part of the ongoing rulemaking process, FDA has launched product tracing pilots.
Recall Authority	No authority to mandate recalls; relies on voluntary efforts	Prior to FSMA, FDA had no authority to mandate recalls (except infant formula). FSMA §206 provides for mandatory recall authority where there is a reasonable probability that a food is adulterated or misbranded, and its use or exposure to it will cause serious adverse health consequences or death. Civil/criminal penalties apply for failure to comply with a recall order.

**Source:** Prepared by CRS.

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## **Acknowledgments**

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