

CRS Report for Congress

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Food Safety Agencies and Authorities: A Primer

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Summary

Several federal agencies, in cooperation with state governments, are responsible for regulating the safety of the U.S. food supply. In the wake of an outbreak of food-borne illness and the largest recall of suspected contaminated meat in U.S. history in August 1997, several policymakers have reopened the debate on creating a single, independent, federal food safety agency. They assert that this would provide more effective regulatory control over the entire farm-to-table food production and marketing system by eliminating the overlapping and occasionally competing objectives of multiple agencies. As background for further discussion on this and related food safety issues, this report describes the roles of the primary federal and cooperating state agencies responsible for food safety and enumerates the major legislative authorities currently governing them.

Background²

American consumers spend about \$617 billion annually on food, of which about \$511 billion is spent on foods grown on U.S. farms.³ Federal laws give food manufacturers, distributors, and retailers the basic responsibility for assuring that foods are wholesome, safe, and handled under sanitary conditions. The federal government, along with state, local and international agencies, has played a major role in regulating food quality and safety since the original authorizing laws were passed in the early 1900s. The combined efforts of the food industry and the regulatory agencies generally are

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² The primary source of the information in this report is *Food Safety and Quality: Who Does What in the Federal Government*, U.S. General Accounting Office, RCED-91-19A-19B, December 1990. Agency officials provided updated data for FDA, FSIS, EPA, and NMFS.

³ U.S. Department of Agriculture. *Agriculture Fact Book*, 1996.

credited with making the U.S. food supply the safest in the world. Nonetheless, public health officials estimate that anywhere from 6.5 to 33 million people become sick and 9,000 die annually from food-borne illnesses caused by contamination by any one of seven different microbial pathogens.⁴ The following section describes the roles of the primary federal and cooperating state agencies currently responsible for food safety.

The Agencies and their Roles

The primary federal agencies responsible for regulating the safety of the U.S. food supply — both domestically produced and imported foods — are the **Food and Drug Administration (FDA)**, which is part of the Department of Health and Human Services (DHHS), the **Food Safety and Inspection Service (FSIS)**, which is part of the U.S. Department of Agriculture (USDA), the **National Marine Fisheries Service**, which is part of the U.S. Department of Commerce (DOC), and the **Environmental Protection Agency (EPA)**. The DHHS **Centers for Disease Control and Prevention (CDC)** plays an auxiliary role through its surveillance and investigations of food-borne disease outbreaks. The FDA and USDA together comprise more than 90% of both the total funding and the total staffing of the government's regulatory system to assure that food is safe, according to Government Accounting Office (GAO) reports.

Food and Drug Administration (DHHS). The FDA is responsible for ensuring that domestic and imported food products — except for most meats and poultry — are safe, sanitary, nutritious, wholesome, and are honestly labeled. FDA has jurisdiction over meats from animals or birds that are not under the regulatory jurisdiction of FSIS. These include rabbit, deer, moose, buffalo, quail, or ratites (ostriches, emu and rheas) that have not been submitted for inspection under a voluntary FSIS ratite inspection program. 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 also is the primary federal agency responsible for ensuring that all domestic and imported seafood products, including those from aquaculture, do not endanger public health (FDA spends about \$42 million annually on seafood safety). The agency's budget devoted annually to all food safety regulation is approximately \$213 million. 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 inspection force numbers roughly 800 and is located in field offices in 49 states, the District of Columbia, and Puerto Rico. About 53,000 food establishments are subject to periodic FDA inspection for compliance with regulations in the areas of sanitation, ingredient labeling, nutrition labeling, good manufacturing practices, low-acid canned foods, acidified foods, and food standards. Some FDA inspectors are located at airports, seaports, and other locations where FDA carries out inspection of imported foods. Twenty-one district offices with affiliated laboratories administer the day-to-day operations of the field offices. FDA regulates food establishments' safety practices by relying on food companies' self-interest in producing safe products and by working with

⁴ *Campylobacter jejuni*, *Salmonella enteritidis*, *Shigella*, *E. coli* 0157:H7, *Yersinia*, *Listeria monocytogenes*, and *Vibrio vulnificus* are the seven leading pathogens causing food-borne illness.

the industry to improve production practices. According to GAO, unannounced compliance inspections of individual establishments by FDA officials now occur roughly once every 10 years.⁵ 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.

FDA's 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. CFSAN's staff numbers 790, according to FDA.

FDA's Center for Veterinary Medicine 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 Center employs 247 people at its headquarters, and has a field inspection staff of 91.

FDA's Relationship to State Inspection Programs. The FDA cooperates with about 400 state agencies across the nation that carry out a wide range of food safety regulatory activities. FDA holds the statutory authority for ensuring the sanitary operation of 560,000 food service establishments; 150,000 retail food stores; 1 million food vending locations; 126,000 Grade A dairy farms; 770 milk pasteurization plants; 750 shellfish processors; 1,100 shellfish shippers; and 850 shellfish-growing areas. However, the state agencies are primarily responsible for their actual inspection. FDA works with the states to set the safety standards for these 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 statutory responsibilities. For example, FDA contracts with states to monitor medicated animal feeds and to investigate incidents of pesticide or drug residues in foods and toxins in shellfish.

Food Safety and Inspection Service (USDA). FSIS regulates the safety, wholesomeness, and proper labeling of most domestic and imported meat and poultry sold for human consumption. Under the Federal Meat Inspection Act of 1906, as amended [21 U.S.C. 601 et seq.], FSIS inspects 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, and guineas. FSIS also offers a voluntary fee-for-service inspection program for emu, ostriches and rheas (ratites). As mentioned above, FDA has jurisdiction over exotic and

⁵ U.S. General Accounting Office. *Food Safety: Risk-Based Inspections and Microbial Monitoring Needed for Meat and Poultry*. GAO/RCED-94-110. May 19, 1994.

alternative meats not inspected by FSIS, and shares the responsibility for egg safety with FSIS. 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's current budget is \$589 million.

The FSIS inspection force in the field numbers 8,000 and is responsible for inspection at roughly 6,500 meat and poultry slaughtering and processing plants. FSIS personnel inspect all meat and poultry animals at slaughter on a continuous basis and one or more federal inspectors are 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 is responsible for certifying that foreign meat and poultry plants are operating under an inspection system that is 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 meat from cattle, sheep, swine, goats, and equines and imported poultry meat from chickens, turkeys, ducks, geese, and guineas before they are released into domestic commerce. FDA is responsible for ensuring the safety of imported meat from any other species.

FSIS's Relationship to State Meat and Poultry Inspection Programs. Approximately 27 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 10 states under which *state* inspection personnel are authorized to carry out *federal* inspection in roughly 255 meat and/or poultry plants. Products from these plants may travel in interstate commerce.

National Marine Fisheries Service (DOC). Although the FDA is the primary agency responsible for ensuring the safety, wholesomeness and proper labeling of domestic and imported seafood products, the NMFS 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. Agency officials estimate that the program covers about 20% of the seafood consumed annually in the United States. If contracted to provide the service, NMFS personnel may inspect fishing vessels and processing plants to ensure that sanitary practices are in keeping with FDA standards; they periodically may evaluate products at processing facilities for general condition, wholesomeness and proper grading and labeling; and they may sample products for laboratory testing for chemical and microbiological contamination, decomposition, and species identification. There are roughly 144 NMFS inspectors and about 100 USDA and state meat inspectors cross-licensed to perform seafood inspection services under this program. In FY1997, \$12 million in user fees was collected for inspection services. The agency also spent about

\$14 million in FY1997 on research in the areas of safety, quality, and identity, to support its inspection program. 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.].

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. In FY1998, the budget for the food safety activities of the Office of Pesticide Programs is \$57.9 million. 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.

Centers for Disease Control (DHHS). CDC is responsible for (1) monitoring, identifying, and investigating food-borne 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 a collaborative project with the FDA and USDA — called FoodNet — to improve the data collection on food-borne illness causes and outbreaks. The FoodNet system includes active surveillance of clinical microbiology laboratories to obtain a more accurate accounting of positive test results for food-borne illness; a physician survey to determine testing and laboratory practices; population surveys to catch 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 will permit CDC to have a clearer picture of the incidence and causes of food-borne illness and to establish baseline data against which to measure the success of changes in food safety programs. In FY 1997, CDC had a budget of \$4.5 million for its food safety related activities. In support of the Administration's 1997 Food Safety Initiative, Congress appropriated an additional \$10 million for CDC's surveillance work in FY1998. The Public Health Service Act, as amended [42 U.S.C. 201 et seq.] provides the legislative authority for CDC's food safety related activities.

Other Federal Agencies with Food Safety Responsibilities. USDA's Agricultural Research Service (ARS) performs food safety research in support of FSIS's inspection program. In FY1997 \$50 million (7%) of ARS's research budget was targeted for this purpose. 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). Of APHIS's \$512 million FY 1997 budget, roughly \$200 million (40%) was for pest and disease exclusion and \$96.5 million (19%) for pest and disease management (not all of the work in these categories relates directly to food safety, however).

The Treasury Department's Bureau of Alcohol, Tobacco, and Firearms enforces the laws that cover the production, distribution, and labeling of alcoholic beverages. By

agreement with FDA, the Bureau also has primary federal responsibility for ensuring the safety of alcoholic beverages. The Treasury Department's Customs Service assists other federal food safety agencies in carrying out their import monitoring and inspection responsibilities, by collecting samples for testing, for example.

**Summary of Federal Agencies with Major Roles in
Food Safety Regulation (not including CDC)**

	DHHS/FDA	USDA/FSIS	EPA	DOC/NMFS
Foods covered	All food except major commercial meat and poultry; primary responsibility for seafood; partial responsibility for eggs	Products from major commercial meat and poultry species; partial responsibility for eggs	Responsible for regulating chemicals in foods	Seafood submitted for voluntary inspection program
Budget for food safety activities	\$213 million	\$589 million	\$57.9 million	\$12 million from user fees for inspection services; \$14 million for research
Number of facilities under jurisdiction for inspection	53,000	6,500	---	344 facilities; plus 300 additional requests for reimbursable services per month, on average
Staffing for food safety activities	800 field inspectors; 790 Center for Food Safety and Applied Nutrition staff; 247 Center for Veterinary Medicine staff, and 91 field staff	8,000 inspectors; 1,250 FSIS headquarters staff	669 staff	144 inspectors
State and local cooperators	400 state public health regulatory agencies	255 plants at which state inspectors carry out federal-state cooperative inspection	---	100+ cross-licensed USDA and state inspectors
Laws	Federal Food, Drug, and Cosmetic Act; Public Health Service Act; Egg Products Inspection Act	Federal Meat Inspection Act; Poultry Products Inspection Act; Egg Products Inspection Act	Federal Insecticide, Fungicide, and Rodenticide Act; Food, Drug, and Cosmetic Act	Federal Agricultural Marketing Act of 1946

Note: This table summarizes the facts from the body of the report for ease of reference. The table cannot be used to make comparisons among agencies for analytical purposes because the agencies' statutes and responsibilities differ substantially.