

CRS Issue Brief for Congress

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Food Safety Issues in the 107th Congress

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LEGISLATION

Food Safety Issues in the 107th Congress

SUMMARY

The Centers for Disease Control and Prevention (CDC) estimate that each year in the United States 76 million people get sick, 325,000 are hospitalized, and 5,000 die from food-related illnesses. Food-borne illness is a serious public health problem. Often, people do not seek medical help and their illness is not officially reported. Yet consumers have become aware of the serious consequences of illnesses linked to a growing variety of foods, produced domestically or imported. Consumers want the government to regulate the food supply, and industry is interested in producing foods that are safe at a reasonable price. As a result there is congressional interest in oversight and legislation in this area.

Several federal agencies, along with cooperating agencies in the states, are responsible for assuring the safety, wholesomeness, and proper labeling of all foods for human consumption in the United States. The Federal Food, Drug, and Cosmetic Act (FFDCA) gives the Food and Drug Administration (FDA) in the Department of Health and Human Services (DHHS) authority to set and enforce standards for safety of all domestic and imported foods, except for meat and poultry. FDA also ensures that all animal drugs and feeds are safe, are labeled properly, and produce no human health hazard when used in food-producing animals. Also under FFDCA, the Environmental Protection Agency (EPA) sets legal limits (tolerances) on amounts of pesticide residues that can be found in or on food. The Federal Meat Inspection Act and the Poultry Products Inspection Act authorize the U.S. Department of Agriculture (USDA) to set and enforce standards for the safety of red meats and poultry.

The food safety activities of these agencies consist of inspecting, testing, researching,

and monitoring the food supply. In response to limited federal funding, FDA and USDA adopted an approach to food safety and inspection known as the Hazard Analysis and Critical Control Point (HACCP) system. It identifies where hazards could enter food during its preparation for market and steps that can be taken to prevent hazards.

Given concerns about the safety of the food supply after the September 11th tragedy, the 107th Congress is debating a number of proposals to protect the food supply against intentional adulteration. A few bills would extend to FDA new authorities to register, recall, and monitor imports. Others want to fund more research at USDA and the National Institutes of Health. Two bills are proposing to consolidate into a single agency all food safety inspection and labeling activities, now held by several agencies.

The 107th Congress had begun considering safe food proposals prior to the tragedy earlier this year. Congress had passed a law (P.L. 107-9) which requires reports on inter-agency activities to assess, prevent, and control “mad cow disease” and foot and mouth disease. These diseases appear on lists of potential threats to the food supply. Other proposals would require mandatory labeling of country-of-origin of foods, and two would increase the number of inspections at the border. In appropriations’ bills, both House and Senate have supported funding for an emerging public health problem: antimicrobial resistance, a growing concern as more people are taking antibiotics prophylactically against the threat of anthrax infection.



MOST RECENT DEVELOPMENTS

Since September 11th, growing concerns in Congress about the vulnerability of the U.S. food supply to terrorism have challenged the Administration to reexamine and in some instances reenforce the current regulatory system. Several bills introduced in the last month would expand FDA's and USDA's authorities to detain and monitor food. Most of these proposals build on the current structure for ensuring the safety of the food supply by expanding resources and authorities available to the agencies. Some bills call for the federal registration of food processing and handling facilities (H.R. 3184, S. 1551), and for each food facility to keep records to allow for the recall of unsafe food (H.R. 3075, H.R. 3127, H.R. 3184, S. 1551). Others would set up a more thorough system for monitoring the safety of imports with more inspectors, sampling and testing, and country-of-origin labeling (H.R. 1605, H.R. 3075, H.R. 3184, S. 1551, S. 1563). One bill proposes user fees to pay for this activity (H.R. 3075). Two other bills would reorganize the whole federal system for food safety to create a single food safety system (H.R. 1671, S. 1501). Other bills would strengthen the agencies' enforcement powers by allowing agencies to levy civil monetary penalties when infractions are found, and would fund greater research efforts for the development of diagnostic tests (H.R. 3075, H.R. 3174, H.R. 3184, S. 1551, S. 1563). The Administration has proposed a more modest set of changes and wants Congress to consider giving the Secretary of Health and Human Services authority to detain violative food if found through inspections at the border or domestically. It would like the authority to debar "bad actor" importers who repeatedly violate U.S. laws, require food manufacturers to keep records that FDA officials can then inspect and copy, and have importers notify FDA prior to importing a food. While these proposals would extend the current system, the Administration testified October 10, 2001, that it has confidence that it could respond to intentional terrorist threats because, in the last 4 years, it has strengthened the federal food safety system and has now in place systems to identify and respond quickly to foodborne illness outbreaks. In addition, the different federal agencies have worked together to put risk-based prevention programs into place for seafood, meat, poultry, and fruit and vegetable juices. For these reasons, some in the Administration claim that extensive new authorities are not needed to ensure a safe food supply.

BACKGROUND AND ANALYSIS

Introduction

While most experts agree that the U.S. food supply is among the safest in the world, every year food-borne pathogens in the food supply make many people ill. Consumers have expressed increasing concerns about microbial and other contaminants in their foods and are asking whether the federal regulatory system adequately deals with those problems. The nation's food safety system consists of activities carried out by several federal, state, and local government agencies that inspect, test, research, and monitor the food supply. For the most part, these agencies monitor whether food manufacturers are adhering to their legal responsibility of assuring the production of safe food. However, reported occurrences of outbreaks of food-borne illnesses have been increasing, and current safety efforts are not providing the confidence in the food supply that U.S. consumers demand.

In response, in 1997, the Clinton Administration launched several efforts to correct and augment the safeguards in the food safety system with a “farm-to-table” initiative. In 1998, this Administration finalized guidance to the industry on the production, handling, and processing of fresh fruits and vegetables. In January 2001, the President’s Council on Food Safety released a long-term strategic plan which recommended that Congress, rather than creating a single food safety agency, should ensure that coordination among agencies is strengthened, that comprehensive legislation governing food safety is rewritten, and that the allocation of resources is based on scientific and risk-based evidence. Some claim that reorganizing the regulatory structure for food safety would better protect the public health. On the other hand, the food industry and some government officials have resisted proposed changes in the food safety structure claiming that the agencies need no new authority to enforce food safety requirements and need only to better enforce current rules.

This issue brief characterizes the public health problems caused by food-borne pathogens and other contaminants and describes activities of federal agencies charged with ensuring that consumers can purchase “safe” food from appropriately regulated food companies. It briefly discusses the President’s several food safety initiatives, and describes requested resources for federal funding and for cooperation among federal agencies involved in food safety activities.

Public Health Problems

CDC estimates that food-borne diseases cause approximately 76 million illnesses, 325,000 hospitalizations, and 5,000 deaths each year in the United States. These estimates are based on data from a variety of sources including new surveillance systems, death certificates, and academic studies. Experts claim that rather than any changes in disease frequencies, better surveillance data have contributed to the increased numbers. Often, victims mistake food poisoning for some other illness and do not report it to a doctor. Some experts estimate that over 40 million cases of food-borne illness go unreported each year. Different population groups, such as the elderly, the very young, pregnant women, and people with HIV/AIDS and cancer, are particularly vulnerable to diseases caused by food-borne pathogens. While many food-borne illnesses are mild and non-life-threatening, 1-3% of those afflicted develop secondary complications such as reactive arthritis, kidney failure, and Guillain Barré Syndrome — a form of acute paralysis.

Officials of the Department of Health and Human Services (DHHS) note that there has been a 20% decrease in illnesses due to the major bacterial food pathogens. They project, however, that the reported incidence of food-borne disease may increase by 10-15% during the next decade. Some postulate that changes in production practices, centralized product distribution, environmental conditions, and food consumption patterns could be contributing to the changes in old pathogens and the emergence of new microbial threats to health.

Several factors are contributing to the concern of public health officials about the increased risk of getting ill from food. The U.S. population is aging and there are more people living with compromised immune systems. The highly mechanized, efficient production and distribution practices of the food industry make it possible for a contaminated product to be quickly distributed nationally or even internationally. Long-distance distribution channels also give more opportunity for time and temperature abuse. With people eating out frequently, and more retail establishments processing foods on-site, there is more opportunity for a

contaminated food to cause illness in more people. In addition, more cases of illness from pathogenic organisms on fresh fruits and vegetables have been reported as consumers eat more produce for its nutritional benefits.

Food-borne diseases are caused primarily by bacteria, viruses, parasites, and fungi that produce toxic substances. There also may be long-term health effects from chemical residues or drug residues found in food. Nonpathogenic microorganisms may become pathogenic when they mutate or adapt to changing environments. For instance, one strain of *Escherichia coli*, a common, harmless bacteria found in intestines of all birds and mammals, has mutated into a deadly form known as *E. coli* O157:H7 and into other serotypes. It is now found not only in hamburger, but also in unpasteurized apple juice, alfalfa sprouts, and packaged lettuce. A more virulent type of *Salmonella* Enteritidis (SE) called phage type 4, has been found in chickens and dairy cows. Both pathogens have contributed to the growing number of food borne outbreaks.

USDA's estimated costs associated with medical expenses and losses in productivity from five major types of food-borne illnesses are \$6.9 billion annually (in August 2000 dollars). These major food-borne illnesses include illnesses caused by *Campylobacter*, *E. coli* O157:H7, *Shiga toxin-producing strains of E. coli*, *Listeria monocytogenes*, and *Salmonella*. Adjusting for age of death lowers or raises the cost. For example, the annual cost of food borne illnesses caused by *Salmonella* decreases from \$3.7 billion to \$2.4 billion when adjusted for age of death because over 2/3rds of the deaths from salmonellosis occur in people over 65. Adjusting food borne illness costs for *E. coli* O157:H7 by age of death increases the estimates by \$68 million because most deaths occur in children under 5.

Federal Regulatory Framework for Food Safety

The food industry makes available to U.S. consumers a wide variety of food that is produced domestically or imported. The federal government attempts to ensure that the food supply is safe from the farm and ports to consumer tables under statutory mandates and regulatory policies. Federal regulatory jurisdiction depends on the type of food, the way the food is processed, or the type of adulterant to be found in a particular food. Critics charge that the agencies' overlapping jurisdictions and duplication of effort are wasting taxpayers' money. Overlapping jurisdictional responsibilities inhibit efforts to focus where the risk of adulteration and contamination is the greatest, they claim. Federal officials, however, argue that by working cooperatively and through formal understandings among the agencies, federal agencies now, for the most part, avoid duplicating efforts.

Agency Regulatory Responsibilities

Federal regulatory responsibilities for food safety vary. For example, the U.S. Department of Agriculture (USDA) regulates red meat, poultry, and certain egg products while the Food and Drug Administration (FDA) is responsible for the safety of all other foods. Preventing and detecting food-borne contamination is currently the job of three federal agencies: the Food Safety Inspection Service (FSIS) and the Animal Plant Health Inspection Service (APHIS) of USDA; two centers within FDA (an agency of DHHS) — the Center for Food Safety and Applied Nutrition (CFSAN) and the Center for Veterinary Medicine (CVM);

and the Office of Pesticide Programs (OPP) of the Environmental Protection Agency (EPA). In addition, the Centers for Disease Control and Prevention (CDC), also part of DHHS, tracks food-borne illness incidents and outbreaks, and provides data and information to the other food safety agencies. Of the illnesses whose food source is known, about 85% are associated with food products regulated by FDA such as fish, shellfish, fruits, vegetables and salads. The remaining 15% are associated with meat and poultry, products under FSIS's jurisdiction.

Even with all these federal agencies playing a role in ensuring the safety of foods, manufacturers, producers, and distributors of food have the primary responsibility of ensuring that the food, when marketed in interstate commerce, is not harmful or unfit and does not contain unacceptable chemical residues. To assist in this effort, federal agencies set standards for producers, processors, and manufacturers that minimize food hazards. Federal agencies then enforce these standards through inspections and verification of documents.

Federal laws mandate how each federal agency approaches its role in food safety, and these laws dictate very different approaches. The Federal Food, Drug, and Cosmetic Act (FFDCA) prohibits the entry into interstate commerce of adulterated or misbranded foods. Section 402 of the FFDCA defines food as "adulterated" if it "contains any poisonous or deleterious substance which may render it injurious to health." FDA is responsible for establishing guidance and regulatory requirements for assuring that food is safe and not adulterated. FDA monitors through inspections whether food manufacturers adhere to their legal responsibility of producing foods that are not found to be defective, unsafe, filthy, or produced under unsanitary conditions. FDA also monitors more than 3.7 million imported food entries annually. However, as noted below, these inspections occur infrequently. FDA also is authorized to seize contaminated food and review petitions for approval of food and color additives, among other things.

The meat and poultry acts mandate different inspection requirements. The Federal Meat Inspection Act of 1906, as amended by the Wholesome Meat Act of 1967, requires that USDA continuously inspect all cattle, sheep, swine, goats, and horses brought into any plant to be slaughtered. It also requires that a federal inspector be present at least for part of every shift while a firm is processing meat products for human or animal consumption. Congress instituted similar requirements for poultry in the 1957 Poultry Products Inspection Act, amended by the 1968 Wholesome Poultry Products Act. Under these acts, USDA is responsible for inspecting most meat, poultry, and processed egg products for safety, wholesomeness, and proper labeling. USDA also has established a mandatory program called Hazard Analysis and Critical Control Point (HACCP) for meat and poultry plants.

Under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), EPA regulates pesticide products sale and use and weighs the products costs and benefits. Under the "safety-only" clause, Section 408 of the FFDCA, EPA sets limits for pesticide residues (called tolerances) in or on foods and animal feed. Foods with a residue of a pesticide for which there is no tolerance established, or with a residue level exceeding an established tolerance limit, are declared "unsafe" and "adulterated;" such foods cannot be sold in interstate commerce in the United States. EPA has set over 9,000 pesticide residue tolerances. FDA and USDA enforce those tolerances on their portions of the food supply. The Food Quality Protection Act of 1996 (P.L. 104-170) changed the so-called "zero-risk" standard of Section 409 of the FFDCA (the Delaney Clause) so that all food, both raw and processed, have tolerances set

under a standard that requires all residues be “safe,” and ensures that there is a “reasonable certainty of no harm” from the pesticide residues.

State, county, and local public health and agriculture departments along with the CDC play a major role in helping FDA and USDA carry out their responsibilities. Even though federal law mandates the safety of all food, more than 3,000 state and local regulatory agencies monitor most retail food establishments to ensure that consumers are protected from unsafe food and are following procedures outlined in an FDA guidance manual called the Food Code. U.S. retail establishments include approximately 57,000 food establishments. CDC’s primarily assists state and local health departments in investigating outbreaks of illness and in identifying the cause of the outbreak. State health departments send CDC reports of confirmed food-borne illnesses for a national surveillance database.

Federal agencies carry out five activities to ensure that food is safe: 1) provide guidance to industry about what is expected, and develop policies and regulations; 2) enforce compliance by inspections and programs; 3) give pre-market approval to additives that will be added to food and to be listed in the labeling; 4) track food-borne illnesses in the United States and overseas; and 5) conduct research on all phases of food science including detection methods for contaminants.

Establishing Guidance and Regulatory Requirements. FDA promulgates regulations and issues guidance and advisories, known as “good manufacturing practices” (GMPs), to food manufacturers and both FDA and USDA publish regulatory requirements which food processors must meet. Standards and requirements are developed through a public rule-making process. In developing GMPs, for example, FDA considers a variety of sources, including advice from international organizations. GMPs for food production represent generally recognized practices for food processing and handling to avoid contamination with poisonous or deleterious substances, filth, or potentially harmful microorganisms. GMPs address layout and maintenance of facilities, personnel qualifications, equipment and utensils, processes and controls, and other measures required to ensure basic sanitation and cleanliness.

FDA and USDA have adopted a preventive approach called the “Hazard Analysis and Critical Control Point” (HACCP) program to ensure the safety of food. FDA has been using a similar program in its low-acid canned foods regulations for more than 30 years. FDA instituted HACCP in December 1997 for seafood products and finalized a rule on January 18, 2001, requiring HACCP for fruit and vegetable juices, except citrus juice who had already demonstrated processing procedures to FDA that reduced contaminants sufficiently. USDA requires HACCP for red meat and poultry. The HACCP program for food safety gained support in 1993, when President Clinton and Vice President Gore issued a report under the National Performance Review initiative calling for a uniform science-based approach to food safety, and favored giving more responsibility for assuring the safety of the food supply to the food industry. A HACCP program typically applies seven principles, based on a scientific and technical analysis of the production process. The seven principles are (1) analyze hazards; (2) identify critical control points to control identified hazards; (3) establish the point at which a preventive action must be taken; (4) establish procedures to monitor the control points; (5) establish corrective actions to be taken when monitoring shows that a critical limit has not been met; (6) establish procedures to verify that the system is working consistently; and (7) establish effective record keeping to document the HACCP system. Once the system is in

place, FDA and USDA review the records of monitoring at the critical control points to ensure compliance and evaluate the products and facility.

The most important and controversial step is the choice of the critical control points or CCPs. CCPs are where control *must* be exercised because loss of control at a CCP is likely to result in contamination of a food. An example of a CCP would be a heat treatment step where a specific combination of time and temperature is maintained to eliminate all pathogens. Under HACCP, food companies are responsible for identifying and setting the limits of this critical step and putting in place control measures that are activated when the limits are breached. The federal government role is to give guidance, oversee safety programs, and monitor records of those CCPs and to determine that the company corrected problems. FDA is currently collecting information, through a voluntary pilot program, on how HACCP might be implemented for food service and food retail establishments.

HACCP for Meat and Poultry. USDA's final regulations for Pathogen Reduction/HACCP in meat and poultry processing have four elements: (1) each plant had to develop sanitation standard operating procedures (SSOPs); (2) all plants must meet performance standards and keep records that ensure the *Salmonella* incidence rate is below the national baseline level established by USDA; (3) every plant must test for the bacterium *E. coli* (all strains, not specifically O157:H7) to verify that the process is controlling fecal contamination; and (4) every meat and poultry plant must develop a critical control point under a HACCP plan to identify where hazards occur and how to prevent them.

HACCP for Seafood. On December 18, 1997, FDA implemented HACCP regulations for the seafood industry. Each seafood plant must have a HACCP plan available for FDA's review. Plant managers also must have monitoring records of its critical control points to show whether the plan is being properly implemented. FDA is supposed to inspect all domestic seafood processors to ensure compliance with this regulation. Critics, however, charge that FDA has not inspected the plants on a regular basis. FDA officials state that, although many plants need to take further action to comply with HACCP requirements, many of the violations are minor and have no impact on the safety of the products.

Enforcing Compliance with Inspections and Sanctions. The FFDCAs and other statutes give FDA the responsibility to prohibit entry of adulterated or misbranded foods and other products into interstate commerce. FDA regulates about 85% of food products associated with food-borne illnesses. FDA officials (fewer than 700 and some state officials under contract with FDA) are authorized to enter and inspect, at reasonable times, any factory, warehouse, or establishment in which foods are manufactured, processed, packed, or held prior to introduction into interstate commerce or in a vehicle transporting food. Inspections of 57,000 food establishments under FDA's jurisdiction occur on average once every 5 years. If violations are found, FDA can request that the Justice Department initiate an injunction, seizure, or prosecution. FDA also uses a number of administrative enforcement tools. It sends warning letters and other regulatory correspondence, requests voluntary recalls, creates import alert lists, detains imported foods, and prosecutes misdemeanors and felonies through the Department of Justice. It has no power to mandate recalls or look at state records kept by the plant. If further action is necessary, FDA requests the Department of Justice to impound the contaminated foods.

FSIS inspectors, under the authority of the Federal Meat Inspection Act and the Poultry Products Inspection Act, must be continuously present at all the 6,000 meat and poultry plants while processing. FSIS inspectors (more than 7,500), who examine each meat and poultry carcass slaughtered and are present in all meat and poultry processing plants daily, have summary powers to withdraw their inspection services, which stops processing operations, condemn foods, and obtain plant records. FSIS compliance staff investigate any alleged violations of the meat and poultry inspection acts. FSIS can detain the product in the plant or institute a seizure action requesting a federal district court to direct a U.S. Marshall to take custody of the product. It does not have mandatory recall authority. It is likely that there will be legislation introduced into the 107th Congress that, if passed, would provide FSIS with authority to require a recall of unsafe meat and poultry products and FDA with recall authority over the products it regulates.

Approving Food Additives and Labeling. The FFDCFA, Section 409 defines food additives to include not only directly and indirectly added substances to foods but also certain substances used in “producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food, and including any source of radiation intended for any such use.” An industry or sponsor with a proposed food additive must file a petition for pre-market approval with FDA that includes test data showing that the food additive meets the FFDCFA standard of “safe.” “Safe” means that there is a “reasonable certainty that no harm would result from the substance under its intended conditions of use.” In its petition review process, FDA determines the types of food in which an additive can be used, the maximum quantity of the additive that can be used, and the information that must appear on the label. During the review, the agency assesses the risks associated with the additives. If the petition establishes an adequate basis for finding that the use of a substance is safe, the agency publishes in the *Federal Register* a regulation prescribing safe conditions for use. In addition, the statute permits use, without prior agency approval, of a substance with a long history of use, if it is considered “generally-recognized-as-safe” (GRAS).

Food Contact Substances. If FDA concludes that a substance used in manufacturing, packing, packaging, transporting, or holding food might reasonably be expected to migrate into the food, the substance is regulated as a “food contact substance.” Most of the time, the risk from these substances is extremely small or *de minimis*. The sponsor or manufacturer notifies the agency of the substances identity, and its intended use, and submits all necessary information to show that the substance is safe. Unless FDA specifically objects, the manufacturer can begin using the food contact substance. This Premarket Notification Program (PMN) diminished the time the agency spent reviewing “food contact substance” petitions for approval.

Food Irradiation. As shown above, the FFDCFA definition of a food additive includes the phrase “any source of radiation intended for any such use.” On December 2, 1997, FDA approved the use of irradiation of red meats. Approval came after FDA examined the impact on the nutrient content of irradiated products, potential toxicity concerns, and the death of microorganisms in or on irradiated products. In December 1999, USDA finalized its rule governing the use of irradiation in raw meats and meat by-products to control disease-causing microorganisms and to extend shelf life (64 FR 9089-9105). It extended the same rules to poultry products. On July 20, 2000, FDA approved irradiation on eggs in shell to reduce the level of pathogens, particularly *Salmonella*. The agency is currently reviewing 5 petitions that would extend approval of the use of irradiation to ready-to-eat foods, shellfish, and processed

meats. The House report for the FY2002 agriculture appropriations bill asks FDA to meet with stakeholders early in the process of developing petitions to irradiate foods, to speed up the review of petitions once they are submitted, and to ensure that labeling of irradiated foods can be understood by the general public.

Critics of irradiation are concerned that some producers, processors, and consumers will have unrealistic assumptions about the safety of the products and, believing that their food is safe, will not be careful with sanitary food-handling practices. Critics also say that irradiation treatment of food kills helpful bacteria that aid digestion, may alter the nutritional value of a food, and could cause genetic damage in animals, humans, or cell cultures. Supporters, however, irradiation as giving the industry another “safety” tool to control food-borne pathogens. Irradiation may become a primary tool in ensuring the safety of fresh produce such as alfalfa sprouts. The FY2001 agriculture appropriations report language directed FDA to finalize regulations by March 1, 2002 to make the size of the label (disclosing that a product had been subjected to ultraviolet irradiation) not larger than the ingredient declaration.

Tracking Food-borne Illnesses. In 1998, the Administration initiated PulseNet, a system for linking electronically investigators at CDC, FDA, and USDA to public health laboratories in 46 states (by the end of 2001.) This network of state and local laboratories is designed to rapidly identify strains of all food-borne pathogens by matching DNA “fingerprints” of pathogens found both in food and in people stricken with gastro-intestinal illness. These data are collected in addition to data under FoodNet, a cooperative active surveillance project for food-borne disease in eight targeted locations in the United States. FoodNet, also supported by CDC, FDA, and USDA, began in 1995 because public health officials, who rely on epidemiology to identify and track the source of outbreaks of food-borne illness, did not have an accurate accounting of outbreaks. Many times, when people are diagnosed with a food-borne illness, their doctor or the laboratory that detects a pathogenic organism in a fecal sample may or may not report the incident to the local county health department. That department only reports periodically cases that it knows about to the state department of health. States collect local data and send reports to CDC which updates a national surveillance database. Preliminary data from FoodNet for 2000 indicate a decline of 20% in food borne illnesses caused by the nine most common pathogens during 1996-1999. There is substantial regional and year-to-year variation in food borne illnesses.

Research. Discovery of food-borne microorganisms that have acquired pathogenic characteristics raises concerns over whether the current food safety system is adequate to detect and identify new pathogens and their sources before they reach consumers. In January 2001, the Clinton Administration released a *Public Health Action Plan to Combat Antimicrobial Resistance*. According to the plan, the numbers and susceptibility of bacteria that resist antibiotics are growing and the plan gives a blueprint for coordinated federal actions to address the emerging threat of antimicrobial resistance. One goal is to increase basic and clinical research on the physiology, genetics, and mechanisms of resistance. In fact, the Antibiotic Resistance Prevention Act of 2001 (H.R. 1771) introduced May 9, 2001 by Representative Sherrod Brown would provide funding for the top priority action items in this interagency public health action plan that has been developed in response to the problem of antimicrobial resistance. However, the bill limits the authorization to those activities involved are within the jurisdiction of the Department of Health and Human Services.

Recent Initiatives to Reduce Food-borne Illnesses

Food-borne disease outbreaks have recently received much media attention and have shaken public confidence in food safety. Between 1995 and 2000, over 10 food borne illness outbreaks were associated with sprouted seeds. Since 1997, there has been a series of highly publicized outbreaks of food-borne illness: Hepatitis A associated with frozen, sliced and sugared strawberries from Mexico in a school lunch program, *Cyclospora* associated with lettuce, basil, and Guatemalan raspberries, *E. coli* O157:H7 in frozen beef patties from a packing plant, and *Salmonella Agona* in dry oat cereal in 11 states. In late May 2000, illnesses caused by *E. coli* O157:H7, found in the city drinking water of Walkerton, Ontario, Canada, caused 7 people to die, most of whom were aged 56 to 92. The same pathogen caused 27 cases of illness in Minnesota in November 2000, attributed to the consumption of ground beef patties and forcing a recall of 1.1 million pounds of beef. Between May to December 2000, 29 illnesses caused by *Listeria monocytogenes* were identified in 10 states and linked to deli turkey meat. Infections from *Listeria* causes an estimated 2,500 illnesses and 500 deaths each year. This pathogen can lead to premature delivery or miscarriage.

The “Farm-to-Table” Food Safety Initiative

The Clinton Administration’s Food Safety Initiative, with support from the last two Congresses, has improved the methods of tracking and preventing microbial food-borne illnesses. A May 1997 report, entitled *Food Safety From Farm to Table*, laid out six major areas for federal activity: an early warning system for food-borne disease surveillance, coordination of response to interstate outbreaks, risk assessment, research, improved inspections and compliance, and education. With appropriated resources, the agencies expanded FoodNet, PULSENET, and eLexNET, national early warning systems. The initiative increased resources for research to develop tests that detect microbes that cause food-borne illness, to expand inspections to improve compliance, and to support educational programs, such as “Fight BAC,” which stresses four key points: clean hands and surfaces often; keep hot foods hot; keep cold foods cold; separate foods and don’t cross contaminate.

Appropriations for Food Safety

For the last 4 years, both FDA and USDA have requested funding for food safety under six categories of activities of the National Food Safety Initiative: surveillance, emergency outbreak coordination, inspections and compliance, risk assessment, education, and research. The Bush Administration no longer tracks funding for food safety in the same way as the Clinton Administration. It has broadened the definition of what is included in activities related to food safety so that food safety not only includes the prevention of microbial contamination, but also the tracking of pesticide residues and other chemical hazards found in foods. The broader definition also includes the entire appropriation for USDA’s Food Safety Inspection Service (FSIS) rather than having a separate accounting for activities under the Initiative. The Clinton Administration did not include funding for FSIS inspections under the Initiative because these inspections included a variety of other responsibilities and were not strictly focused on eliminating microbial pathogens in the U.S. food supply. Consequently, with different definitions, it is impossible to compare this year’s recommended funding levels with previous years funding levels.

For FY2002, the House passed its agriculture appropriations bill (H.R. 2330) July 11, 2001, while the Senate passed its bill (S. 1191), October 25, 2001. For FDA appropriations, the House began its discussions with a newly defined category for “food safety” which led to an expanded FY2001 base figure of \$335.3 million. It then added \$22.7 million to this base for a total recommendation of \$358 million for food safety activities in FY2002. The Senate began with last year’s appropriations of \$216.674 million, added \$18.133 million, and has now set \$234.807 million for food safety activities. The difference in the increased funding recommendation is not large; it is \$4.6 million (the House with \$22.7 million and the Senate, \$18.1 million). The difference in the total recommended appropriation is \$123.2 million; it is large because the Senate uses the much narrower definition. The bills are now in conference.

Congressional Oversight Structure for Food Safety

Congressional oversight for food safety is shared among several committees. In the Senate, food safety issues are considered by the Committees on Agriculture, Nutrition, and Forestry; Energy and Commerce; Science, and Transportation; Environment and Public Works; Government Affairs; and Health, Education, Labor and Pensions. In the House, food safety is considered by the Committees on Agriculture; Energy and Commerce; Government Reform and Oversight; and Science. The Appropriations Committees also serve an oversight role in how the major agencies set and carry out policies affecting the safety of foods.

Issues

Do Federal Agencies Need More Authority and Resources?

There is a growing concern among many Members of Congress that contamination from acts of bioterrorism that could have an impact on the safety of food animals, produce, and imported foods. Currently under discussion in the Senate is a comprehensive bioterrorism bill that is likely to have new authorities and funds to ensure safe food. In addition, there is concern about whether agencies currently have adequate authority and resources to monitor for food-borne disease problems domestically and at the border. Some in Congress would like more resources be directed to federal agencies to prevent any contaminated food product from entering the food chain: Food Supply Protection Act (H.R. 3174); the Agricultural Bioterrorism Countermeasures Act of 2001 (S. 1563); and Protecting the Food Supply from Bioterrorism (H.R. 3184, S. 1551) or from being imported into the United States (Imported Food Safety Act of 2001, H.R. 3075 and H.R. 3184, S. 1551). Others bills (Unsafe Meat and Poultry Recall Act of 2001, H.R. 3127; H.R. 3184, S. 1551, and S. 1563) are interested in authorizing recall authority to allow the agencies to act quickly in response to terrorist acts or to require more coordination among academia, industry, and government. Others are concerned about the potential spread of Bovine Spongiform Encephalopathy (BSE) or “mad cow disease” and foot-and-mouth disease (FMD).

A Reorganized Regulatory Structure for Federal Food Safety?

Recently, in light of the September 11th tragedy, Members of Congress are questioning whether the current monitoring and inspection systems of USDA and FDA are capable of

safeguarding the nation's food supply. At an October 10, 2001 hearing GAO recommended that a single food safety agency be responsible for administering laws needed to deal with emerging food safety issues including deliberate acts of contamination. (See GAO-02-47T, *Food Safety and Security: Fundamental Changes Needed to Ensure Safe Food*.)

The January 2001 strategic plan of the Council on Food Safety supported a unified framework for food safety and laid out 3 recommendations: 1) to include risk analyses to support decisions about reform; 2) to streamline the existing system where overlapping jurisdictions occur; and 3) to develop a plan that addresses food safety functions that could comply with a unified statute. There was support of a single federal official to be responsible for federal food safety policy but not for a single agency.

Several Members of Congress are also rethinking the current organizational structure for food safety activities within the Federal Government. Some want a single food safety agency to undertake all food safety responsibilities as currently mandated in the statutes. The Safe Food Act of 2001 (H.R. 1671 and S. 1501) proposes to consolidate into a single independent agency all current responsibilities regarding food safety, labeling, and inspection now divided among FSIS, FDA, and the Department of Commerce. It does not propose changing the statutes that today authorize current food safety regulatory activities.

Supporters claim reorganization will address the problem of several agencies performing food safety functions which, they assert, at times overlap and at times leave undone necessary activities to protect the public health from food-borne illness. Supporters point to the fact that meat pizzas must be inspected by USDA, whereas other pizzas without meat yet made in the same plant come under FDA inspectors purview. Supporters say that a single food safety agency can identify the most serious public health risks, respond quickly to outbreaks, research testing methodologies, conduct risk assessments, and identify the most cost-effective interventions without regard to the type of food or to bureaucratic "turf." Critics of reform believe that the time is not right for major reform because of fear that a new agency would cause dislocation and upheaval. Parent agencies would need to relinquish their current budget authority and control. Other opponents claim that reorganization proposals do not address the flaws in the fundamental regulatory structure for food safety created by current statute.

Should Bioengineered Foods Be Labeled and Regulated?

Questions have been raised in the 107th Congress, as to whether genetically modified or bioengineered foods are safe, and whether they should be labeled. Bioengineered foods, or genetically engineered foods (GE foods), refer to the use of recombinant DNA and related techniques to alter the genetic makeup of living organisms. These techniques allow scientists to identify and isolate genes of interest from any organism and put them into other organisms. All the food safety agencies, FDA, USDA, and EPA, are involved in the regulatory process for GE foods. EPA has recently proposed and finalized rules for GE crops that produce their own pesticides, called Plant-Incorporated Protectants or PIPs. Currently, GE food crops planted and marketed by U.S. farmers include 45 kinds of corn, canola, tomatoes, potatoes, soybeans, and sunflowers. (For more information, see CRS Report RL30198, *Food Biotechnology in the United States: Science, Regulation, and Issues*).

On January 18, 2001, FDA published a proposed rule, supported by the industry, that would require that a food company notify the agency 120 days prior to marketing a

bioengineered food and, at that time, supply the agency with safety test data. The agency also strongly urged companies to consult the agency prior to the mandated notification deadline in order to ensure agreement on the types of safety testing that will be needed. After reviewing the submitted data, FDA will either issue a letter to the company saying it has no safety concerns or expressing why the product should not be marketed.

Currently, FDA does not require labeling of GE foods. However, on January 18, 2001, FDA published in the *Federal Register* a “Draft Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering.” (It has been reported that the agency has received over 84,000 comments on this draft guidance.) In this document, FDA reaffirmed that it believes most genetically engineered foods are substantially equivalent to their conventional counterparts, and it decided it would not require special labeling of all bioengineered foods because it believes that the use of bioengineering, or its absence, does not itself cause a material difference in the food. However, the agency did suggest that because of the strongly divergent views on labeling, manufacturers may consider providing more information on the label about bioengineered food. The information given, however, must be truthful and not misleading. To avoid false or misleading statements about the absence of bioengineered ingredients (because there are no established threshold levels of bioengineered constituents or ingredients in foods), or to avoid implying that one food is superior to others, FDA suggests not using statements such as “GM free” or “biotech free.” The agency does suggest the word “biotechnology” is preferred by some consumers over “genetic engineering” or “genetic modification.” It also claims that if validated testing is available, it can be used to verify whether the label is truthful. Or manufacturers could keep records to document the reasons why a food’s label is truthful. (See CRS Report RS20507, *Labeling of Genetically Modified Foods*.)

H.R. 115, named the “Food Biotechnology Information Initiative Act,” would require the development of a program to tell consumers about the scientific basis of the safety of foods produced with biotechnology and provide \$10 million for research to address economic and environmental impacts of biotechnology on the food supply.

Supporters claim that GE foods have environmental benefits because there is less need to use pesticides and farmers benefit from lower input costs. They also say these foods have been carefully tested by industry, and that, in fact, genetic engineering is more precise than traditional cross-breeding, a technique that often transfers unwanted genes to the food plant. However, critics question whether the agencies have scrutinized properly the long-term effects of these products on human and environmental health. These critics want mandatory labeling and consultation with the agency prior to marketing.

Is Antimicrobial Resistance a Growing Public Health Problem?

Antimicrobials, a set of agents that include among others, antibiotics and disinfectants, have benefitted the public health by treating diseases that were un-treatable earlier. Antibiotics are also fed to farm animals to speed their growth, to promote the efficient use of the feed, and they are sprayed on crops similar to pesticides. Their widespread use, particularly now that several antibiotics are being used prophylactically against anthrax exposure, may in the future cause some of these drugs to lose their ability to control disease, and some people to become resistant to a number of antibiotics that are crucial for treatment of certain diseases and infections. Although resistance to antibiotics has been noticed since they were introduced

in the 1940's, more tracking (surveillance) and publicity has recently raised concern among some Members of Congress over this public health problem, particularly the use of antibiotics in food animals to promote growth. Some experts expect resistance problems to worsen in the future. (See CRS Report RL30814, *Antimicrobial Resistance: An Emerging Public Health Problem.*)

Defining appropriate legislative responses is particularly difficult given the complexity of the antimicrobial resistance problem, the lack of data to assess the problem, and the disagreement over the seriousness of the extent of the health threat of resistance. Use of antimicrobials in human medicine, for example, is thought to be the primary source of resistance. Many public health officials are concerned about the trends in antibiotic use following the scares from the threat of anthrax infection. For example, CDC has recently urged physicians to be cautious about indiscriminately prescribing Cipro, particularly to people who have no chance of having been exposed to anthrax, because of concerns about the development of drug-resistant organisms.

Included in the debate are the uses of antibiotics in the agricultural sector. The conflict there is over how much antibiotic use, both for treating disease and promoting growth, in food-producing animals contributes to resistant strains of bacteria. A study by the Union of Concerned Scientists, *Hogging It: Estimates of Antimicrobial Abuse in Livestock*, estimated a total non-therapeutic use of 24.6 million pounds of antimicrobials in cattle, swine, and poultry. The American Health Institute, representing drug manufacturers, has put the same use at 17.8 million pounds. The AMA, at its annual meeting in June 17-21, 2001, passed a resolution opposing the routine use of antimicrobial drugs in agriculture. The AMA resolution called for increased surveillance of antimicrobial use and resistance in food animals.

On January 18, 2001, an Interagency Task Force on Antimicrobial Resistance, co-chaired by CDC, FDA, and NIH, released a "Public Health Action Plan to Combat Antimicrobial Resistance." The Plan reflects a broad-based consensus of federal agencies¹ on what actions the government should take to combat antimicrobial resistance. The Plan contains goals and 84 action items—13 of which are considered "top priority": surveillance, prevention and control, research, and product development. Each action item specifies the coordinator, participating agencies, and timelines. It asks all federal agencies to standardize detection methods, design and implement a national surveillance plan, and to monitor patterns of antimicrobial drug use in human medicine, agriculture, and consumer products.

Currently, surveillance for resistance in both humans and animals is underway. However, the surveillance of human drug use necessary to weigh which practices cause resistance is not being conducted. This lack of use surveillance is partly due to the difficulties in collecting such data. A system that tracked human use would require extensive linkages with prescribing physicians, data from pharmacies, and insurance reimbursement data. For animal use, where there is over-the-counter antibiotic use, the data is proprietary and drug companies appear to be reluctant to share this information.

¹ Members include: Agency for Healthcare Research and Quality (AHRQ), CDC, FDA, Health Care Financing Administration (HCFA), NIH, and the Health Resources and Services Administration (HRSA), several agencies of USDA, the Department of Defense (DoD), the Department of Veterans Affairs (DVA), and the Environmental Protection Agency (EPA).

The Plan also calls for a public health education campaign to promote prudent antimicrobial drug use. It advocates the use of vaccinations to prevent infections from occurring in patients residing in nursing homes, among other places. It calls for the implementation of the FDA framework for antibiotics in food animal production. It supports research on resistance genes by public and private groups. Such research would develop rapid diagnostic tests and novel therapies to better control resistance. It recommends the creation of an interagency antimicrobial resistance product development working group to identify and publicize public health needs for new products. It also calls upon the federal government to identify incentives that can be used to promote the development of new human and animal drugs and their judicious use.

On May 9, 2001, the Antibiotic Resistance Prevention Act of 2001 (H.R. 1771) was introduced, which would authorize funding for the top priority action items in the interagency public health action plan. It would only authorize activities and funding for the problems of antimicrobial resistance within the jurisdiction of the Department of Health and Human Services. An amendment to the FY2002 Appropriations Act requires that, of the total FDA appropriation, \$5 million be made available for carrying out the plan's antibiotic activities.

LEGISLATION

P.L. 107-9 (S. 700)

Animal Disease Risk Assessment, Prevention, and Control Act of 2001. Directs Secretary of Agriculture to submit a preliminary report to specified congressional committees concerning: interagency measures to assess, prevent, and control the spread of foot and mouth disease and bovine spongiform encephalopathy ("mad cow disease") in the United States; related federal information sources available to public; and the need for additional legislative authority or product bans. Directs Secretary to submit a final report to such committees that discusses such diseases' economic impacts, public and animal health risks, and related legislative authority or product bans. Introduced April 5, 2001; referred to Committee on Agriculture, Nutrition, and Forestry. Passed Senate April 5, 2001; passed House May 9, 2001; signed by President May 24, 2001.

H.R. 115 (Holt)

Food Biotechnology Information Initiative Act. Amends Food, Agriculture, Conservation, and Trade Act of 1990 to provide for a program to educate public regarding use of biotechnology in producing food for human consumption, to support additional scientific research regarding potential economic and environmental risks and benefits of using biotechnology to produce food, and for other purposes. Introduced January 3, 2001; referred to Committees on Agriculture and Energy and Commerce.

H.R. 713 (Tierney)

To require Secretary of Agriculture to complete a report regarding the safety and monitoring of genetically engineered foods, and for other purposes. Introduced February 14, 2001; referred to the House Committee on Agriculture.

H.R. 1605 (Bono)

Produce Consumers' Right-to-Know Act. Amends the Perishable Agricultural Commodities Act, 1930 to require retailers to provide consumers with country of origin labeling of perishable agricultural commodities. Exempts food service establishments from such requirement. Authorizes fines for violations of such provisions. Introduced April 26, 2001; referred to Committee on Agriculture.

H.R. 1671 (DeLauro)

To consolidate in single independent agency in executive branch responsibilities regarding food safety, labeling, and inspection currently divided among several Federal agencies. Introduced May 1, 2001; referred to Committee on Agriculture, Subcommittee on Department Operations, Oversight, Nutrition and Forestry, and Subcommittee on Livestock and Horticulture, May 14, 2001. Referred to Committee Energy and Commerce, May 1, 2001, and referred to Subcommittee on Health, May 15, 2001.

H.R. 1771 (Brown)

Antibiotic Resistance Prevention Act of 2001. To provide for funding for top priority action items in interagency public health action plan that has been developed in response to problem of antimicrobial resistance, to extent the activities involved are within jurisdiction of Department of Health and Human Services. Introduced May 9, 2001; referred to Committee on Energy and Commerce.

H.R. 1817 (Pallone)

A bill to establish comprehensive program to ensure safety of food products intended for human consumption which are regulated by FDA. Introduced May 10, 2000; referred to Committee on Energy and Commerce.

H.R. 2051 (Smith)

Authorizes the National Science Foundation to make grants for the establishment of regional plant genome and gene expression research and development centers. Introduced June 15, 2001; referred to Committee on Science, Subcommittee on Research.

H.R. 2649 (Burr)

National Uniformity for food Act of 2001. Amends the FFDCA to provide for uniform food safety warning notification requirements, and other purposes. Introduced July 26, 2001; referred to Committee on Energy and Commerce.

H.R. 3075 (Dingell)

Imported Food Safety Act of 2001. Amends the FFDCA to improve border inspections, increase the number of inspections and tests of imported food, requires that imported food have country-of-origin labeling, establishes criminal penalties for adulterating imported food, establishes user fees to pay for additional inspections, and provides FDA with new authority and resources to inspect and detain food. Introduced October 10, 2001; referred to Committee on Energy and Commerce.

H.R. 3127 (Udall)

Unsafe Meat and Poultry Recall Act of 2001. Amends the Federal Meat Inspection Act and the Poultry Products Inspection Act to authorize the Secretary of Agriculture to order

the recall of meat and poultry that is adulterated, misbranded, or otherwise unsafe. Introduced October 12, 2001; referred to Committee on Agriculture.

H.R. 3174 (Pomeroy)

Food Supply Protection Act. Authorizes additional appropriations to combat bioterrorism. Introduced October 25, 2001; referred to Committee on Agriculture.

H.R. 3184 (DeLauro)

Protecting the Food Supply from Bioterrorism Act. (Identical to S. 1551) Amends the FFDCFA to add provisions regarding protecting the United States food supply. Introduced October 30, 2001; referred to House Energy and Commerce Committee.

S. 1494 (Lincoln)

Amendment to the FFDCFA to limit the use of the name “catfish” in marketing of only fish from the family Ictalariidae. Introduced October 3, 2001; referred to Committee on Health, Education, Labor, and Pensions.

S. 1501 (Durbin)

Safe Food Act of 2001. To consolidate in a single independent Executive Branch agency the responsibilities regarding food safety, labeling, and inspection currently divided among several Federal agencies. Introduced October 4, 2001; referred to Committee on Governmental Affairs. Hearing held October 10, 2001 before Subcommittee on Oversight of Government Management, Restructuring and the District of Columbia.

S. 1546 (Roberts)

Biological Chemical Attack bill. Directs the Secretary of the Treasury to provide funding to the Secretary of Agriculture: (1) in FY2002 for specified bio-security initiatives, bio-safety animal research facilities, Agricultural Research Service/Animal and Plant Health Inspection Service facilities, an animal disease laboratory, and agroterrorism rapid detection field test kits and training; and (2) in each of FY2002 through FY2011 for specified counter-bioterrorism research initiatives. Introduced October 15, 2001; referred to Committee on Agriculture, Nutrition, and Forestry.

S. 1551 (Clinton)

Protecting the Food Supply from Bioterrorism Act. (Identical to H.R. 3184) Amends the FFDCFA to add provisions to register food facilities with FDA, authorize detention and record keeping, to recall unsafe food, to strengthen import inspections through standards and notices of import, expand food security research and surveillance, and establish education and information systems on foodborne bioterrorism, among other things. Introduced October 15, 2001; referred to Committee on Health, Education, Labor, and Pensions.

S. 1563 (Hutchison)

Agricultural Bioterrorism Countermeasures Act of 2001. The Act would expand research on threats of agricultural bioterrorism, promote interagency and academic collaboration and strengthen Federal regulatory capacities to respond to a bioterrorist attack. Introduced October 17, 2001; referred to Committee on Agriculture, Nutrition, and Forestry.