Order Code RS22600
Updated June 18, 2007

CRS Report for Congress

The Federal Food Safety System: A Primer

Geoffrey S. Becker
Specialist in Agricultural Policy
Resources, Science and Industry Division

Donna V. Porter
Specialist in Life Sciences
Domestic Social Policy Division

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 and resources to adequately combat foodborne illness, which sickens an estimated 76 million people and kills an estimated 5,000 each year in this country. The 110th Congress may face calls for a review of federal food safety agencies and authorities, and proposals for reorganizing them have been introduced (e.g., H.R. 1148; S. 654). Other bills that would alter some agency responsibilities include S. 1274, H.R. 2108, S. 1082, H.R. 1600, H.R. 2629, and S. 887. Among the issues likely to arise are whether reform can improve oversight, and the cost to industry, consumers, and taxpayers. This report provides a brief introduction to the system and the debate on whether reorganization is needed.

Background[1]

Americans spent more than $1 trillion on food in 2005, nearly half of it in restaurants, schools, and other places outside the home.[2] 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

[1] Background on the agencies is based largely on CRS Report 98-91, *Food Safety Agencies and Authorities: A Primer*, by Jean M. Rawson, Alejandro E. Segarra, and Donna U. Vogt (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.

[2] Roughly two-thirds of the $1 trillion was for domestically produced farm foods; imports and seafood account for the balance. Source: USDA, Economic Research Service, data accessed February 2007 at the "Food Sector" Web page at [http://www.ers.usda.gov/Browse/FoodSector/].

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.[3] At issue is whether the current system has the resources and structural organization to protect consumers from these dangers. Also at issue is whether federal food safety laws, 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 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.[4] FSIS's FY2006 budget was approximately $980 million, $832 million of it appropriated funds and the balance industry-paid user fees. FDA's budget for foods was approximately $440 million in FY2006; oversight of animal drugs and feeds totaled another $99 million, of which approximately $90 million was appropriated and the balance user fees.[5]

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 (DOC), 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 seafood products, including those from aquaculture, do not endanger public health. 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

---

[3] U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, *Foodborne Illness: Frequently Asked Questions*, at [http://www.cdc.gov/foodsafety/].

[4] *High Risk Series: An Update* (GAO-07-310), January 2007.

[5] *Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations for 2007*, hearings before a Subcommittee of the Committee on Appropriations, House of Representatives, 109th Cong., 2nd sess. (Part 5, pp. 755 and 848).

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. About 57,000 food manufacturers are subject to periodic FDA inspection for regulatory compliance. According to GAO, unannounced compliance inspections of individual establishments by FDA officials occur roughly once every five years. 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.

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 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, 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. 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 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.

Approximately 28 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.[6]

Centers for Disease Control and Prevention (HHS). 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, as amended (42 U.S.C. 201 et seq.), provides the legislative authority for CDC's food safety related activities.

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, 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. The primary legislative authority for NMFS's

---

[6] See also CRS Report RL32922, *Meat and Poultry Inspection: Background and Selected Issues*, by Geoffrey S. Becker.

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 responsible for coordinating agencies' 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.

Reorganization of the Federal Food Safety Regulatory Structure

In its annual (January 2007) report, GAO designated food safety oversight as one of 29 "high risk" federal program areas. The report stated: "Any food contamination could undermine consumer confidence in the government's ability to ensure the safety of the U.S. food supply, as well as cause severe economic consequences. The current fragmented federal system has caused inconsistent oversight, ineffective coordination, and inefficient use of resources. GAO has recommended that Congress consider a fundamental re-examination of the system and other improvements to help ensure the rapid detection of

and response to any accidental or deliberate contamination of food before public health and safety is compromised."[7]

Earlier, the Institute of Medicine of the National Academy of Sciences (IOM/NAS) and the National Commission on the Public Service studied the issue and recommended options for change.[8] IOM/NAS has been among those who maintain that reorganizing agencies, by itself, would not provide safer food; its 1998 report recommended a more science-based statute and additional inspection resources, among other things. Opponents of major food safety changes, including many in the food and agricultural industries, assert that the system already is scientifically based, that the statutes are adequate, and that food companies already produce and distribute safe food, making the U.S. system a model for food safety around the world.

Legislative proposals to combine these agencies and responsibilities into a single federal food safety agency were introduced in past Congresses, but did not advance. In the 110th Congress, the first bills to establish a new Food Safety Administration were offered on February 15, 2007, as H.R. 1148 by Representative DeLauro and S. 654 by Senator Durbin. On February 8, 2007, the House Appropriations Subcommittee on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies, which is chaired by Representative DeLauro, held a hearing on food safety reorganization.

Another bill that would alter some agency food roles is S. 1082, the Senate-passed FDA Revitalization Act, which includes an amendment requiring establishment of a new FDA-administered food safety notification system. A similar provision is part of two broader companion measures, the Human and Pet Food Safety Act of 2007 (S. 1274/H.R. 2108). Also, H.R. 1600, H.R. 2629, and S. 887 propose to return agricultural border inspectors to APHIS, where they resided before their responsibilities were moved to the Department of Homeland Security.[9]

Lawmakers may be asked to consider these or other proposals that would either reorganize or consolidate the federal food safety organization. A range of policy options could be debated, including whether the current regulatory approaches and their authorizing statutes remain appropriate, particularly given the diversity of food types, different health risks, methods of production, and sources of supply; the continuously evolving science on foodborne illness and how to prevent future outbreaks; the impacts on industry competitiveness, particularly in a global economy; and funding constraints.

---

[7] GAO, *High Risk Series: An Update*. Numerous earlier GAO reports reiterated this theme.

[8] See National Research Council, Institute of Medicine, *Ensuring Safe Food From Production to Consumption*, Washington, DC, National Academy Press, 1998; and National Commission on the Public Service, *Urgent Business For America: Revitalizing the Federal Government For the 21st Century*, Washington, DC, 2003.

[9] See also CRS Report RL32521, *Agroterrorism Threats and Preparedness*, by Jim Monke; and CRS Report RS22664, *U.S. Food and Agricultural Imports: Safeguards and Selected Issues*, by Geoffrey S. Becker.