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Food Safety Issues in the 109th Congress

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Summary

Foodborne illness is a serious public health problem. 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. There are many who maintain that these estimates understate the problem because many people do not seek medical help for foodborne illness and so those episodes of illness are not included in official counts. Most consumers look to the government to regulate and protect the food supply, and industry is interested in producing foods that are safe at a reasonable price. Consequently, Congress has an 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. The responsibilities under the current federal system are divided among two departments and one independent agency. The U.S. Department of Agriculture (USDA) regulates meat, poultry, and certain egg products while the Food and Drug Administration (FDA), in the Department of Health and Human Services (DHHS), sets and enforces standards for safety of all other domestic and imported foods. The FDA is also responsible for ensuring that all animal drugs and feeds are safe, labeled properly, and produce no human health hazard when used in food-producing animals. The CDC, also part of DHHS, tracks foodborne illness outbreaks. The Environmental Protection Agency (EPA) sets legal limits (tolerances) on the amounts of pesticide residues allowed in or on food.

Production of food is often a multistage process involving many different vendors and producers. Congress maintains close oversight over federal food safety activities, which consist of inspecting, testing, research, and monitoring the food supply. In response to limited federal funding, FDA and USDA adopted an approach to food safety known as the Hazard Analysis and Critical Control Point (HACCP) system. It requires food companies to identify where hazards could enter food during its preparation for market and to take steps to lower the risk of contamination.

Fears of terrorist attacks spawned legislation that has been assisting the federal government in protecting the food supply. The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (P.L. 107-188) requires FDA to register food processors, inspect their records, and detain adulterated food. It also requires that FDA issue regulations to ensure the safety of imported foods. In addition, the Act authorizes appropriations for USDA, to be used for enhanced border inspection of food imports of plant and animal origin, lab biosecurity upgrades, and increased research.

Food safety issues implicate food security, “mad cow” threats to the food supply, new enforcement authorities for FDA and USDA, and methylmercury in fish. Some Members of Congress continue to be interested in the regulation of bioengineered foods, the growing public health problem of antimicrobial resistance, the safety of fresh produce, egg safety, and reorganizing the federal food safety structure. This report will be updated regularly.

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Introduction

While most experts agree that the U.S. food supply is among the safest in the world, every year foodborne pathogens in the food supply make many people ill, which causes some consumers to lose confidence in its safety. Concerns have been raised about whether the federal regulatory system, as currently structured, adequately deals with problems in the food supply. U.S. consumers worry that current safety efforts may not be enough to provide the level of safety in the food supply that they demand.

The nation's food safety system consists of activities carried out by many different federal, state, and local government agencies. Together they inspect, test, research, and monitor the food supply. The type and amount of oversight depend on the food product. For the most part, these agencies monitor whether the food industry are adhering to their legal responsibility of ensuring the production of safe food.

This report provides an overview of federal food safety activities and issues of concern to Congress. The major areas of concern include illnesses caused by foodborne pathogens, the cost of these illnesses, and the vulnerability of the food supply to terrorist acts. It also describes activities of federal agencies charged with ensuring that consumers can purchase "safe" food from appropriately regulated food companies, and gives past and proposed appropriations for food safety. It describes the new bioterrorism law which gives the Food and Drug Administration (FDA) more direct authority over the food supply, particularly imports. Additionally, it discusses a number of other issues including the debate in Congress over food security issues, enforcement powers such as recalls, proposals to reorganize the food safety regulatory structure, questions about regulating bioengineered food, the growing problem of antibiotic resistance, and the safety of fresh produce.

Problems in the Food Supply

The U.S. diet is composed of food produced all over the United States and the world. For example, many U.S. consumers have become more weight conscious, and are eating more lettuce as a lower calorie-alternative food. Lettuce consumed domestically may be grown domestically, or imported. Once lettuce is harvested, it usually goes to a packing house where it is washed multiple times and packaged. Increasingly, lettuce products are produced that contain pre-cut or mixed greens. Then the product is transported throughout the country to food distribution warehouses or facilities. At each stage in its journey, ownership of the lettuce may change, and it may be handled by different people or machinery. Contamination or adulteration, either intentional or inadvertent, can creep in at any point in this

process. Accountability for food safety is often difficult because information about product handling, processing and shipping may be limited and/or incomplete.

Public Health Problems. The Centers for Disease Control and Prevention (CDC) estimate that foodborne diseases cause approximately 76 million illnesses, 325,000 hospitalizations, and 5,000 deaths each year in the United States.[1] These estimates are based on data from a variety of sources including surveillance systems, death certificates, and academic studies. Often, victims of food poisoning do not report their illness to a doctor or they mistake food poisoning for some other illness such as influenza. CDC's current estimates are higher than prior estimates due, in part, to better surveillance data rather than changes in disease prevalence. Even so, the most recent CDC preliminary surveillance data for 2004 indicate substantial declines in the incidence of infections caused by *Campylobacter*, *Cryptosporidium parvum*, *Escherichia coli* O157, *Listeria*, *Salmonella*, and *Yersinia enterocolitica* when compared with 1996-1998 data.[2]

While bacterial-based food illness shows a decline, bacteria can mutate. For example, one strain of *Escherichia coli (E. coli)*, a common bacteria found in intestines of all birds and mammals, has mutated into a deadly form known as *E. coli* O157:H7. It has been found in hamburger, and also in unpasteurized apple juice, alfalfa sprouts, and packaged lettuce. A common but unusually virulent type of *Salmonella*, called phage type 4, has been found in chickens and dairy cows. Both pathogens have contributed to a number of foodborne illness outbreaks.[3]

In addition to bacteria, foodborne diseases and illnesses can be caused by viruses, parasites, and fungi, directly, or by toxins produced by the pathogens. Chemical or drug residues found in food can also have health effects.

Most cases of foodborne illnesses are classified as "acute." These are usually self-limiting and of short duration, although they can range from mild to severe. Gastrointestinal problems and vomiting are common acute symptoms of many foodborne illnesses. Deaths from acute foodborne illnesses are rare. However, FDA estimates that 2 to 3% of all acute cases develop secondary long-term illnesses, called "chronic sequellae." Chronic sequellae of foodborne illness can occur in any part of the body and subsequently can affect the joints, nervous system, kidneys, or heart. These chronic illnesses may afflict the patients for the remainder of their lives or

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[1] U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, "Food-Related Illness and Death in the United States," *Emerging Infectious Diseases*, vol. 5, no. 5 (Sept.-Oct. 1999), available at [http://www.cdc.gov/ncidod/eid/vol5no5/mead.htm].

[2] U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, "Preliminary FoodNet Data on the Incidence of Infection with Pathogens Transmitted Commonly Through Food — 10 Sites, United States, 2003," *Morbidity and Mortality Weekly Report*, vol. 54, no. 14 (Apr. 15, 2005), pp. 352-356, available at [http://www.cdc.gov/mmwr/].

[3] U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, "Surveillance for Foodborne-Disease Outbreaks — United States, 1993-1997," *Morbidity and Mortality Weekly Report*, vol. 49, no. SS-1 (Mar. 17, 2000), available at [http://www.cdc.gov/mmwr/].

result in premature death. For example, *Campylobacter* infections are estimated to be responsible for 20 to 40% of Guillain-Barre syndrome cases (a major cause of paralysis unrelated to trauma) in the United States.[4] About 15% of *E. coli* O157:H7 disease patients develop hemolytic uremic syndrome (also known as HUS), which involves red blood cell destruction, kidney failure, and neurological complications such as seizures and strokes.[5]

Several factors contribute to public health officials' increasing concern about the risk of getting ill from food: (1) some sensitive 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 foodborne pathogens; (2) as people eat out more frequently, and retail establishments process foods on-site, there is increased opportunity for contaminated food to cause illness; (3) more cases of illness from pathogenic organisms on fresh fruits and vegetables have been reported and consumers are eating more produce for its nutritional benefits; and (4) the highly mechanized, efficient production and long-distance distribution practices of the food industry make it possible for a contaminated product to be quickly distributed nationally or even internationally and give more opportunity for time and temperature abuse, which can promote the growth of harmful organisms.

Costs of Illness. Foodborne illness imposes costs on the U.S. economy. According to the U.S. Department of Agriculture (USDA), foodborne illness costs are borne by the food industry, households whose members become ill, employers and the public and private health sectors. USDA estimates costs associated with medical expenses and losses in productivity from five major types of foodborne illnesses at $6.9 billion annually (in August 2000 dollars).[6] These costs include medical costs, productivity losses from missed work, and an estimate of the value of premature deaths, but exclude travel costs in obtaining medical care, and time lost from work in caring for sick children. This methodology produces estimates that vary based on the expected age distribution of those who become ill. For example, the annual cost of foodborne illnesses caused by *Salmonella* decreases from $3.7 billion to $2.4 billion when adjusted for age of death because over two-thirds of the deaths from salmonellosis occur in people over 65. Adjusting foodborne illness costs by age of death raises cost estimates for *E. coli* O157:H7 because most deaths occur in children under five. That estimate is $659.1 million. Estimates of *E. coli* and

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[4] Jeremy H. Rees, Sara E. Soudain, Norman A. Gregson, and Richard A.S. Hughes, "*Campylobacter jejuni* Infection and Guillain-Barre Syndrome," *New England Journal of Medicine*, vol. 333, no. 21 (Nov. 23, 1995), pp. 1374-1379.

[5] Craig S. Wong, Srdjan Jelacic, Rebecca L. Habeeb, Sandra L. Watkins, and Phillip I. Tarr, "The Risk of the Hemolytic-Uremic Syndrome After Antibiotic Treatment of *Escherichia coli* O157:H7 Infections," *New England Journal of Medicine*, vol. 342, no. 26 (June 29, 2000), pp. 1930-1936.

[6] *Campylobacter, E. coli* O157:H7, *Shiga* toxin-producing strains of *E. coli, Listeria monocytogenes,* and *Salmonella.* See [http://www.ers.usda.gov/Emphases/SafeFood/].Also see [http://www.ers.usda.gov/Topics/View.asp?T=102802].

related pathogens costs are $329.7 million for a combined total of $988.8 million for all *E.coli*-related illnesses and deaths in 2000.[7]

Aftermath of the Terrorist Attacks. The fall 2001 terrorist and anthrax attacks have forced Congress, federal food safety policymakers, and food industry officials to consider the nation's readiness to protect against and respond to intentional acts of food adulteration or the targeting of food production. There is widespread concern that naturally occurring pathogens such as *E. coli* O157:H7, *Salmonella*, *Listeria*, and botulinum toxin could be used as bioterrorist weapons and could be spread through the multi-link food distribution chain. In addition, there are chemicals (dioxin) and heavy metals (lead or mercury) that could be introduced intentionally along the stages of the food chain. Such an attack would be particularly lethal to children, the elderly, and the immune-compromised.

One likely goal of a terrorist action would be to cripple some part of the farm to table continuum. Any link in the food production chain is potentially susceptible to an attack. Such an attack could cause an erosion of public confidence in the food supply and economic ruin for certain food producers.

Experts recognize weaknesses in the ability of most nations to prevent and contain a biological attack on their food supply. Limited inspection capabilities, lack of rapid diagnostic tools, inadequate coordination among inspection agencies, and little biosafety training of the industry workforce are among the cited weaknesses. Even tracing contaminated food back to its point of origin is problematic. Most nations have responded by instituting a variety of policies that help to prevent or, if necessary, respond to an attack. U.S. activities are discussed below.

Statutory Authority

The federal government attempts to ensure that the food supply is safe from the farm or port to the consumer's table through statutory mandates and science-based regulatory policies. Federal laws mandate how each federal agency approaches its role in food safety, and these laws dictate very different approaches.

FDA. The Federal Food, Drug, and Cosmetic Act (FFDCA), which prohibits the entry into interstate commerce of adulterated or misbranded foods, is implemented by FDA. 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 has interpreted this authority broadly to include food that is defective, contaminated, unsafe, etc. Under this authority, the agency has established guidance and regulatory requirements for manufacturers to assure that food is safe and not adulterated. To enforce the requirements, FDA monitors food manufacturers through periodic inspections to judge whether they are producing foods appropriately. For FY2004, FDA plans to use approximately 476 full-time equivalent (FTE) positions in the inspection of domestic food manufacturers. This translates into about one

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[7] "Economics of Foodborne Disease: Feature," available at [http://www.ers.usda.gov/briefing/FoodborneDisease/features.htm].

inspection every five years for most domestic food producing facilities.[8] FDA also monitors more than 11 million imported food entries annually at 300 ports of entry and has increased its import examinations from 104,000 in FY2003 to a target of 129,000 in FY2005.[9]

As part of its responsibility to prevent adulterated food from reaching consumers, FDA has direct authority (Section 409 of the FFDCA) to approve of food and color additives. The law defines a food additive to be any substance added directly or indirectly to a food, including any substance used in "producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food, and including any source of radiation intended for any such use."[10] 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 FFDCA 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."

USDA. Meat and poultry inspection requirements contrast sharply with FDA's mandate. 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 for at least part of every shift while a firm is processing meat products for human consumption. Congress instituted requirements for poultry in the 1957 Poultry Products Inspection Act, amended by the 1968 Wholesome Poultry Products Act. Under the meat and poultry acts, 7,680 Food Safety and Inspection Service (FSIS) inspectors are responsible for inspecting meat, poultry, and processed egg products for safety, wholesomeness, and proper labeling at 6,200 plants and import facilities. Such standards are similar to FDA's mandate from the FFDCA that calls for a prohibition of adulterated and misbranded food. USDA also has established a mandatory program called Hazard Analysis and Critical Control Point (HACCP) for meat and poultry plants. (See below.)

EPA. Under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), the Environmental Protection Agency (EPA) regulates the sale and use of pesticide products. Under the authority of the "safety-only" clause, Section 408 of the FFDCA, EPA sets limits (called tolerances) for pesticide residues in or on foods and animal feed. Certain foods containing residues of pesticides are declared "unsafe" if there is no tolerance established for the particular food/residue combination, or if the residue level exceeds an established tolerance limit. Should this happen, the food is considered "unsafe" or "adulterated" and cannot be sold in interstate commerce in the United States. EPA has set over 9,000 pesticide residue tolerances. FDA and USDA test and enforce those tolerances. The Food Quality Protection Act of 1996 changed the so-called "zero-risk" standard of Section 409 of the FFDCA (the

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[8] U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration, Statement of Lester M. Crawford, Deputy Commissioner, Food and Drug Administration, before the Senate Committee on Governmental Affairs, Nov. 19, 2003.

[9] U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration, Justification of Estimates for Appropriations Committees, Fiscal Year 2005.

[10] 21 U.S.C. § 321(s).

Delaney Clause) so that all food, both raw and processed, has tolerances set under a standard that requires all residues to be "safe," and ensures that there is a "reasonable certainty of no harm" from the pesticide residues.[11]

Agency Framework for Food Safety

The statutory structure governing food safety yields a regulatory system that makes jurisdiction over food dependent 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 overlapping jurisdictions and duplication of effort waste taxpayers' money and result in a fragmented system that prevents an effective focus of resources on areas where the risks of adulteration and contamination are greatest. Federal officials argue that, by working cooperatively and through formal understandings among the agencies, federal agencies now, for the most part, avoid duplicating efforts.

Federal Agencies' Responsibilities

The diversity of federal agencies and departments with responsibilities for food safety can be confusing. Specifically, within **USDA**, the Food Safety and Inspection Service (FSIS) regulates meat, poultry, and processed egg products. Additional agencies in USDA, the Cooperative State Research, Education and Extension Service (CSREES), the Agricultural Research Service (ARS), and the Economic Research Service (ERS), support intramural or extramural research on food safety and the economics of foodborne illness. Other USDA agencies, the Food and Nutrition Service (FNS) and the Agricultural Marketing Service (AMS), ensure the safety of foods distributed through school nutrition programs. The FDA, CDC and NIH, all housed within **DHHS**, play roles in food safety. Two centers in FDA — the Center for Food Safety and Applied Nutrition (CFSAN) and the Center for Veterinary Medicine (CVM) — ensure that all food produced domestically or imported (other than meat, poultry, and processed eggs) is safe and that drugs given to animals raised to be used for human food do not cause health problems for humans. The CDC tracks foodborne illness incidents and outbreaks, and provides data and information to the other food safety agencies. The NIH is responsible for research on the health effects of foodborne illness and the effectiveness of possible treatments. The Office of Pesticide Programs (OPP) of the **EPA** is responsible for setting tolerances: the limit of the amount of residues from chemicals that can be found in or on food and for promoting safer means of pest management. The National Marine Fisheries Service (NMFS), in the Department of Commerce (**DOC**), provides fisheries inspection services to assure the safety of commercial fisheries products.

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[11] 21 U.S.C. § 348(c)(3)(A), the Delaney Clause, states "that no additive shall be deemed to be safe if it is found to induce cancer when ingested by man or animal or if it is found, after tests which are appropriate for the evaluation of the safety of food additives, to induce cancer in man or animal. ..." It means that no substance that induces cancer should be added to the food supply, and implies that no substance that might cause cancer should even be in the food supply whatever its source.

In essence, the different agencies' food safety responsibilities encompass four basic functions that, when combined, have created a system that tries to assure the safety of the food supply: (1) providing guidance to industry about what is expected, and developing policies and regulations; (2) enforcing compliance by inspections and programs; (3) giving pre-market approval to additives that will be added to food and listed in the labeling; and (4) tracking and responding to foodborne illnesses in the United States and overseas. Each federal entity may take a different approach when implementing these functions.

Establishing Guidance and Regulatory Requirements. Federal agencies develop regulations to minimize food hazards and guide the production of safe food. These regulations, collectively called "good manufacturing practices (GMPs)," are proposed after consultations with the industry, experts, the public, and other interested parties and go through rigorous notice and comment periods. As required by law, both FDA and USDA publish the GMP regulatory requirements in the *Federal Register*. They then enforce these standards through inspections and verification of documents. 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 also address layout and maintenance of facilities, personnel qualifications, the cleaning of equipment and utensils, and the processes and controls required to assure basic sanitation and cleanliness. The major parties responsible for complying with the GMPs, the manufacturers, producers, and distributors of food, must ensure that food, when marketed in interstate commerce, is not adulterated and does not contain unacceptable chemical residues.

In addition to publishing GMPs, FDA and USDA have adopted in the 1990s a preventive approach to ensure safety of food. Called the "Hazard Analysis and Critical Control Point" (HACCP) approach or system, it is a uniform science-based approach to food safety. An HACCP program typically applies seven principles, based on a technical analysis of the food production process, that is carried out by the food plant itself. The seven principles are (1) analyze hazards; (2) identify critical control points to control identified hazards;[12] (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. The key to HACCP is the use of a microbiological approach to pathogen and contamination control to prevent the contamination of food.

The HACCP approach has been used by FDA in its low-acid canned foods regulations for more than 30 years. The HACCP approach also gained industry

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[12] The most important and controversial step in HACCP is the choice of the critical control points, or CCPs. CCPs are points where control *must* be exercised because loss of control of a CCP is likely to result in contamination of a food. An example of a CCP would be a heat-treatment step (cooking) 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.

support when it called for giving more responsibility for assuring the safety of the food supply to the food industry. Once the system is in place, FDA and FSIS review industry records of monitoring at the critical control points to assure compliance and evaluate the food products and facilities. In the mid- to late 1990s, both agencies mandated that certain food products (including seafood, fruit and vegetable juices, and meat and poultry) have plans in place for a HACCP approach.

The federal government role is different under HACCP from its enforcement role for GMPs because GMPs are very specific requirements that are published in the *Code of Federal Regulations* and have statutory authority behind them. HACCP plans, in contrast, are developed by the industry, and are tailored to the individual facility or manufacturing line. When GMPs are not followed, official government inspectors have the authority to determine that a food is adulterated and have the food seized. Under HACCP the government role is to give guidance, oversee safety programs, monitor records of the critical control points kept by the company, and determine whether the company has corrected any problems that are discovered. Some in industry argue that the HACCP rules are cumbersome, layered on top of existing regulations, and are expensive to implement. Consumer groups argue that HACCP plans need to be combined with GMP rules for HACCP plans alone may not provide adequate regulatory oversight to assure food safety.

Enforcing Compliance with Inspections and Legal Requirements. FDA has certain enforcement tools which it uses to assure that food is safe. Enforcement generally begins with inspection. FDA officials, and some state officials under contract with FDA, are authorized to enter and inspect, at reasonable times, any factory, warehouse, establishment in which foods are manufactured, processed, packed, or held prior to introduction into interstate commerce or in a vehicle transporting food. Inspections of the 57,000 food establishments under FDA's jurisdiction occur on average once every five years. If violations are found, FDA has had the authority since June 2002 to order the detention of a food during an inspection. The detention is possible only if an FDA district director finds credible evidence showing the food presents "a threat of serious adverse health consequences or death to humans or animals." In addition, FDA can request that the Justice Department initiate an injunction, seizure, or prosecution. However, to bring the case to the Justice Department, FDA officials must have substantial evidence that the food is adulterated. Some critics of the current policy suggest that FDA needs further enforcement powers such as mandatory recall authority to prevent contamination in the food supply.

FDA uses a number of other administrative tools to enforce its safety requirements. It sends warning letters and other regulatory correspondence, if evidence has turned up from its inspections. The agency also creates import alert lists which name importers who have previously tried to import a contaminated food. It requests voluntary recalls, if a food has been tested and determined not to meet the criteria under the law. However, it has no power to mandate recalls, nor can FDA inspectors look at records kept by the plant to meet a state's record-keeping requirements unless the facility permits it.

In contrast, USDA has more day-to-day involvement with the foods for which it is responsible. Under the authority of the Federal Meat Inspection Act and the

Poultry Products Inspection Act (as mentioned above), FSIS inspectors (more than 7,680) must be continuously present at all the meat and poultry slaughter plants. For other processing plants, inspectors make daily visits. This latter group has summary powers to withdraw inspection services (which stops processing operations), condemn foods, and obtain plant records.[13] 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. Similar to FDA, FSIS does not have mandatory recall authority.[14]

Approving Food Additives and Labeling. As mentioned above, FDA has statutory authority to review food additive petitions. In its petition review process, FDA determines within 90 days of submission (with a possible 90-day extension) 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 risk associated with an additive. 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) such as salt, pepper, vinegar, and baking powder — substances found on a list maintained by FDA.

When FDA concludes that a non-food substance used in the manufacturing, packing, packaging, transporting, or holding of food might reasonably be expected to migrate into the food even though its risk to human health is extremely small, the agency regulates the substance as a "food contact substance." At one time, these substances were regulated as food additives, but, since 1997, the sponsor or manufacturer only has to notify the agency of the substance's identity, and its intended use, and submit all necessary information to show that the substance is safe. Unless FDA specifically objects, the manufacturer can begin using the food contact substance immediately.

Genetically engineered (GE) food (foods made from seeds altered by biotechnology or foods developed by other processes) may be reviewed by FDA for safety. There is no mandatory review because the agency has ruled these foods as equivalent to conventional foods. The agency concluded that GE food should be treated similarly to "food contact substances." In January 2001, FDA proposed a rule that would require a food company to notify the agency 120 days prior to marketing

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[13] In December 2001, the U.S. Court of Appeals for the Fifth Circuit handed down a decision prohibiting USDA from suspending inspections services based solely upon failure of the salmonella performance standard. *Supreme Beef Processors, Inc. v. USDA*, 275 F.3d 432 (5th Cir., 2001). Despite the ruling, USDA has maintained the ability to initiate a withholding, suspensions, or withdrawal action based on sanitation or hazard analysis and critical control points (HACCP) violations. Sarah Muirhead, "USDA Sets New Procedures for Salmonella Testing," *Feedstuffs*, vol. 74, no. 34 (Aug. 19, 2002), p. 3.

[14] For further information, see CRS Issue Brief IB10082, *Meat and Poultry Inspection Issues*, by Jean M. Rawson.

this food and, at the same time, supply the agency with test data showing its safety.[15] The rule has not been finalized and several consumer groups, worried about safety, have been urging Congress to require FDA to create a more formal safety system for GE foods. One bill has been introduced into the 109th Congress which would require FDA to set up a system requiring approval prior to the release of a GE food onto the market. (See below for a further discussion.)

Tracking Foodborne Illnesses. As mentioned above, CDC has estimated that each year large numbers of people get sick as a result of foodborne illnesses. Such estimates spurred the Department of Health and Human Services (DHHS) to enhance its tracking systems of these illnesses in order to recognize outbreaks more quickly and begin steps to prevent their spread. In 1996, the FoodNet surveillance system began collecting information about laboratory-diagnosed cases of foodborne illnesses caused by nine pathogens, the major microbial pathogens found in the U.S. food supply.[16] FoodNet was created by CDC, FDA, and USDA because public health officials, who rely on epidemiology to identify and track the source of outbreaks of foodborne illness, did not have an accurate accounting of foodborne illnesses. Under this system, doctors and laboratories report to local health departments when certain pathogenic organisms are found in samples from ill patients. States then collect these data and send reports to CDC where officials can then update the national surveillance database and track foodborne illnesses. The most recent findings of the FoodNet program, preliminary data from 2004, suggest an encouraging track record in preventing foodborne illness compared to 1996 when tracking began, with incidence of illness from some major pathogens having decreased, while the incidence from others, relatively minor pathogens, remaining unchanged.[17]

If an outbreak is identified by CDC's FoodNet's active surveillance system, strains of foodborne pathogens can be analyzed by CDC's PulseNet, a networked computer system linking public health laboratories in 50 states, as well as seven FDA laboratories, and eight Canadian laboratories.[18] This shared network system is used by laboratories to rapidly identify strains by matching DNA "fingerprints" of pathogens found both in food and in people stricken with foodborne illness, allowing officials to detect outbreaks that cross state lines and to identify and remove contaminated foods from commerce. With the help of this network, on June 2, 2005, the Florida State officials asked FDA to begin to traceback fresh basil that had caused

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[15] 66 *Federal Register* 4706-4738 (Jan. 18, 2001).

[16] *Campylobacter, Cryptosporidium, Cyclospora, E. coli* O157:H7*, Listeria, Salmonella, Shigella, Yersinia,* and *Vibrio*.

[17] U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, "Preliminary FoodNet Data on the Incidence of Infection with Pathogens Transmitted Commonly Through Food — 10 Sites, United States, 2004" *Morbidity and Mortality Weekly Report*, vol. 54 no. 14 (Apr. 15, 2005), pp. 338-343, available at [http://www.cdc.gov/mmwr/].

[18] See [http://www.cdc.gov/ncidod/eid/vol7no3/swaminathanG4.htm].

clusters of gastrointestinal illnesses caused by a parasite *Cyclospora*. So far there were 293 laboratory-confirmed cases in 32 Florida countries.[19]

Role of State and Local Agencies in Food Safety

More than 85 state and 3,000 local regulatory agencies, including public health and agriculture departments, license and inspect more than 1 million retail food establishments (grocery stores, restaurants, nursing homes, etc.) under state laws and regulations to ensure that consumers are protected from unsafe food. Often these government officials use an FDA guidance manual called the *Food Code*, a hands-on model of standards for state and local agency officials to follow when they carry out inspections to prevent foodborne illnesses and to ensure that the food is not a vehicle for communicable disease.[20] The Food Code does not have the status of a regulation for it has never been put through a notice-and-comment period for regulations. It is, however, filled with advice and guidance based on the latest science and is updated every two years. It contains, for example, suggested time and temperature controls for cooking hamburgers, pork, and poultry and safe practices for handling food to prevent cross-contamination. Of the 56 states and territories, 48 (86%) have adopted state food safety codes patterned after some version of the FDA Food Code. Many other states are conducting the rule-making process to adopt a more recent version of the Food Code.

Congressional Oversight Structure for Food Safety

Several committees share congressional oversight for food safety. In the Senate, food safety issues are considered by the Committees on Agriculture, Nutrition, and Forestry; 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 Science. The Appropriations Subcommittees on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies also serve an oversight role in how the major agencies carry out policies affecting food safety.

Funding

Table 1 provides the total appropriations for food safety activities of both FDA and FSIS/USDA for FY2002 through FY2006. Total funding for all federal food safety activities increased 2.7% between FY2002 and FY2003, 2% from FY2003 to FY2004, and 5.6% from FY2004 to FY2005. For FY2006, the President requested an increase of $60.5 million (+4.4%) for food safety and defense; the House passed an increase of half that amount or a $30.2 million (+2.2%) increase. The Senate has not yet acted on its bill. The funding for FSIS includes all its inspection activity costs

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[19] Food and Drug Administration, *FDA Works to Trace Source of Foodborne Illness in Florida*, Press Release, June 3, 2005.

[20] For further information, see [http://www.cfsan.fda.gov/~ear/fcadopt.html].

in its food safety appropriation, while only parts of FDA's total inspections are budgeted for food safety because FDA inspectors also check on the production and marketing of drugs, biologics, etc.

According to the Administration, the FDA appropriation for FY2006 for food safety and defense is intended to be used to increase funding for food defense activities, including increasing testing capacity for the Food Emergency Response Network (FERN, see below), research, domestic and import food-related inspections, Emergency Response and Operations Network development, and coordination of food surveillance activities within the bio-surveillance initiative, a proposed surveillance program for early detection of bioterrorism, which would include data on food testing.

The FSIS appropriation for FY2006 for food safety is intended to support USDA's Office of Food Security and Emergency Preparedness activities to coordinate the development of infrastructure to prevent, prepare for, and respond to an intentional attack on the U.S. food supply.[21]

Table 1. Food Safety, Security, and Defense Appropriations FY2002 - FY2006

(in millions)

Agency	FY2002	FY2003	FY2004	FY2005[a]	FY2006 Requested	FY2006 House Passed
Food and Drug Administration	$499.0	$507.6	$508.1	$543.3	$571.3	$553.4
Food Safety and Inspection Service	$730.1	$754.8	$779.9	$817.2	$849.7	$837.3
Total	$1,229.1	$1,262.4	$1,288.0	$1,360.5	$1,421.0	$1,390.7

a. With the 0.8% rescission.

Sources: Food and Drug Administration, Office of Budget and Program Analysis, Budget Formulation and Presentation Division. U.S. Department of Agriculture, Office of Budget and Program Analysis, Budget Control and Analysis Division.

Recent Initiatives to Improve Food Safety and Security

Food security is defined broadly as protecting the food supply from deliberate contamination and is therefore a subset of food safety with which it shares many

[21] U.S. Department of Homeland Security, "Fact Sheet: Strengthening the Security of Our Nation's Food Supply," July 6, 2004, [http://www.dhs.gov/dhspublic]

common activities. Since the terror attacks of 2001, a greater awareness of the possibility of intentional tampering at any point in the food production, processing and distribution chain has led to increased efforts to define and implement specific preventive measures. In fact, Tommy Thompson, the Secretary of Health and Human Services, as he announced his resignation, expressed concern about the possibility of a terrorist attack on the nation's food supply by saying "For the life of me, I cannot understand why terrorists have not attacked our food supply because it is so easy to do!" and pointed to vulnerabilities that infected food could be imported from the Middle East.[22] Others said that the threat is equally serious for domestically produced food and that U.S. citizens could be poisoned and not know it was intentional.[23]

When Congress passed the Public Health Security and Bioterrorism Preparedness and Response Act (P.L. 107-188) on June 12, 2002, it gave FDA further authority over food, particularly imports, to better ensure the prevention and tracking of potential food adulteration, and to give the agency more information about the food supply.[24] Among other provisions, the Act required that FDA promulgate regulations for the registration of food processors; prior notification of proposed food imports; and the establishment and maintenance of records. FDA has published interim final rules but has not finalized these rules. It also allowed its inspectors to flexibly enforce the rules (FDA calls this their "transitional compliance policy") while establishments and traders become accustomed to the new rules.[25] In addition, the agency has launched an extended education program here and abroad to inform participants along the farm to table continuum about the new requirements.

Registration of Food Processors. The Bioterrorism Act requires all domestic and foreign facilities that manufacture, process, pack, or hold food for human or animal consumption in the United States to register one-time with the FDA by December 12, 2003. FDA published an interim final rule on October 10, 2003. The exact date for final enforcement of this requirement has been not been set. The registering food facility gives the agency information about the identities (brand names) and the general food categories under which business is conducted, and the addresses of all the companies' facilities.[26] The agency is encouraging the information be submitted electronically rather than by mail, although mail-in

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[22] Robert Pear, "U.S. Health Chief, Stepping Down, Issues Warning," *New York Times*, Dec. 4, 2004.

[23] Elizabeth Becker, "Shared Nightmare over the Food Supply," *New York Times*, Dec. 11, 2004.

[24] All four proposed rules exempt firms and products regulated exclusively by USDA.

[25] U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration, "FDA and CBP Announce their Transitional Compliance Policy on Food Imports Under the Bioterrorism Act," *FDA News*, Dec. 11, 2003, p. 103, at [http://www.fda.gov/bbs/topics/NEWS/2003/NEW00995.html].

[26] U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration, "Notice: Compliance Policy Guide Sec. 110.300 — 'Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002,' Availability," 68 *Federal Register* 58894-58973 (Oct. 10, 2003).

registrations will be accepted. Restaurants, certain retail stores, non-profit feeding establishments, fishing vessels, trucks and other motor carriers, and farms are exempt from these registration requirements. The Act protects registry data and any registration documents from public disclosure under Section 552 of Title V, U.S. Code (the Freedom of Information Act). As of June 8, 2005, 256,576 facilities (113,185 domestic and 143,391 foreign) have registered. On November 8, 2004, FDA published a revised compliance policy guide for its inspectors which also announced the full implementation of the agency's registration policy for domestic food facilities. For foreign facilities, the registration requirement will be enforced through the prior notice of imported food rule.[27]

Supporters believe the registration system permits FDA to obtain an accurate inventory of its regulatory purview and enhances the agency's capability to trace intentionally and unintentionally contaminated food. Critics argue, however, that this method of registration creates an enormous record keeping burden for FDA and the industry without evidence that it would help facilities respond in an emergency.

Prior Notice of Imported Food Shipments. The Bioterrorism Act also required food importers give advance electronic notification prior to importation of food.[28] FDA is to be notified within no fewer than two hours of arrival of shipments by road, four hours by air or rail, and eight hours by water of a food shipment. The shipment must have a U.S.-located agent accompany it. If the agent accompanies the food into the country, the notification period will depend on his/her mode of transportation. Such time frames appear to provide FDA with sufficient time to review, evaluate and assess the information and determine whether to inspect the imported food shipment. If notice is not given, the food will be refused entry and be held at the port or in secure storage. The intent is that the notification will protect U.S. consumers from unscrupulous importers and will help FDA ensure that imports comply with U.S. regulations. As part of the interim final rule, FDA and the Bureau of Customs and Border Protection (CBP, part of the Department of Homeland Security) announced that they have integrated their information systems so food importers, when filing prior notice of imports, will be able to provide the required information using the CBP's existing Automated Commercial System. The prior notice for importers allows FDA and CBP to target import inspections more effectively, according to FDA. Critics claim that the CBP system will be overloaded with the amount of information that will be required.

On November 8, 2004, FDA published a revised compliance policy guide on prior notice requirements for its inspectors. It will allow inspectors temporary discretion (until the final rule takes effect) to make enforcement adjustments when

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[27] U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration, "Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002," Guidance for FDA Staff, *Compliance Policy Guide*, Nov. 2004.

[28] U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration, "Prior Notice of Imported Foods Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002," 68 *Federal Register* 58974-59073, (Oct. 10, 2003); *Compliance Policy Guide* § 110.310, revised March 2005.

prior notices do not contain all the required information. This enforcement flexibility will allow for the food industry to adjust to the requirements before the final prior notice rule is published. For those shipments allowed entry thereafter, the agency will apply risk assessment findings to target its inspections to those shipments deemed highest risk. FDA is expected to be able to inspect 2% of all shipments in this way.

A few critics are concerned that the administrative cost of staff hours for complying with these new rules may raise the price of food. However, with the phased-in enforcement process, supporters argue that the earlier anxiety has diminished as shipments have not been held up as anticipated.

Establishment and Maintenance of Records. The Act also requires the FDA to promulgate rules requiring food manufacturing establishments (which must register) to keep production and distribution records. On December 6, 2004, FDA published final regulations and issued draft guidance to FDA inspectors and the food industry detailing how the agency will request the records.[29] Companies will be required to make the records available within 24 hours if the FDA has a reasonable belief that an article of food presents a serious threat. Under this final rule, FDA inspectors would have access to all processing, packing, transporting, receiving, holding, importing, and distribution records (including lot, code number, or other identifier if the information exists) in the event of a suspected food safety problem (including terrorism-related contamination). The records must document the "immediate previous source" of the food as it enters the facility and "immediate subsequent distribution point" of the food as it leaves the facility. The rule also will permit access to the firm's records kept to comply with other "federal, state, or local laws or as a matter of business practice." It requires companies to keep the required information from six months to two years depending on the shelf life of the food. The rule also allows firms to keep the information in any form that they prefer (i.e., paper or electronic) and use existing records to satisfy the requirements. All but small firms must comply within 12 months. Small businesses (under 499 employees) have 18 months to comply, and very small businesses (under 10 employees) have 24 months.

Access to these records is important because of the multi-staged nature of food production, according to the agency. Such rules will allow the FDA to better track and control a food product suspected of being used in a biological attack or in the general context of protecting the public health. The rule limits access to records that may contain trade secrets or confidential information on recipes, and financial, pricing, personnel, research, and sales data; it directs the Secretary to ensure that there are effective procedures to prevent the unauthorized disclosure of any trade secret or confidential information that is obtained during review of records. FDA reemphasizes in instructions to agency personnel the importance of current

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[29] U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration, "Establishment and Maintenance of Records Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002; Final Rules and Notice, 21 CFR Parts 1 and 11," 69 *Federal Register* 71562-71655 (Dec. 9, 2004). See also [http://www.fda.gov/bbs/topics/news/2004/NEW01143.html].

protections and legal requirements against the unauthorized disclosure of any trade secret or confidential information. As with facility registration, access to industry data is expected to make it easier for the agency to determine the cause and scope of distribution of an adulterated or misbranded food and allow FDA to address credible threats of serious adverse health consequences or death to humans or animals.

Statutes governing meat and poultry inspection allow FSIS to inspect slaughter and processing plant records. FDA has never before had the authority to either require that food processors keep records or to inspect them. Opponents are concerned that the records inspection requirements could force a company to retain lot numbers for each article it sends or receives, a costly activity because, pallets often contain lots from multiple-sources so this would require breaking pallets open to record lot numbers. They suggest instead that the agency should have required information, within 24 hours after purchase, the sources and recipients of ingredients at the most precise level possible.

Administrative Detention. On June 4, 2004, FDA finalized its rule on administrative detention — the authority to detain food imports or hold them in place — under certain conditions. Although this authority came into effect immediately upon the Bioterrorism law's signing, so far FDA has not used it. In the final rule, FDA described the "credible evidence" needed to prove that a food presents a threat of serious adverse health consequences or death to humans or animals.[30] An FDA district director or a more senior official can now order the detention of a suspected food for up to 30 days, if necessary. The owners must pay the expense of moving any detained food to secure storage. Perishable foods (fruits, vegetables and seafood, for example) will be subject to an expedited detention process with a fast appeals process.

Other Food Safety and Security Provisions in P.L. 107-188. The Act prohibits any importer who is a convicted felon for offenses related to the importation of food, or has a pattern of importing adulterated food, from presenting any further shipments for entry into the United States. It also authorizes the Secretary of HHS to commission officials of other federal agencies to conduct examinations, inspections, investigations, and related activities at facilities jointly regulated by HHS and another agency. (FDA has already begun to do so with CBP officials.) The Act also authorizes appropriations to be used for additional food bioterrorism activities. Proponents contend that this funding is needed because of the cost of preparing for a bioterrorist attack. Critics of these provisions point out that FDA, together with the food industry, has developed and promoted, since the September 11, 2001 attacks, the adoption of "best practices" for the security of manufacturing facilities (see below). Some food industry representatives claim that the industry needs no further funding, guidance, or inspection to ensure facility safety.

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[30] U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration, "Administrative Detention of Food for Human or Animal Consumption Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002; Final Rule," 69 *Federal Register* 31659 (June 4, 2004).

Other Food Security Activities and Issues. On February 3, 2004, the Department of Homeland Security made public "Homeland Security Presidential Directive no. 9" (HSPD 9) requiring improved coordination by all the food safety agencies to improve surveillance systems, and to complete vulnerability assessments and plans for response and recovery in the event of a terrorist incident.[31] The agencies are also developing common inspection procedures for imported agriculture and food items. In a July 6, 2004 fact sheet from DHS, both FDA and USDA announced that by working together many of their current food safety activities are being modified to comply with HSPD 9. For example, both agencies have conducted vulnerability assessments to determine where intentional contamination could cause illness or death, or simply disrupt the food supply to U.S. consumers. These assessments have not been made public for security reasons. As described above, the path that food travels is complex and food is often not carefully watched or controlled. Both agencies have issued various guidelines on how the food industry can prepare itself to identify and respond to bioterrorist threats. In March 2003, FDA finalized two guidance documents — for operators of domestic food establishments and food importers — giving criteria on how they could lower the risk of intentional contamination.[32] The guidelines identify actions the food operators can take to minimize the risk that the food they produce or manufacture could be contaminated. For example, all the documents suggest that the food processing plant's management develop a recall strategy and plans to pre-screen staff before a suspicious event and to investigate suspicious activity, to restrict access to certain areas, inspect visitors and delivery personnel, and to secure the facility with fencing or other appropriate barriers. On the same day, FDA released draft guidance for retail food stores and food service establishments which gave similar suggestions.

On January 14, 2005, FDA announced a new Office of Food Safety, Defense, and Outreach, combining many of the education and outreach activities with counterrorism activities. In 2003, USDA had set up a special Office for Food Security and Emergency Preparedness. Both offices increased the agencies' surveillance and ability to test for pathogens related to bioterrorist threats. Both agencies have special homeland security teams trained to recognize threats to the food system and others who coordinate agency activities with each other, the Department of Homeland Security's Bureau of Directorate, Customs and Border Protection, the Federal Bureau of Investigation, and other agencies involved in food safety.[33]

FDA and USDA/FSIS also have set up FERN, the Food Emergency Response Network, to integrate 72 state and federal laboratories to analyze food samples implicated in threats, terrorist events, or contamination. It links local, state, and federal information to allow officials to prevent or respond to incidents of

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[31] See [http://www.dhs.gov/dhspublic/interapp/press_release/press_release_0453.xml].

[32] These guidances are part of FDA's support of Operation Liberty Shield, a comprehensive national plan designed to increase the protections for U.S. citizens and infrastructure, while maintaining the free flow of goods and people across U.S. borders. This multidepartment, multiagency national effort is an attempt to minimize disruption of economic activity and travel. *FDA News*, Mar. 19, 2003, pp. 3-18.

[33] See CRS Report RL32521, *Agroterrorism: Threats and Preparedness*, by Jim Monke.

contaminated food. On May 25, 2005, FDA published an announcement in the *Federal Register* requesting applications from state laboratories to enable them to purchase equipment and train personnel in the testing of chemicals related to intentional chemical terrorism events. The three-year awards will allow the agency to train state employees of food testing laboratories for surge capacity in the event of an attack.[34]

In April 2005, the Administration devised 15 scenarios that simulated attacks on various sectors of the United States so all government agencies could assess what might be required if these scenarios took place. One of these scenarios simulated that anthrax had been inserted into ground beef at a West Coast production facility. Packages of beef were shipped to various cities on the West Coast and within days there were estimations of 500 fatalities, 650 hospitalizations, and 1,800 illnesses from this attack. The point of the exercise was to see what parts of the food system would be most affected. The exercise concluded that there was strong potential for having a significant long-term financial impact on the beef market and other income from food could be affected negatively by society's perception of unsafe food in the food supply. There could also be long term implications because this attack would generate demand for an increase in costly federally directed food security measures to reduce future attacks.[35]

Other Food Safety Issues

Although Congress has addressed certain food safety related issues in the context of bioterrorism legislation, some observers argue that other and larger reforms are necessary to improve the overall performance of the nation's food safety system.

Mad Cow Disease. On June 10, 2005, Secretary of Agriculture Mike Johanns announced that an older U.S. beef cow had tested positive for mad cow disease. The beef cow could not stand, was first tested last November and had passed three initial tests. Then the Agriculture Department's inspector general, in reviewing the department's mad cow testing program, requested that the cow and two other previously suspect animals be tested again with a different technology that is used in Europe. One cow's tissue tested positive. Further tests are being done on brain tissue at a British laboratory and at USDA's Ames, Iowa, laboratories. Secretary Johanns also announced that the meat from this cow had not entered the U.S. food or feed supply and that there was no food safety threat.[36] Since December 23, 2003, when the first U.S. dairy cow was identified as having bovine spongiform

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[34] Department of Health and Human Services, Food and Drug Administration, Food Safety and Security Monitoring Project: Availability of Cooperative Agreements; Request for Applications: RFA-FDA-ORA-05-1; *Catalog of Federal Domestic Assistance* 93.448; 70 *Federal Register* 30121-30126 (May 25, 2005).

[35] See [https://www.llis.dhs.gov/member/secure/detail.cfm?content_id=11802].

[36] Alexei Barrionuevo, "Government Is Checking Possible Case of Mad Cow," *New York Times*, June 11, 2005.

encephalopathy (BSE), the safety of the meat supply has been questioned. Although experts claim that the risk to human health from consumption of meat from this BSE infected cow is minimal, some have urged the Administration to carry out additional activities to safeguard the food supply.[37]

BSE was first recognized in British cattle in 1986. Experts believe that feed, made from rendered ruminant animal parts left after slaughter, was the source of infection in cattle. To prevent an outbreak of BSE in the United States, FDA in 1997 instituted a ban on feeding certain rendered animal protein products to ruminants. Since then FDA has made regular inspections of all renderers and feed mills and announced that 99% are complying with the 1997 ban.[38] Additional safeguards were added through import restrictions and BSE surveillance.

After BSE was found in the United States, the then-Secretary of Agriculture, Anne Veneman, announced an immediate ban on the use of any non-ambulatory or "downer" cattle in human food. On January 12, 2004, USDA published final rules requiring that any animal tested for BSE could not be marked "inspected and passed" until a negative test result were received; prohibiting use in the food supply any brain from cattle over 30 months of age; prohibiting the inclusion of any central nervous system tissue in advanced meat recovery systems; and prohibiting the killing of cattle with air injection stunning to ensure that portions of the brain are not dislodged into the tissues of the carcass.[39] Supporters of these policies had wanted to see such department actions taken long ago, but critics were concerned that removing downer cattle from the surveillance systems at the slaughter houses may make it more difficult to detect cattle with BSE if they are present in the population.

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[37] See CRS Issue Brief RL32922, *Meat and Poultry Inspection: Background and Selected Issues,* by Geoffrey S. Becker; CRS Issue Brief IB10127, *Mad Cow Disease: Agriculture Issues for Congress,* by Geoffrey S. Becker; CRS Report RL32269, *Transmissible Spongiform Encephalopathies (TSEs), Including "Mad Cow Disease": Public Health and Scientific Issues*, by Sarah Lister and Judy Johnson; and CRS Report RL32199, *Bovine Spongiform Encephalopathy (BSE, or 'Mad Cow Disease'): Current and Proposed Safeguards,* by Geoffrey S. Becker and Sarah Lister.

[38] Technical briefing and webcast with U.S. government officials on BSE case. Comments made by Dr. Lester Crawford, Deputy Commissioner of the Food and Drug Administration Dec. 30, 2003 at [http://www.usda.gov/Newsroom/0451.03.html].

[39] U.S. Department of Agriculture, Food Safety and Inspection Service, news release, "USDA Issues New Regulations to Address BSE," Jan. 8, 2004, at [http://www.fsis.usda.gov/oa/news/2004/bseregs.htm].

In June 2004, USDA began an expanded surveillance effort for BSE.[40] The goal is to test as many cattle as possible in the high-risk population, as well as sample older healthy animals (including some that were born before the feed ban took effect), over a 12- to 18-month period. Through June 12, 2005, USDA has tested more than 381,900 mostly high-risk U.S. cattle for BSE. Approximately 36 million cattle are slaughtered annually in the United States, though most are younger than the age (30 months) at which BSE is thought to manifest. Some argue that any testing goal is still insufficient to ensure the safety of the meat supply.

To prevent the spread of prion-infected materials, FDA published an interim final rule on July 14, 2004, prohibiting specified risk material and other cattle materials from being used in human food, dietary supplements, and cosmetics.[41] It also proposed a rule that would require manufacturers and processors of food and cosmetics to keep records for two years showing that products do not contain the prohibited cattle materials. On the same day, together with USDA, FDA published an advance notice of proposed rulemaking (ANPR)[42] and solicited comments on whether to prohibit specified risk material from all animal feed including pet food to control the risk of cross-contamination; to prohibit the feeding of mammalian and poultry products to other ruminants; to prohibit the use in animal feed of materials from nonambulator disabled cattle and dead stock; and to further minimize the possibility of cross-contamination of ruminant and non-ruminant animal feed by requiring equipment, facilities or production lines to be dedicated to non-ruminant animal feeds. There has been no further action as of June 2005.

Critics claim that some of these animal feed measures, now in the ANPR, should have been finalized rather than published for comment, for they would significantly strengthen the multiple firewalls that protect U.S. consumers from BSE. In February 2005, GAO published a report that also claimed that FDA's management

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[40] U.S. Department of Agriculture, "Veneman Announces Expanded BSE Surveillance Program," Press Release No. 0105.04, Mar. 15, 2004. In February 2004, the USDA Secretary's Advisory Committee on Foreign Animal and Poultry Diseases recommended a enhanced surveillance program targeting cattle from the populations considered at highest risk for the disease (cattle showing symptoms of central nervous system disease, non-ambulatory cattle, and cattle that die on farms); and increasing the random sampling of apparently normal, aged animals. The Committee also stated that a system should be implemented to facilitate the collection of samples from dead and non-ambulatory cattle, and federal funding assistance for their safe disposal. The Committee also recommended the establishment of a verifiable national animal identification and tracking system; federal support to approve additional regional laboratories to conduct rapid screening tests for BSE; and the dissemination of accurate BSE information to the media and members of the public.

[41] See 69 *Federal Register* 42256 (July 14, 2004). Specified risk material is the brain, skull, eyes, trigeminal ganglia, spinal cord, vertebral column and dorsal root ganglia of cattle 30 months and older and the tonsils and distal ileum of the small intestine of all cattle, as well as the small intestine of all cattle. Also prohibited in food are material from nonambulatory disabled cattle, cattle materials not inspected and passed for human consumption, and mechanically separated beef.

[42] 69 *Federal Register* 42288 (July 14, 2004).

of the feed ban had improved but still saw some weaknesses in their program.[43] Critics also say that FDA has not delivered on its promise to prohibit blood and blood products, poultry litter,[44] and restaurant plate waste as feed ingredients for ruminants, and should have finalized these measures.[45] (See CRS Issue Brief IB10127, *Mad Cow Disease: Agricultural Issues for Congress*).

Enforcement Authorities. Recall authority and civil monetary penalties are also receiving the attention of Congress and the Administration. Well-publicized recalls of food products (including 27.4 million pounds of fresh and frozen poultry luncheon meats considered at risk of containing *Listeria monocytogenes*; and green onions (scallions) associated with hepatitis A outbreaks) have raised concerns over whether the two major food safety agencies, the USDA and the FDA, have enough authority to prevent contaminated food products from reaching consumers. Under current statutes, both agencies must ask food firms to voluntarily recall any hazardous product. Observers have charged that companies may be hesitant to issue a recall in a timely manner, or may not recall as much product as food safety experts suspect is contaminated. Some Members have suggested giving the regulatory agencies mandatory recall authority in order to obtain a speedier response from the food companies and to better protect consumers. Critics of mandatory recall authority assert that such recalls would be costly to industry without necessarily resulting in public health benefits. Critics also are concerned that the government might take action before obtaining sufficient proof of adulteration, which could cause economic harm to a company even if the recall subsequently turned out to be unnecessary.

Language in the FY2005 agricultural appropriations conference agreement requires both FSIS and FDA now list all their recall press releases the website address of the manufacturer of the recalled product, if any, and, if it would assist consumers and the media in identification of the product, a photograph of the recalled product or label.

In previous Congresses, bills were introduced to require mandatory notification of the regulatory agency when a federally inspected establishment believes that its food product was adulterated or misbranded, and issues a recall of the product. In

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[43] U.S. Government Accountability Office, *Mad Cow Disease: FDA's Management of the Food Ban Has Improved, but Oversight Weaknesses Continue to Limit Program Effectiveness*, GAO-05-101, February 2005.

[44] Poultry litter consists of bedding, spilled feed, feathers, and fecal matter that are collected from living quarters where poultry is raised. This material is then used in cattle feed in some areas of the country where cattle and large poultry raising operations are located near one an other. Poultry feed may legally contain protein that is prohibited in ruminant feed, such as bovine meat and bone meal. The concern is that spillage of poultry feed in the chicken house occurs and that poultry feed (which may contain protein prohibited in ruminant feed) is then collected as part of the poultry litter and added to ruminant feed.

[45] Plate waste consists of uneaten meat and other meat scraps that are currently collected from some large restaurant operations and rendered into meat and bone meal for animal feed. The use of plate waste confounds FDA's ability to analyze ruminant feeds for the presence of prohibited proteins, compromising the agency's ability to fully enforce the animal feed rule.

addition, other bills would have given FDA and USDA the authority to suspend food processing by issuing a cease and desist order, and impose civil penalties on plants that do not comply after they are notified.[46]

Reorganization of the Federal Food Safety Regulatory Structure. For many decades there has been a debate about the effectiveness of the federal regulatory structure for food safety and whether it should be changed. Some have proposed that the several different federal agencies having responsibility for food safety be consolidated into a single entity. Slightly changed from the 108th Congress, the Safe Food Act of 2005 (S. 729 [Durbin] and its companion bill H.R. 1507 [DeLauro]) was introduced on April 6, 2005. These bills would place several centers and functions of USDA, FDA, the Department of Commerce, and EPA together in a single Food Safety Administration with one Administrator. To be moved from USDA would have been FSIS, the shell eggs surveillance services of AMS, and the food safety and animal feed research of the Research, Education, and Economics area, and the inspection responsibilities of the Animal Health and Plant Inspection Service (APHIS). To be moved from FDA would have been CFSAN, CVM, the functions of the Office of Regulatory Affairs (ORA) related to inspections of food establishments and imports, and the resources and facilities of the FDA Commissioner's office for CFSAN, CVM, and ORA. The seafood inspection program of the Department of Commerce's National Marine Fisheries Service (NMFS) and EPA's resources and facilities used to control and regulate pesticide resides in foods would have moved to the new entity. The bills build on the existing state systems of consumer outreach and education.

At a May 17, 2005, hearing before the House Committee on Government Reform, Subcommittee on the Federal Workforce and Agency Organization several witnesses debated the pro and con of combining under a single agency the different agencies that inspect food.[47] Proponents of the single-agency concept charge that the current system is fragmented and ill equipped for meeting challenges from potential terrorist acts, from emerging pathogens, and from increasing levels of food imports. They maintain that a single agency with one inspection force basing its inspection frequency on risk would result in a more consistent and efficient system for regulating food. It would eliminate, for example, the inefficiencies of FDA inspecting the cheese pizza and USDA inspecting the meat pizza in the same establishment. Opponents maintain that a reshuffling of bureaucracies would not

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[46] U. S. General Accounting Office, *Food Safety — Actions Needed by USDA and FDA to Ensure That Companies Promptly Carry Out Recalls*, GAO 01-222, Aug. 2002. The report criticized the agencies' efforts in making sure that companies carry out recalls quickly and efficiently, particularly of products that may carry severe risk of illness. GAO also stated that neither FDA nor FSIS compiles sufficient information on companies' recall schedules or methods, and that determining the need for mandatory recall authority could not be done until such data were available.

[47] U.S. Government Accountability Office, *Overseeing the U.S. Food Supply: Steps Should Be Taken to Reduce Overlapping Inspections and Related Activities* GAO 05-549T, May 17, 2005. See also U.S. Government Accountability Office, *Oversight of Food Safety Activities: Federal Agencies Should Pursue Opportunities to Reduce Overlap and Better Leverage Resources*, GAO 05-213, March 2005; and *Food Safety: Experiences of Seven Countries in Consolidating Their Food Safety Systems*, GAO 05-212, February 2005.

necessarily provide safer food or additional resources needed for proper inspections. They also claim that food companies are producing and distributing safe food and that the U.S. system is held up around the world as a model for food safety.

Regulation and Labeling of Genetically Engineered Foods. Questions have been raised in various Congresses 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 in plants or living organisms. These techniques allow scientists to identify and isolate genes of interest from any organism and put them into other organisms. Scientists have developed several types of engineered crops that contain traits making them either herbicide tolerant (HT) or insect resistant because they contained the gene for the pesticide produced by *Bacillus thuringiensis* (Bt), a natural pesticide. U.S. farmers have rapidly adopted varieties of these crops. In 2004, 85% of the total soybean acreage was planted with HT soybeans; 76% of the cotton acreage was planted with HT cotton; and 45% was planted with HT corn.[48] Other GE food crops planted and marketed by U.S. farmers include canola, tomatoes, potatoes, papaya, squash, and sunflowers.[49]

On January 18, 2001, FDA published a proposed rule,[50] 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 proposed rule 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 would be needed. After reviewing the submitted data, FDA would either issue a letter to the company saying it has no safety concerns or expressing why the product should not be marketed. FDA has not finalized this rule.

Currently, FDA does not require labeling of GE foods. In the same January 2001 *Federal Register*, FDA published a draft guidance for industry on voluntary labeling of foods developed using bioengineering. In this document, FDA reaffirmed that it believes, as it did in its 1992 regulatory guidance, that most genetically engineered foods are substantially equivalent to their conventional counterparts. The agency 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

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[48] U.S. Department of Agriculture, Economic Research Service, National Agricultural Statistics Service, [http://www.ers.usda.gov/Data/BiotechCrops/]

[49] For more information, see CRS Report RL30198, *Food Biotechnology in the United States: Science, Regulation, and Issues*, by Donna U. Vogt and Mickey Parrish.

[50] 66 *Federal Register* 4706 (Jan. 18, 2001).

that one food is superior to others, FDA suggests not using statements such as "genetically modified (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.[51]

Supporters of labeling have used the StarLink episode as being illustrative of the need for truthful labeling. In 1998, EPA approved a gene-altered variety of yellow corn called StarLink for use only as animal feed and set a zero-tolerance level for its use in human food. The corn contains a naturally occurring bacterium (Bacillus thuringiensis, or Bt.). Bt does not break down easily in the human digestive system, is heat resistant, and could prove allergenic. A group supporting the labeling of GE foods detected StarLink corn in taco shells in September 2000. The agencies took quick action and millions of pounds of corn suspected of contamination were destroyed. No illnesses nor allergic reactions from eating the food made with Starlink corn were confirmed.

Since then, USDA has strengthened field-testing requirements for permits on genetically engineered traits in plants that are not intended for food production, such as pharmaceuticals and veterinary biologics. The agency added new safeguards as a condition for all permits allowing the confined release of such products into the environment.[52] These specific safeguards include confinement procedures, performance standards, and required monitoring/auditing practices for ensuring that out-crossing or commingling with other seeds and commodities are prevented. The new requirements are intended to prevent any pollen drift that could bring with it intermittent low levels of genetically engineered-genes in food and feed crops under development until all appropriate safety standards are met. These new requirements took on a new urgency when one firm, ProdiGene, failed to manage former test sites in Iowa and Nebraska. Corn containing an enzyme that was used to make a pharmaceutical was mixed with soybeans and led to the destruction of 500,000 bushels of soybeans thought to be contaminated with the plant-based pharmaceutical. The company was fined $250,000 and required to pay for the cost of destroying the soybeans. The incident has caused the food industry to call for a complete separation of plant-based pharmaceutical production from the food supply.[53]

On July 28, 2004, the National Academies released another report concluding that federal agencies should continue to assess the safety of foods, whether produced by genetic engineering or by other genetic modification techniques, such as conventional breeding for desirable traits, on a case-by-case basis to determine whether unintended changes in their composition could adversely affect human

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[51] See CRS Report RS20507, *Labeling of Genetically Modified Foods*, by Donna U. Vogt.

[52] 68 *Federal Register* 11337 (Mar. 10, 2003).

[53] See CRS Report RS21418, *Regulation of Plant-Based Pharmaceuticals*, by Geoffrey S. Becker and Donna Vogt.

health.[54] The report said that the risks from GE foods are not unique, information on the composition of GE foods should be made public, and more post-market surveillance of these foods could create a data base of health effects on humans.

In November 2004, FDA published a draft guidance describing procedures that it recommends be used to assess the safety of new proteins in plant varieties intended for food. The draft addresses the potential of a new protein to cause an allergic reaction in susceptible people or be toxic to people or animals. The agency is recommending that sponsors of new food plant varieties consult with FDA prior to when the plant protein might be planted and inadvertently enter the food supply.[55] Under the proposal, developers would provide FDA with information about the food safety of the new protein at a relatively early stage of development of the crop. Once a developer decides to commercialize a particular crop, the developer would still be expected to participate in FDA's voluntary premarket consultation process. The agency also stated that any potential risk from the low-level presence of GM material in the food supply would be limited to the possibility that it would contain or consist of a new protein that might be an allergen or toxin. Critics of the draft complain that it is vague, fails to specify when safety evaluations must be submitted, what toxins and allergens should be evaluated, and whether crops can be planted while FDA assesses their safety.[56]

Supporters claim that GE 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, including any potential for an unlabeled allergen to become part of the product. These critics want mandatory labeling and consultation with the agency prior to marketing.

Antimicrobial Resistance. Public health experts are concerned about the increasing numbers of people who do not respond to standard medical treatment because the microorganisms causing their illness are resistant to the antibiotics normally used to treat the illness or disease. Antimicrobial resistance in bacteria occurs when genetic changes of a microorganism makes it resistant to antibiotics.

Although antimicrobial agents are used to treat illnesses both in humans and animals, these agents are also used in food animals for nontherapeutic purposes. Nontherapeutic use is when producers of food animals put small amounts of antibiotics in animal feed so their chickens, cattle, and pigs grow faster, use less feed, and don't get sick as often. Nontherapeutic uses are defined formally in proposed legislation as uses of the drug as a feed or water additive for an animal in the absence of any clinical sign of disease in the animal for the purposes of growth promotion,

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[54] National Academy of Sciences, National Research Council, *Safety of Genetically Engineered Foods: Approaches to Assessing Unintended Health Effects* (Washington, DC: National Academies Press, July 28, 2004).

[55] See [http://www.cfsan.fda.gov/~dms/bioprgui.html].

[56] "FDA Guidance on Early Safety-Evaluation of Biotech Food Lacks Detail," *Inside Health Policy*, Nov. 29, 2004.

feed efficiency and, sometimes, disease prevention. Nontherapeutic uses are being questioned because the drugs, when used in food animals, can also promote genetic changes that make microorganisms resistant to antibiotics used to treat human illnesses. However, for some large scale animal producers, a farm might not be commercially viable without the routine use of these drugs in feed. Some think the link between widespread use in animal feed and increased antimicrobial resistance in humans is not strong enough to warrant the added costs to food production. Others think use of antimicrobials should be severely constrained to limit antimicrobial resistance.

The FDA states that due to the diffuse use of antimicrobials, it is difficult to assess precisely whether the growing resistance in foodborne pathogens is attributable to the use of antimicrobial drugs in food producing animals or some other use. On October 23, 2003, FDA released a new guidance document outlining an evidence-based approach to preventing antimicrobial resistance that may result from the use of antimicrobial drugs in animals. The document, *Guidance for Industry (GFI) #152* (Evaluating the Safety of Antimicrobial New Animal Drugs with Regard to their Microbiological Effects on Bacteria of Human Health Concern), is not a regulation. Instead it explains a science-based process that drug sponsors may use when they seek approval of an antimicrobial for use in food-producing animals. The new guidance encourages drug sponsors to use a risk assessment process to demonstrate that an antimicrobial drug used to treat food-producing animals will not create a risk of antimicrobial resistant bacteria likely to lead to human health problems. FDA states that this process can help prevent antimicrobial drugs with a high risk of causing such problems from being improperly used in food producing animals, and thereby potentially leading to antimicrobial resistance in humans.

According to a July 21, 2004, report by the Infectious Disease Society of America, the number of drug-resistant infections including foodborne infections caused by *Salmonella* continues to rise, while the number of new antibiotics in the pipeline to combat the infections is declining drastically.[57] The report contains a table showing that since 1998, only two novel antibiotics (linezolid and daptomycin) have been approved by FDA, and only five new antibiotics are in the drug pipeline out of more than 506 drugs in development.[58] It called upon Congress to increase funding to several federal agencies to increase the number and size of research grants; reduce the cost of clinical trials by providing tax incentives; and establish liability protections to reduce companies' risks. In addition, according to the report, FDA should develop a "wildcard patent extension" in which a company that creates a priority antibiotic could extend the marketing exclusivity period of another FDA-approved drug as long as the company commits to investing a portion of the profits derived during the extension to antibiotic research and development.

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[57] Infectious Diseases Society of America, *Bad Bugs, No Drugs: Antibiotic Discovery Stagnates... A Public Health Crisis Brews*, July 2004. See [http://www.idsociety.org].

[58] On June 1, 2005, Wyeth announced that its new antibiotic drug Tygacil had successfully completed clinical trials. If approved, it will be used in hospitals intravenously for patients with life-threatening abdominal and skin infections that do not respond to older antibiotics.

Following the review process of Guidance 152, an FDA animal health advisory board decided, in October 2004, that a new macrolide antibiotic, Draxxin (tulthromycin), had a low risk of contributing to antimicrobial resistance in humans and could be used in food animals. The drug is injected into swine and cattle to treat their respiratory disease. Critics are concerned that this board did not apply the risk-assessment finding to all uses of macrolides in animal agriculture. Other critics expressed concern that the risk assessment took over a year to complete.

On April 7, 2005, the Preservation of Antibiotics for Medical Treatment Act of 2005 (S. 742) was introduced by Senators Snowe and Kennedy. A similar bill (H.R. 2562) with the same title was introduced on May 24, 2005 by Representative Sherrod Brown. This bill would provide for a phased elimination of the routine feeding to food-producing animals the same antimicrobial drugs also used in humans. The bill would require that manufacturers show that their nontherapeutic use in food animals does not pose a threat to public health. The bill would allow therapeutic use of the drugs to treat sick animals and pets. In addition, the bill would require manufacturers of antimicrobial drugs used routinely in animal feed to report annual sales information and authorize the Secretary of Agriculture to pay animal producers to defray the costs of reducing the use of the antibiotic. Supporters claim that scientific experts have shown that the overuse of antibiotics in human medicine and livestock are the two chief contributors to the growth in antibiotic resistance in this country. Critics claim that other uses of antimicrobials are the major cause of resistance in humans.

On June 3, 2005, Environmental Defense, an environmental nonprofit organization (formerly the Environmental Defense Fund) published a report claiming that over 26 million pounds of antibiotics, important for treating human diseases, are used in animal feed each year.[59] Almost all (90%) of the use occurs in 23 states. This use contributes to an increase in antibiotic resistance in humans, they claimed. This use is also almost seven times the amount of antibiotics used in humans annually, according to the group. The study suggests that people living in areas where antibiotics are heavily used in animal feed are at greater risk of developing infections resistant to antibiotic treatment, the group says. Critics question the methodology used to estimate usage and claim that the national monitoring system has shown stable levels of resistant bacteria in retail meats.[60]

Safety of Fresh Produce. The Florida State officials asked FDA on June 3, 2005 to look into whether gastrointestinal illnesses caused by a parasite *Cyclospora* were related to fresh basil. So far there were 293 laboratory-confirmed cases of illness in 32 Florida countries.[61] This is only one example of recent outbreaks linked to fresh produce. In fact, CDC estimates that about 12% of

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[59] Karen Florini, Richard Denison, Terri Stiffler, Timothy Fitzgerald, and Rebecca Goldburg, *Resistant Bugs and Antibiotic Drugs: State and County Estimates of Antibiotics in Agricultural Feed and Animal Waste*, Environmental Defense June 2005.

[60] Zachary Richardson, "Estimates on Antibiotic Use in Animals Spark Controversy, *Food Chemical News* vol. 47, no. 17 (June 6, 2005), pp. 18-19.

[61] Food and Drug Administration, *FDA Works to Trace Source of Foodborne Illness in Florida*, Press Release, June 3, 2005.

foodborne-outbreak associated illnesses were linked to fresh produce. Contaminated fresh produce may pose a risk of microbial illness because it is often intended to be eaten raw. Also, both consumption and importation of produce are on the rise.

On October 18, 2004, FDA released its 2004 Produce Safety Action Plan. It has four general objectives: (1) prevent contamination of produce; (2) minimize health impact when produce gets contaminated; (3) educate producers, preparers, and consumers about handling produce; and (4) support research. The plan covers fresh fruits and vegetables in the unpeeled natural form, raw, and minimally processed meaning pre-cut or fresh-cut products. Critics were pleased to see that the agency added ways to measure the plan's impact; its draft plan, published in June 2004, did not. The agency is currently developing guidance to the industry in conjunction with some revisions of their good manufacturing processes (GMP) regulations. (See CRS Report RL32746, *Fruits, Vegetables, and Other Specialty Crops: A Primer on Government Programs,* by Jean Rawson.

Egg Safety. Currently it is estimated that 118,000 illnesses are caused by the consumption of *Salmonella* Enteritidis (SE)-contaminated eggs annually. On September 22, 2004, FDA published a proposed rule on the prevention of SE in shell eggs[62] in which it is asking producers to test the environment in poultry houses for SE. If found, the eggs are to be diverted to locations where liquid eggs can be pasteurized or used in other processed products. In addition, the proposed rule would require that a designated person on each farm administer the prevention measures and keep records of testing. Large producers (more than 3,000 laying hens) will have to treat eggs to get a 100,000-fold reduction in SE organisms. The proposal would not cover producers with fewer than 3,000 hens or those producers who sell all their eggs directly to consumers. It also would require a pest and rodent control program, the cleaning and disinfection of poultry houses that test positive for SE, and refrigerated (below 45 degrees Fahrenheit) storage of eggs at the farm, among other things. Industry claims that it is already following many of the recommendations and that with proper storage and cooking most of the risks of SE are eliminated.

On June 1, 2005, FDA extended the comment period for this rule until July 25, 2005 in order to receive more information about programs at the state and regional level that could prevent SE-monitored chicks from becoming infected with SE. The notice extending the comment period also asks for more information about industry practices when pullets are reared until they are placed into laying hen houses. FDA expects to publish the final rule in FY2006.

Methylmercury and Fish. Concerns about exposure to methylmercury (MeHg) from consumption of certain fish continue to prompt government action. FDA is responsible for the safety of commercial fish, while EPA is responsible for the safety of recreational caught fish. Many states also monitor the safety of fish within their borders and issue consumption advisories for recreational-caught fish. Mercury

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[62] U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration, "Prevention of Salmonella Enteritidis in Shell Eggs During Production; Proposed Rule, 21 CFR Parts 16 and 118," 69 *Federal Register* 56823-56906 (Sept. 22, 2004).

occurs naturally in the environment and is released into the air through industrial pollution. Mercury then falls from the air and accumulates in streams and oceans. Bacteria in the water cause chemical changes that transform mercury into MeHg. Fish absorb the MeHg as they feed in these waters. MeHg builds up more in some fish than others depending on what they eat, how long they live, and how high up the food chain they are.

Exposure in young children and fetuses to MeHg has been linked to neurodevelopmental injury, mental retardation, and other effects. A controversial study by the National Academy of Sciences in 2000 estimated that "each year about 60,000 children may be born in the United States with neurological problems that could lead to poor school performance because of exposure to methylmercury *in utero*."[63] Some were critical of numerous assumptions leading to that conclusion, while others have argued that the health benefits of fish were ignored and that consumers would avoid fish altogether.

Although each agency had previously issued separate statements on this food safety concern, on March 19, 2004, FDA and EPA jointly announced a consumer advisory to limit exposure to MeHg in young children and in women who are pregnant, nursing, or planning to become pregnant.[64] The advisory recommended, for those groups, limiting the amount and type of fish consumed to those with lower levels of mercury, while cautioning against any consumption of shark, swordfish, king mackerel, or tilefish because they contain high levels. The advisory also urged limiting consumption of albacore ("white") tuna, which has more mercury than canned light tuna, to six ounces (one average meal) per week. Consumers were also advised to check local fish consumption advisories, and absent advice to the contrary, to limit consumption of locally caught fish as well.

Critics continue to debate the proper balance of negative consumer information about MeHg and positive messages about fish consumption. Some are calling the advisory "insufficiently protective" of certain population groups. On June 21, 2004, the California Attorney General filed a suit against the three largest canned tuna companies, claiming that the businesses had failed to adequately warn consumers that albacore and light tuna may contain MeHg. In doing so, the companies had violated California's Proposition 65, which requires companies to provide warnings of known carcinogens or reproductive toxins. MeHg has been listed as a reproductive toxin in California since 1987.

On November 5, 2004, CDC summarized results of its 1999-2002 National Health and Nutrition Examination Survey (NHANES). Although it found that blood Hg levels in most young children and women of childbearing age were below levels of concern, approximately 6% of childbearing-aged women had levels at or above a reference dose, an estimated level assumed to be without appreciable harm. Therefore, CDC recommended that women who are pregnant or who intend to become

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[63] National Academy of Sciences, "EPA's Methylmercury Guideline Is Scientifically Justifiable for Protecting Most Americans, But Some May Be at Risk," press release, July 11, 2000, accompanying the report, "Toxicological Effects of Methylmercury."

[64] See [http://www.fda.gov/oc/opacom/hottopics/mercury/backgrounder.html].

pregnant should follow federal and state advisories on consumption of fish.[65] Critics, however, are vocal in their concerns about the neurological effect of mercury. The Environmental Working Group (EWG) released its own year-long report on December 13, 2004. The report reviewed a study suggesting that some autistic children may have a metabolic abnormality that would make them more susceptible to the effects of toxins such as mercury. The EWG wants the federal government to do more to control MeHg levels in fish.[66]

[65] See the specific issue at [http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5343a5.htm].

[66] See the EWG report at [http://www.ewg.org/reports/autism/execsumm.php].