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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, 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—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 and to meat and poultry products. Numerous bills addressing various aspects of food safety were introduced into the 110th Congress, including proposals to reorganize oversight authorities, increase funding, tighten regulation of imported foods, and establish new authorities for enforcement, recall, and notification regarding adulterated foods, among others. Portions of several proposals became law; debate on the need for more sweeping changes in the federal food safety system was expected to continue in the 111th Congress.

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Background[1]

Americans spend more than $1 trillion on food each year, 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 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 FY2008 budget was approximately $930 million in appropriated funds plus another estimated $140 million in industry-paid user fees. FDA's budget for foods was $577 million in FY2008, virtually all of it appropriated. Thus, FSIS has approximately 65% of the two agencies' combined food safety budget, and FDA has the other approximately 35%.[5] Conversely, FSIS is responsible for approximately 20% of the U.S. food supply, but FDA is responsible for 80%.[6]

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[1] 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.

[2] 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 accessed January 2008 at the "Food Sector" Web page at http://www.ers.usda.gov/Browse/FoodSector/.

[3] U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, "Foodborne Illness: Frequently Asked Questions," accessed at 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.

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

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

[6] Source for the food supply proportions is GAO, "Revamping Oversight of Food Safety," urgent issues prepared for the 2009 Congressional and Presidential Transition, accessed December 2008 at 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 (continued...)

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 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. 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

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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. Source: ERS Food Availability (Per Capita) Data System, accessed December 29, 2008, at http://www.ers.usda.gov/data/ foodconsumption/.

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. 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.

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 (although the 2008 farm bill will permit interstate shipment in some cases). 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.

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 provides 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 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-related incidents frequently heighten congressional scrutiny of the issue, as a number of developments in recent years have illustrated. For example, more than 200 confirmed illnesses and three deaths were linked in fall 2006 to the consumption of bagged fresh spinach grown in California that was found to carry *E. coli* O157:H7. The incident raised public concern about the safety of all fresh leafy produce and stimulated a number of industry and government initiatives to limit future contamination. In February 2007, FDA announced a nationwide recall of peanut butter due to *Salmonella* contamination, after hundreds of illnesses, dating back to August 2006, were linked to the bacterium.[7]

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.

Attention also had shifted 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.[8] 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 to be 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 boost protein readings; as a result, six infants reportedly were killed and nearly 300,000 sickened there after consuming tainted infant formula.

During the 110th Congress, a series of congressional and Administration reports were issued which cited significant gaps in the federal food safety system. Several dozen bills were introduced addressing one or more aspects of the issue. Provisions affecting food safety were

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[7] For sources and updates see the FDA website: http://www.fda.gov/opacom/7alerts.html.

[8] FDA has the same basic safety standards for human foods and animal feeds, including pet food.

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 provided some increased funding for food safety activities for FY2008 and FY2009.

However, a number of more comprehensive food safety proposals were not enacted by the 110th Congress. These included bills to impose new requirements, and possibly user fees, on food importers; to establish mandatory recall and/or traceability programs for USDA and FDA-regulated foods; and to increase oversight of domestic food producers, for example. Several called for consolidating federal food safety responsibilities under a single, independent new agency. Stakeholders anticipate that new legislation will be introduced and possibly debated in the 111th Congress.

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