

Issue Brief for Congress

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Food Safety and Protection Issues in the 107th Congress

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LEGISLATION

Food Safety and Protection Issues in the 107th Congress

SUMMARY

The Federal Food, Drug, and Cosmetic Act (FFDCA) gives the Food and Drug Administration (FDA), in the Department of Health and Human Services (DHHS), authority to set and enforce standards for safety of all domestic and imported foods, except for meat, poultry, and certain egg products, which are under the authority of the U.S. Department of Agriculture (USDA). The FDA also ensures that all animal drugs and feeds are safe, are labeled properly, and produce no human health hazard when used in food-producing animals. Also under FFDCA, the Environmental Protection Agency (EPA) sets legal limits (tolerances) on the amounts of pesticide residues that can be found in or on food. The Centers for Disease Control and Prevention (CDC), also part of DHHS, tracks food-borne illness incidents and outbreaks, and provides data and information to the other food safety agencies.

Congress maintains close oversight of the FDA's food safety activities, particularly its efforts to address the issue of microbiological contamination, which is responsible for an estimated 76 million illnesses and 5,000 deaths in the United States each year. At issue for many years has been (1) whether the FDA has sufficient statutory authority over the food industry to bring about continued improvements in food safety and to take enforcement actions, and (2) whether the FDA has sufficient resources and personnel to inspect the volume of food it regulates.

In addition to these ongoing concerns, the terrorist attacks and anthrax scares of fall 2001 have raised worries about the FDA's (and USDA's) readiness to prevent and respond to potential bioterrorist attacks on the nation's food supply.

In the weeks following the attacks, Congress added funds for anti-terrorism activities to the law making FY2002 appropriations for the USDA and the FDA (P.L. 107-76). In addition, on January 10, 2002, the President signed a \$20 billion Defense supplemental bill into law that includes \$328 million for USDA and \$151.1 million for FDA food protection activities.

On June 12, 2002, the President is expected to sign major counter-terrorism legislation containing provisions related to food safety and protection – the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (H.R. 3448/S. 1765). The bill authorizes \$545 million for food protection (out of a total of \$2.369 billion for bioterrorism response). The bill contains \$130.25 million in appropriations for HHS and requires FDA to (1) register food processors and inspect their records, (2) detain adulterated food, and (3) take a number of steps to ensure the safety of imported foods (among other provisions). The bill authorizes \$415 million in appropriations for USDA, to be used for enhanced border inspection of imports of plant and animal origin, lab biosecurity upgrades, and increased research.

To date, no further action has been taken on other bills that would (1) give USDA authority to recall foods, and (2) consolidate the activities of the 12 government agencies with current food safety responsibilities into a single independent federal entity. The Administration's proposal for a Department of Homeland Security, and a similar Senate proposal, S. 2452, would transfer some or all of USDA's Animal and Plant Health Inspection Agency to the new department, but would not make any changes in the organization of federal food safety agencies.



MOST RECENT DEVELOPMENTS

On June 6, 2002, President Bush proposed the creation of a cabinet-level Department of Homeland Security. Under this proposal, all of USDA's Animal and Plant Health Inspection Service (APHIS), which conducts border inspections of imports of plant and animal origin (among other things), would be transferred to the new department. The Senate Committee on Governmental Affairs reported out legislation similar to the Administration's proposal on May 22, 2002. The National Homeland Security and Combating Terrorism Act of 2002 (S. 2452), would transfer only APHIS's border inspection activities to a Department of National Homeland Security.

On May 22 and 23, 2002, the House and Senate, respectively, passed the conference agreement on major counter-terrorism legislation that includes provisions intended to protect the nation's food supply from acts of bioterrorism (H.R. 3448/S. 1765; H. Rept. 107-481).

On May 13, 2002, President Bush signed into law a bill to direct U.S. farm and agricultural policy through 2007 (P.L. 107-171, the 2002 farm bill). Within this far-ranging law is a provision that would establish a 15-member Food Safety Commission charged with preparing a report for the President and Congress that will make specific recommendations on how the safety of the entire U.S. food supply could be improved. This law also authorizes appropriations for (1) a competitive grants program to construct and upgrade the security of facilities conducting anti-terrorism related research at public colleges and universities; and (2) research and extension programs to improve bioterrorism prevention, preparedness, and response.

On May 13, 2002, Senator Ted Kennedy introduced legislation that would require the Food and Drug Administration to approve antimicrobial animal drugs only if the manufacturer can demonstrate that there is a reasonable certainty that their use in animal feeds at subtherapeutic levels does not contribute to the development of antibiotic resistance, among other things (S. 2508). On February 27, 2002, Representative Sherrod Brown introduced a similar bill that would also regulate antibiotics in animal feed. (H.R. 3804).

BACKGROUND AND ANALYSIS

Most of the food safety related legislative and regulatory changes over the past decade have been aimed at protecting the nation's food supply from microbiological, chemical, and toxic hazards that occur either naturally or accidentally in the lengthy farm-to-table food supply chain. The fall 2001 terrorist and anthrax attacks have forced Congress, federal food safety officials, and food industry policymakers to consider the nation's readiness to protect against and respond to intentional acts of food adulteration or agricultural resource contamination. There is widespread concern that naturally occurring pathogens such as *E. coli* O157:H7, *Salmonella*, *Shigella*, and *Cyclospora* could spread easily through the multi-link food chain and could be used as a bioterrorist weapon. These pathogens already cause approximately 76 million illnesses, 325,000 hospitalizations, and 5,000 deaths each year in the United States. Such an attack would be particularly lethal to children, the elderly, and the immune-compromised. Government officials and food industry observers speculate that

the foods most vulnerable to contamination would be those that are minimally processed at a central location, and/or are ready-to-eat, such as milk and fresh produce.

Bioterrorism against the food supply would also directly harm the U.S. economy. U.S. agriculture contributes \$1 trillion to our gross domestic product (GDP) annually and provides 22% of all jobs. Food production exceeds \$200 billion, with over \$55 billion in exports each year. The production and consumption of food is so extensive (coming from 500,000 farms and handled by 57,000 food processors and 6,000 meat, poultry, and egg products processors) that if even a small number of contaminants were intentionally introduced to some part of the food chain, such an incident could seriously damage public confidence in the food supply and could result in staggering economic losses.

Federal Agencies with Food Safety Responsibilities

Several federal agencies have regulatory responsibilities for food safety. The U.S. Department of Agriculture's (USDA's) Food Safety and Inspection Service (FSIS) regulates red meat, poultry, and certain egg products. The Animal Plant Health Inspection Service (APHIS) inspects cargo and passengers at U.S. ports of entry for animal and plant pests, and responds to animal disease outbreaks, among other duties. The Agricultural Research Service (ARS) conducts research on animal diseases, food safety, and other subjects to support FSIS's regulatory activities.

The Federal Food, Drug, and Cosmetic Act (FFDCA) gives the Food and Drug Administration (FDA) responsibility for the safety of all other foods. The FDA is an agency of the Department of Health and Human Services (DHHS). Most of FDA's activities lie within two centers — the Center for Food Safety and Applied Nutrition (CFSAN), which establishes guidance and regulatory requirements for assuring that food is safe and not adulterated, and the Center for Veterinary Medicine (CVM), which ensures the safety and efficacy of all drugs used in food animals and feeds. In addition, the Centers for Disease Control and Prevention (CDC), also part of DHHS, tracks food-borne illness incidents and outbreaks, and provides data and information to the other food safety agencies. State health departments send CDC reports of confirmed food-borne problems for a national surveillance database. Of the illnesses whose food source is known, 80% are associated with FDA-regulated food products such as fish, shellfish, fruits, and vegetables; the remaining 20% come from foods under FSIS's jurisdiction.

Under the FFDCA, the FDA is required, through oversight and inspection, to ensure that food manufacturers, producers, and distributors deliver into interstate commerce foods that are free of contamination and free of unacceptable chemicals. The agency works with the food industry to set manufacturing standards to minimize the opportunities where contamination can occur. FDA monitors how well the food industry is meeting the standards through occasional inspection, but largely takes regulatory action only when problems arise. FDA maintains the same requirements for imported foods as for domestic foods. The agency annually inspects roughly 1% of all imported foods over which it has jurisdiction. This level of oversight over foods has been a recurrent issue among some Members of Congress.

Under the meat, poultry, and egg inspection statutes, USDA's Food Safety and Inspection Service (FSIS) has much more regulatory control over its products than the FDA exercises over the rest of the food supply. Meat animals and poultry cannot be slaughtered

unless FSIS inspectors are present. Every plant that processes meat, poultry, and egg products receives a daily visit from an inspector who checks operations and the plant's compliance with extensive record-keeping requirements. Meat and poultry imports can come only from countries whose inspection systems FSIS has certified to be at least equal to the U.S. system, and then only from plants that FSIS has approved. Imports receive various levels of reinspection by FSIS before they are released into commerce.

Current Level of Preparedness for Food Safety and Security

Since the September 2001 attacks, federal food safety agencies have taken many steps to increase their readiness in the event of a bioterrorist attack.

DHHS/Centers for Disease Control and Prevention Surveillance Networks.

In the last decade, the CDC established more than 10 surveillance systems to identify and track the source of outbreaks of food-borne illnesses and to assist regulatory agencies in their food safety activities. Consequently, the agency now has separate surveillance systems to track botulism, Creutzfeldt-Jakob disease (the human form of "mad cow" disease), *Escherichia coli* O157:H7, *Giardia*, *Salmonella*, and *Salmonella enteritidis*, viral hepatitis, trichinellosis, typhoid fever, and *Vibrio* infections in foods. Since September 11, 2001, CDC has been adapting these and other surveillance systems to track intentional acts of terrorism directed towards the nation's food supply. For example, FoodNet, established in 1995 by USDA and FDA, is now on heightened alert to track the incidence rate of illnesses caused by these same nine pathogens in nine different geographic areas. A different program, PulseNet, which compares genetic patterns of bacteria isolated from patients and/or contaminated food, is gearing up to identify any intentional hazards that may show up in food.

Continued reforms in food safety activities and surveillance appear to be having a positive effect. On April 19, 2002, CDC published preliminary numbers mentioning that Pathogen Reduction/Hazard Analysis Critical Control Point (HACCP) systems regulations in meat and poultry slaughter, egg processing, and seafood, better agricultural practices (particularly for produce), new technologies to reduce food contamination, and increased public education in food preparation practices, may be responsible for the reduction in food borne illness reports.

CDC's surveillance systems, for the most part, depend on the reporting capabilities of local- and state-level health and agriculture officials. Since September 11, 2001, the agency has been training these officials and laboratory technicians to recognize hazards in foods. It has also begun to refurbish public health laboratories in most states to increase the capacity of these facilities to quickly identify acts of terrorism.

CDC also is a participant in the intergovernmental Foodborne Outbreak Response Coordinating Group (known as FORC-G), which was created in 1998 under the previous administration's Food Safety Initiative. The group is composed of representatives of FDA, USDA, CDC, and EPA, as well as state and local food safety officials. Since FORC-G was established by executive order, the Bush Administration would have to reactivate it in order for it to reconvene. Currently, the group is not meeting.

DHHS/Food and Drug Administration. Since the fall 2001 attacks, FDA has been refocusing its attention and realigning its policy priorities and resources to try to prevent potential terrorist attacks on the U.S. food supply. Its efforts have been concentrated on immediate actions to deter or prevent terrorist activity by: (1) increasing inspection capability; (2) improving surveillance programs for determining food hazards; (3) strengthening assessments of threats to food; and (4) setting up a system to respond to potential threats.

Working with the U.S. Customs Service, FDA by the end of September 2001 had placed additional inspectors at ports of entry to create a presence designed to deter wrongdoers. FDA also began inspecting and sampling more food imports and domestic plants that could be processing vulnerable foods such as milk.

For the long term, the agency continued upgrading its computer surveillance data systems, particularly its Operational and Administrative System for Import Support (OASIS), a computerized screening system that uses a variety of risk-based criteria to target food import shipments for further inspection. It is also developing an in-house surveillance network system called eLEXNET that will improve the abilities of the agency's laboratories to diagnose infectious or toxic agents and to link food safety experts in federal, state, and local food safety laboratories. FDA also has strengthened its ties to CDC's surveillance programs, particularly FoodNet and PulseNet.

On January 9, 2002, FDA published two sets of guidelines, one for the food industry and the other for food importers. The guidelines, developed by the agency with industry input, encourage operators to review sequentially controls where their food product might be vulnerable to tampering, or criminal and terrorist attacks. FDA has identified a step-by-step process for the food industry to determine hazards in foods that could pose the highest risk to public health. It suggests categories where food manufacturers should examine possible threats to avoid any potential tampering in raw material, packaging, and finished products — for example, foods prepared in a central facility for distribution using unscreened and transient field employees.

The agency has also begun to assess the gaps in the federal, state, and local safety nets by determining whether rapid testing technology exists that is capable of identifying hazards in foods, and whether there are sufficient numbers of trained laboratory personnel who can identify various hazards. Also, the FDA is in contact with regulatory agencies abroad to maximize coordination to protect food. International coordination will allow FDA to trace back and respond quickly to any threats to the U.S. food supply.

According to agency officials, FDA is revising its existing emergency plan by identifying its response team, providing the training and equipment needed to contain a terrorist threat, revisiting its FORC-G emergency response plans, and developing a list of contacts in other federal agencies, including the Environmental Protection Agency, the Federal Bureau of Investigation, USDA, and 3,000 state and local offices with responsibility for monitoring retail food establishments and their employees. In addition, the FDA has communicated with consumers on its web page about the importance of vigilance as it pertains to potential threats to the food supply.

USDA/Food Safety and Inspection Service. On March 14, 2002, Under Secretary for Food Safety Elsa Murano testified before the House Agriculture Appropriations subcommittee on the steps FSIS and the Department currently are taking administratively to address food biosecurity issues. At the Department level, the USDA Homeland Security Council coordinates anti-terrorism activities across USDA and with other federal agencies. The Protection of the Food Supply and Agriculture Production subcouncil coordinates FSIS/APHIS preparedness and response activities. In the event of a food-related biosecurity event, the Food Emergency Rapid Response and Evaluation Team (FERRET) authorized by the Agricultural Research, Extension and Education Reform Act of 1998 (P.L. 105-185) would join forces with the subcouncil. Within FSIS, the Food Biosecurity Action Team (F-BAT) has placed the agency's 7,600 inspectors on high alert to look for ante-mortem and post-mortem irregularities in meat animals and poultry, has conducted mock exercises to improve response time and communication in emergency situations, and is working with slaughtering and processing operations to improve the security of both the physical plant and the workforce. The Food Threat Preparedness Network (PrepNet) is a joint FSIS/FDA group that works on threat prevention and emergency response.

The livestock industry also has launched a food-industry-wide effort (the Alliance for Food Security) to develop bioterrorism risk management plans that coordinate with federal preparedness and emergency response plans. Industry officials note that these activities build upon efforts that began several years ago to forestall the introduction and spread of mad cow disease, and more recently, foot-and-mouth disease.

USDA/Animal and Plant Health Inspection Service. APHIS, in cooperation with other state and federal agencies, is charged with protecting against accidental introductions of plant pests and animal diseases through inspection of craft, cargo, and passengers at U.S. ports of entry. APHIS is also responsible for establishing quarantines, controlling the interstate commerce of regulated articles, and directing and coordinating eradication efforts with state and federal agencies inside areas of quarantine. While APHIS has, in the past, successfully kept out or intercepted many foreign pests and diseases flowing through commercial and trade channels, some concerns have been raised about its ability to respond to deliberate, and perhaps domestically initiated, introductions of disease agents or pests. These concerns were heightened recently by the USDA's Office of the Inspector General (OIG) report (available at [<http://www.usda.gov/oig/audit/rpt/50601-3-Ch.pdf>]) stating that deficiencies in APHIS-FSIS coordination of meat cargo inspection procedures could increase the possibility of the introduction of foot-and-mouth and mad cow diseases.

In response to the threats highlighted by last September's attacks, APHIS officials have announced that the agency is increasing the inspection staff at U.S. ports of entry by 350 and is adding 20 veterinarians to imported and domestic disease surveillance and control programs. APHIS also is stepping up the agency's smuggling interdiction activities and making \$1.5 million in grants available to states specifically to help them plan their response to potential foreign animal disease outbreaks.

Under the President's June 6 proposal for a cabinet-level Department of Homeland Security, all of APHIS would become part of the new department under its Border and Transportation Security function. A similar Senate proposal for a new executive security department, which the Senate Committee on Governmental Affairs reported out on May 22,

2002, would transfer only APHIS's border inspection function to the department (S. 2452, the National Homeland Security and Combating Terrorism Act of 2002).

USDA/Agricultural Research Service. ARS is USDA's in-house research agency, and is responsible for supporting the regulatory missions of APHIS and FSIS with scientific information. It operates animal disease bio-containment laboratories in Plum Island, NY, and Ames, IA. In light of the events of fall 2001, ARS is increasing the security of its pathogen culture collections used in disease diagnosis and treatment research. According to USDA officials, laboratory security has been increased at several facilities involved in research of animal pathogens such as foot-and-mouth disease and anthrax. Concerns about a lack of adequate physical and biological security and about deteriorating facilities have been raised since 1992, when an internal USDA review pointed out serious infrastructure problems. Earmarks for improvements of sensitive facilities totaled \$16 million in FY2001 appropriations (see Funding section for supplemental appropriations under more recent acts).

The President's proposed Department of Homeland Security would become the new home of two joint ARS/APHIS animal disease labs, one in Ames, Iowa, and one on Plum Island off Greenport, New York. These labs perform research on the most dangerous animal disease and pest organisms and are among those most in need of upgrading and security enhancement. S. 2452, the Senate proposal for a Department of National Homeland Security, does not contain this provision.

State and Local Government Role in Food Safety. State, county, and local public health and agriculture departments, along with the CDC, play a major role in helping FDA and USDA carry out their responsibilities. Even though federal law mandates the safety of all food, more than 3,000 state and local regulatory agencies monitor over 1.2 million retail food establishments to ensure that they are following procedures outlined in an FDA guidance manual called the Food Code. CDC primarily assists state and local health departments by investigating outbreaks of illness and by preparing and training state and local officials in identifying the cause of the outbreak or intentional contamination.

Funding

Appropriations for Food Safety and Bioterrorism. On September 18, 2001, the President signed P.L. 107-38 (H.R. 2888), the 2001 Emergency Supplemental Appropriations Act for Recovery from and Response to Terrorist Attacks on the United States. The Act appropriated \$40 billion to be used by the President for relief efforts and anti-terrorism activities. The Act divided the funds in half, giving the President immediate control over disbursement of the first \$20 billion, and requiring Congress to pass separate legislation to allocate the remaining \$20 billion. Out of the first \$20 billion, FDA received \$1.75 million to secure the physical plants of the agency and its laboratories.

Congress included the legislation allocating the second \$20 billion as an attachment to the FY2002 Defense Appropriations Act, signed by the President on January 10, 2002 (H.R. 3338, P.L. 107-117). For USDA, P.L. 107-117 contains \$328 million for a variety of activities within ARS, APHIS, FSIS, and the Office of the Secretary to enhance security and conduct counter-terrorism research. The Act allocates \$151.1 million to FDA for a wide range of counter-terrorism activities. The FY2002 FDA appropriation, which was signed in December 2001, directs the agency to receive an additional \$6.8 million, bringing the total

for counter-terrorism activities to \$157.9 million. FDA has stated its intention to hire 400 border personnel, including inspectors; 151 laboratory analysts; 84 compliance officers; and 38 risk assessors to improve its capacity to respond to terrorist threats.

The President's FY2003 proposed budget requests \$159.1 million to support ongoing counter-terrorism activities for FDA. The request reflects an increase of \$1.2 million over FY2002 funding of \$157.9 million. Of this \$159 million, \$98.1 million is slated for counter terrorism activities related to food safety, particularly the development of tests to detect bioterrorist agents and to increase the safety of imported foods. The remaining \$61 million would be used for general counter-terrorism activity support.

FY2003 Appropriations for Food Safety Activities. For FY2003, the President has requested \$404.2 million for FDA's food safety activities apart from those activities designated under the counter-terrorism request. The funding request includes \$91.5 million to be used for microbiological food safety activities; \$79 million for the testing of chemicals and pesticide residues in foods; \$22.1 million to continue BSE-related activities; \$134.7 million for additional inspections; \$44.1 million for what is called premarket analysis and approval of food additives; \$23.5 million for pay increases for the entire food safety program; and \$9.3 million for the testing of dietary supplements.

The FY2003 budget proposal requests a \$905 million program level for USDA's meat, poultry and egg inspection programs. The request includes an increase of \$14.5 million to upgrade FSIS's computerized inspection information system. (The proposal does not designate any funds specifically for anti-bioterrorism activities.)

Proposed New Authorizations for Appropriations. The conference agreement on the Public Health Security and Bioterrorism Preparedness and Response Act (H.R. 3448/S. 1765; H. Rept. 107-481), which the House passed on May 22 and the Senate on May 23, 2002, authorizes \$545.25 million (out of a total of \$2.369 billion in the bill) to be appropriated for food safety counter-terrorism activities for FDA and USDA (see **Table 1**). Of the \$2.369 billion total appropriations authority in the Act, \$545.25 million (or 23%) is authorized for food protection and security related activities for the current fiscal year. For subsequent fiscal years, the bill authorizes such sums as necessary to carry out the activities. For FY2002, this bill provides for HHS and FDA together \$130.25 million, or 5.5%, of the bill's total authorizations, and for USDA \$415 million, or 17.5% of the total. The following table summarizes the proposed distribution of funds.

Table 1. Proposed Authorizations for Food Protection for FY2002 in the Public Health Security and Bioterrorism Preparedness and Response Act of 2001

(H.Rept. 107-481 as passed by both chambers)

| Section | Allocation | Proposed Authorizations |
|---------|---|-------------------------|
| 301 | HHS/Food Safety and Security Strategy | \$.75 million |
| 302 | HHS/FDA Protection Against Adulteration of Food | \$100 million |
| 311 | HHS/ Grants to States/Tribes For Inspections of Food Facilities | \$10 million |

| | | |
|-----|--|--|
| 312 | HHS/Surveillance and Information Grants and Authorities | \$19.5 million |
| 331 | USDA/APHIS Security | \$30 million |
| 332 | USDA/FSIS Security | \$15 million |
| 333 | USDA/ARS BioSecurity Upgrades Plum Island Research Center, Greenport, NY ARS/APHIS Research Facility, Ames, Iowa | \$180 million (\$100 million) (\$80 million) |
| 335 | USDA/Research and Development | \$190 million |
| | Total HHS/FDA | \$130.25 million |
| | Total USDA | \$415 million |
| | TOTAL PROPOSED FUNDING | \$545.25million |

Food Safety and Protection Measures in H.R. 3448 Conference Agreement

The food safety and protection measures included in the conference agreement on H.R. 3448 (H.Rept. 107-481) build upon long-standing concerns about the federal food safety system. These concerns include (1) whether FDA has sufficient statutory authority to oversee the food industry, and sufficient resources and personnel to carry out its mandate; and (2) whether FSIS has sufficient authorities and resources to assure the safety of meat and poultry. In this Act, Congress authorized the following extensions of FDA authority over food, particularly imports, to ensure better the prevention and tracking of food adulteration.

Registration of Food Processors. The Act requires FDA to establish a one-time registration system, within 18 months of enactment, for any domestic or foreign facility that manufactures, processes, packs, and handles food in or for the United States. The Act gives FDA authority to record all the identities (brand names) and the general food categories under which business is conducted, and the addresses of the facilities. In return, the Act requires each facility to be given a number so the list of registered facilities can be kept up to date. It allows the use of electronic submissions to register as long as there are validating protocols in place. Foreign facilities must name a U.S. agent in their registration. Restaurants, certain retail stores, non profit food and feeding establishments, fishing vessels, trucks and other motor carriers, and farms are exempt from registration requirements. The conference managers point out that a registration system will permit FDA to obtain an accurate inventory of its regulatory purview and will enhance its capability to trace back contaminated food. Critics argue, however, that registration creates an enormous and ineffective burden for FDA.

Record Keeping and Inspection. The Act authorizes the FDA to publish rules to require that food manufacturing establishments keep 2 years of production and distribution records. Under these rules FDA inspectors will have access to all processing, packing, holding, importing, and distribution records in the event of a suspected food safety problem. FDA is allowed to reduce the requirements for small businesses. The Act limits access to records that may contain trade secrets and/or confidential information on recipes, and financial, pricing, personnel, research, and sales data. The statutes governing meat and

poultry inspection already allow FSIS access to records of this type. As with facility registration, access to industry data will make it easier for the agency to determine the cause and scope of distribution of an adulterated or misbranded food. Such authority also allows the FDA to track and control better a food product suspected of being used in a biological attack, particularly if the records show an “immediate previous source” and “immediate subsequent source.” Opponents, however, are concerned that the standard permitting record inspection is very high and that the agency may not have the freedom to act if they need to.

Detention Authority. The Act gives FDA the authority to detain food imports under certain conditions. Currently, FDA must seek authorization from a judge to seize contaminated food and/or get an injunction to prohibit the food from entering commerce. The agency cannot require the owner of the product to hold it from further distribution. With new authority under the Act, and if “credible evidence” indicates that a food presents a threat of serious adverse health consequences or death to humans or animals, an FDA employee with the approval of the Secretary of HHS, can detain a suspected food for 20 days and up to 30 days, if necessary. The Act requires FDA to promulgate procedures that will expedite the processing of perishable foods so as not to unnecessarily ruin its marketability. An appeal of the detention is possible. The conference managers see such detention authority as helping prevent violative products from reaching consumers when a public health emergency is declared. Critics claim, however, that the phrase “a threat of serious adverse health consequences or death to humans or animals” is vague and therefore would be difficult to implement.

Prior Notice, Marking, and Prohibition of “Port Shopping”. The Act gives authority to FDA to prevent tampered or contaminated food from entering the country by requiring importers to give prior notice of the intent to import food with enough time for the Secretary to receive, review, and respond to the notice. If a notice is not given, the food will be considered adulterated. Food imports that are refused entry are to be marked *United States: Refused Entry*, and the Act makes the importer responsible for bringing the refused food shipment into compliance with U.S. regulations. These new FDA authorities, according to the conference managers, will protect U.S. consumers from unscrupulous importers and will help FDA ensure that imports comply with U.S. regulations. They also put into statute some of the requirements that FDA published as proposed rules, but never finalized, in the last few years. Critics claim that the increased regulation will likely add to the cost of imported products, and are not necessary because APHIS regulations already require importers to notify U.S. Customs in advance of importing most food products.

Debarment of “Bad Actor” Importers. The Act prohibits any importer who is a convicted felon 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. The Act does protect an innocent purchaser of the food if that person can show the imported food is in compliance with U.S. regulations. Critics say that FDA already has an import alert list of importers who have violated U.S. laws and does not need what they say is a redundant authority.

Authority for Joint Agency Inspections and for Funding to States for Inspections. The Act authorizes the Secretary to commission officials of other federal agencies to conduct examinations, inspections, investigations, and related activities at facilities jointly regulated by HHS and the other agency. The Act also authorizes

appropriations of (1) \$10 million in FY 2002 for grants to states and specified Indian tribes to conduct inspections; and (2) \$19.5 million to states and Indian tribes to expand their participation in food safety surveillance networks. The conference managers see these delegations of authority as rationalizing manpower and resources to provide for more inspections of food facilities. Opponents, however, are concerned about the risk of what they term as “overzealous” state and local officials making judgments about manufacturing procedures.

Research and Surveillance. The Act provides authorization for \$19.5 million for FY 2002 to be granted to states to expand their participation in PulseNet, FoodNet, and other networks that support the foodborne disease surveillance programs run by the CDC. It also requires that the Secretary coordinate surveillance for human and zoonotic diseases (the latter are animal diseases that can be transmitted to humans) through FDA, CDC, and USDA. The Act also will strengthen programs in the Agricultural Research Service and authorizes \$190 million for FY 2002 for state-level research, to enhance the scientific capacity for guarding against and responding to bioterrorism threats, and to continue existing partnerships with institutions of higher education, intelligence communities, and international organizations.

Increased Inspection and Security Upgrades at Food Safety Facilities. The Act authorizes appropriations of additional funds to (1) expand both FDA and USDA inspections; (2) plan for a bioterrorist response; (3) expand, upgrade, and secure their own public food facilities to make them less vulnerable to potential terrorist acts; and (4) collaborate with other federal and state agencies on these efforts. Critics of these provision point out that FDA, together with the food industry, has developed and promoted the adoption of “best practices” for the biosecurity of manufacturing facilities. Therefore, some food industry representatives claim that the industry already has completed this type of preparation and needs no further guidance or inspection.

The Act contains a separate subtitle that requires USDA to regulate hazardous biological agents and toxins contained in its agricultural research facilities by inventorying all such agents and restricting access to them. Finally, the Act creates new authority for civil fines and criminal penalties for anyone who damages or disrupts an animal or agricultural enterprise.

Other Food Safety Issues

Although Congress has addressed certain food safety related issues in the context of bioterrorism legislation, there are many who still maintain that some other and larger reforms are necessary to improve the overall performance of the nation’s food safety system.

Recall Authority. Some policy makers and consumer groups have argued for many years in favor of giving both FDA and FSIS the direct authority to order recalls of suspected contaminated foods. Currently, recalls are ordered by the manufacturer of the product on a voluntary basis, usually after consultation with FDA or FSIS officials. Critics of mandatory recall authority are concerned that it would give too much power to administrative officials and could result in drastic financial losses from suspected contamination incidents that could ultimately be proven false. Furthermore, opponents of mandatory recall say that the threat of adverse publicity from a recall holds most companies in compliance, and that there have

been few instances where companies have refused an FDA or USDA recommendation to issue a recall.

Shortly after September 11, 2001, Representative Udall introduced legislation that would amend the meat and poultry acts to authorize FSIS to recall suspected contaminated meats directly (H.R. 3127). An August 2000 GAO study on FSIS and FDA recalls (*Food Safety — Actions Needed by USDA and FDA to Ensure That Companies Promptly Carry Out Recalls*) 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. In addition to recall authority, civil penalty authority for FSIS has been proposed several times in recent years. One such bill has been introduced in the 107th Congress (H.R. 1276). Consumer groups and food safety advocacy groups have testified in favor of obtaining these new enforcement tools. Interest in these authorities could increase in light of the new awareness of the potential for bioterrorism.

Reorganization of the Federal Food Safety Regulatory Structure. For many decades there has been a debate about the federal regulatory structure 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. Two proposals (S. 1501, the Safe Food Act of 2001, and an identical bill, H.R. 1671) would place USDA's and FDA's food agencies (FSIS, CFISAN, and CVM) and the Department of Commerce's National Marine Fisheries Service into a single independent food safety agency. According to proponents of the single agency concept, the current system is fragmented and ill-equipped for meeting challenges from potential terrorist acts, as well as from emerging pathogens, aging populations, and increasing level of food imports. Supporters say that a single agency would result in a more consistent and efficient system for regulating food. Opponents maintain that a reshuffling of bureaucracies would not necessarily provide safer food or the additional resources needed for proper inspections. They also claim that food companies are doing their job in producing and distributing safe food.

At an October 10, 2001 hearing on food protection post-September 11, the GAO restated its long-standing criticism of the current food inspection system and reemphasized the National Academy of Sciences's (NAS's) 1998 report calling for greater coordination and statutory reform (see *Ensuring Safe Food from Production to Consumption*, available on the GAO Web site at [<http://www.gao.gov>]). On March 15, 2002, Food and Drug Administration Deputy Commissioner Lester Crawford said that he was taking calls for a single food safety agency seriously. Crawford's remarks followed those of Homeland Security Director Tom Ridge, who said at a recent food industry meeting that the Bush Administration is examining whether the food safety system, as it has evolved over several decades, is the best one for meeting future needs and threats. The Farm Security and Rural Investment Act of 2002, which the President signed into law on May 13, 2002, (H.R. 2646/S. 1731, the 2002 farm bill), contains a provision creating a 15-member Food Safety Commission that would review all the existing recommendations to improve food safety and within 1 year deliver a report to the President and Congress making comprehensive recommendations for enhancing the U.S. food safety system. Proposals to reorganize federal food safety agencies are absent from the President's Department of Homeland Security

proposal and from S. 2452, the National Homeland Security and Combating Terrorism Act of 2002.

Antimicrobial Resistance. Antimicrobials, a set of agents that include among others, antibiotics and disinfectants, have benefitted the public health by treating diseases that were un-treatable earlier. Antibiotics are also fed to farm animals to speed their growth, to promote the efficient use of the feed, and they are sprayed on crops similar to pesticides. Their widespread use may be causing some of these drugs to lose their ability to control disease, and some to become resistant to a number of antibiotics that are crucial for treatment of certain diseases. Although resistance to antibiotics has been noticed since they were introduced in the 1940's, more tracking (surveillance) and publicity has recently raised concern among some Members of Congress over this public health issue, particularly the use of antibiotics in food animals to promote growth. Some experts expect resistance problems to worsen in the future. (See CRS Report RL30814, *Antimicrobial Resistance: An Emerging Public Health Problem.*)

Defining appropriate legislative responses is particularly difficult given the complexity of the antimicrobial resistance problem, the lack of data to assess the problem, and the disagreement over the seriousness of the extent of the health threat of resistance. Use of antimicrobials in human medicine, for example, is thought to be the primary source of resistance. In addition, the uses of antibiotics in the agricultural sector have raised questions. The conflict there is over how much antibiotic use, both for treating disease and promoting growth, in food-producing animals contributes to resistant strains of bacteria.

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

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

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

government to identify incentives that can be used to promote the development of new human and animal drugs and their judicious use. A second plan will consider the implications of resistance internationally.

On February 27, 2002, the Preservation of Antibiotics for Human Treatment Act of 2002 (H.R. 3804) was introduced. The measure would prohibit approvals of new antimicrobial animal drugs unless the manufacturer could demonstrate that subtherapeutic use of the drug in animal feeds would not contribute to the development of antimicrobial resistance. The bill also would rescind existing approvals and exemptions concerning the nontherapeutic use of certain antimicrobial drugs until the same standard of lack of harm to human health is met. On May 13, 2002, Senator Ted Kennedy introduced a bill, the Preservation of Antibiotics for Human Treatment Act of 2002 (S. 2508) that is similar but not identical to H.R. 3804. It would prohibit the use of any antibiotic of the fluoroquinolone class to be used in poultry, and require that any new antimicrobial that would be used nontherapeutically would have to show that there was a lack of harm to human health. The conference report on H.R. 3448 authorizes \$25 million for FY2002 and FY2003 and such sums as may be necessary for FY2004-FY2006 for research and development initiatives for detection of antimicrobial resistance in priority pathogens.

Seafood Safety. The issue of risk of mercury exposure from fish consumption is receiving renewed attention. News media have been covering an environmental group's charge that the FDA does not adequately protect pregnant women and children from consuming too much mercury-containing fish, particularly canned tuna. Critics also claim that FDA has abandoned an ongoing mercury testing program that it ran in the 1990s. FDA officials state that the testing program revealed that mercury levels have remained stable over time, which is why the agency diverted resources to other purposes. They say furthermore that the agency's routine surveillance of the food supply consistently shows that mercury levels of popular seafoods remain below the FDA action level of 1 part per million. On March 6, 2002, Representative Pallone introduced legislation (H.R. 3885) that would require FDA to treat mercury as a food additive under the FFDCa and set a tolerance level for it that would guarantee "a reasonable certainty of no harm" from aggregate dietary exposure (among other things). S. 555 is a similar bill.

LEGISLATION

The bills are listed under their primary topic. The categories are not mutually exclusive.

Proposals Receiving Recent Action

H.R. 3448 (Tauzin/Dingell)

Public Health Security and Bioterrorism Preparedness and Response Act as introduced. As reported to the Senate, Bioterrorism Preparedness Act of 2001. Improves the ability of the United States to prevent, prepare for, and respond to bioterrorism and other public health emergencies. Introduced December 11, 2001; passed the House on December 12, 2001 under a suspension of the rules. On December 20, 2001, the Senate passed S. 1765 *in toto* in the nature of a substitute to H.R. 3448. Conference report (H. Rept. 107-481) filed in the

House on May 21; passed in the House on May 22; and passed in the Senate on May 23, 2002.

S. 1765 (Frist)

Bioterrorism Preparedness Act of 2001. Improves the ability of the United States to prepare for and respond to a biological threat or attack. Introduced December 4, 2001; passed the Senate, December 20, 2001, as a substitute in the form of an amendment to H.R. 3448.

H.R. 2646/S. 1731 (Combest/Daschle)

Farm Security and Rural Investment Act of 2002. Provides for the continuation of agricultural programs through FY2011. Contains provisions on bioterrorism preparedness, country-of-origin labeling of meats, irradiation labeling, and humane treatment of livestock, among other things. Conference agreement passed by the House on May 2 and by the Senate on May 8, 2002. Signed into law by the President on May 13, 2002 (P.L. 107-171).

S. 2452 (Lieberman)

The Department of National Homeland Security and Combating Terrorism Act of 2002. Provides for transferring functions from various regulatory and emergency response agencies to create a Department of National Homeland Security and creates a National Office for Combating Terrorism. Introduced on May 2, 2002; reported out of the Committee on Government Affairs with amendments on May 22, 2002.

Proposals Addressing USDA and FDA Enforcement Authorities

H.R. 1276 (Lowey)

Expands enforcement options under the Federal Meat Inspection Act and Poultry Products Inspection Act to include the imposition of civil money penalties against violators. Introduced March 28, 2001, and referred to the Committee on Agriculture.

H.R. 3075 (Dingell)

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

H.R. 3127 (Udall)

Unsafe Meat and Poultry Recall Act of 2001. Amends the Federal Meat Inspection Act and the Poultry Products Inspection Act to authorize the Secretary of Agriculture to order the recall of meat and poultry that is adulterated, misbranded, or otherwise unsafe. Introduced October 12, 2001, and referred to the Committee on Agriculture.

H.R. 3804 (Brown)

Preservation of Antibiotics for Human Treatment Act of 2002. Amends the FFDCFA to ensure that use of certain antibiotic drugs in animal agriculture do not compromise human health by contributing to the development of antibiotic resistance. Introduced February 27, 2002; referred to the Committee on Energy and Commerce, Subcommittee on Health, March 13, 2002.

H.R. 3885 (Pallone)

Seafood Safety and Mercury Screening Act of 2002. Amends the FFDCFA to require the Secretary of Health and Human Services to establish a tolerance for the presence of methyl mercury in seafood, and for other purposes. Introduced March 6, 2002; referred to the Committee on Energy and Commerce, Subcommittee on Health, March 26, 2002.

S. 555 (Leahy)

Mercury-Safe Seafood Act of 2001. Similar to H.R. 3885, it amends the FFDCFA to require the Secretary of Health and Human Services to establish a tolerance for the presence of methyl mercury in seafood. Introduced March 15, 2001; referred to the Senate Committee on Health, Education, Labor, and Pensions.

Proposals Addressing Consolidation of Food Safety Agencies**H.R. 1671 (DeLauro)**

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

S. 1501 (Durbin)

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

Proposals Addressing Antimicrobial Resistance**H.R. 3804 (Brown)**

Preservation of Antibiotics for Human Treatment Act of 2002. Amends the FFDCFA to ensure that use of certain antibiotic drugs in animal agriculture does not compromise human health by contributing to the development of antibiotic resistance. Introduced February 27, 2002; referred to the House Committee on Energy and Commerce, and on March 13, 2002, was referred to the Subcommittee on Health.

S. 2508 (Kennedy)

Preservation of Antibiotics for Human Treatment Act of 2002. Amends the FFDCFA to preserve the effectiveness of medically important antibiotics by restricting their use as additives to animal feed. Introduced May 13, 2002; referred to Senate Committee on Health, Education, Labor, and Pensions.