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How Vulnerable Is the Nation's Food Supply? Linking Food Safety and Food Security

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OVERVIEW — *This paper reviews the food safety regulatory apparatus in place today. It examines the system's strengths and vulnerabilities, particularly in light of the post-September 11 environment that includes the added threat of terrorism. The paper touches upon legislative and budgetary proposals aimed at improving food security, including the growing but debated interest in a single food safety agency.*

How Vulnerable Is the Nation's Food Supply? Linking Food Safety and Food Security

America's food supply has long been considered among the safest in the world. Long before the September 11 attacks on the United States, however, there was a growing debate over the ability—or, as some feared, the inability—of the current regulatory apparatus to ensure food safety.¹ Since September 11, the added threat of terrorism—deliberate sabotage of the nation's food supply—has added a new perspective to the dialogue. Along with many other issues once considered lower-priority, food safety has now become a national security concern. Some experts are concerned, however, that as the events of September 11 slowly recede from center stage, the demand for radical change will recede as well, despite the public health risks.

Robert A. Robinson, General Accounting Office (GAO) managing director for natural resources and environment, reiterated the significant public health problem posed by foodborne illnesses in his recent testimony before Congress: "Despite spending more than \$1 billion annually on the federal food safety system, food safety remains a concern...[The Centers for Disease Control and Prevention] CDC estimates that foodborne diseases cause approximately 76 million illnesses, 325,000 hospitalizations, and 5,000 deaths each year. In medical costs and productivity losses, foodborne illnesses related to five principal pathogens cost the nation about \$6.9 billion annually, USDA [U.S. Department of Agriculture] estimates."²

The American food industry is big business, accounting for close to 20 percent of the gross national product, employing approximately 14 million people, and providing an additional 4 million jobs in related industries. Further, American consumers spend more than \$617 billion annually on food, of which about \$511 billion is spent on foods grown on American farms.³ Deliberate contamination of the nation's food supply—possibly in a number of areas throughout the country simultaneously—would have devastating economic and geopolitical consequences. But it would not be the first time. One such incident occurred in 1984 when members of a religious cult known as the Rajneeshees contaminated salad bars in Oregon in order to incapacitate voters and affect the outcome of local elections.⁴ "Quietly, the small cadre of experts and federal officials who understood the power of germ weapons began to wonder if the attack in Oregon was an anomaly or a harbinger."⁵

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The CDC has cited the following biological agents as potential weapons that could be used to deliberately poison the nation's food supply: *Clostridium botulinum* (the causative agent of botulism), *Salmonella*, *Escherichia coli* 0157:H7 (better-known as *E. coli*), and *Vibrio cholerae* (the causative agent of cholera). Some experts have warned that terrorists could intentionally add these or other agents into legally or illegally imported foods, whereas other experts maintain that "the best way to sicken large numbers of people is to contaminate a giant processing center where meat or other foods are produced, packaged or distributed."⁶

It is possible that inspectors could discover deliberately placed or naturally occurring bacterial infections in a processing plant. Both before and after September 11, however, food experts have expressed a fundamental concern about fragmented and inconsistent inspection systems that lie at the core of the nation's food safety and food security vulnerabilities.

To assess these vulnerabilities, it is important first to understand how food safety is regulated across the food production chain. Then, areas of vulnerability can be identified and solutions designed to strengthen and improve both the safety and the security of the food supply. In addition to improving and strengthening surveillance systems and laboratory capacity, the proposals that have received the most attention include the establishment of a single food safety agency and the passage of a single food safety statute. While experts continue to debate the merits of each approach, inspectors across the country have been placed on high alert as they continue to monitor the nation's food supply.

MONITORING FOOD SAFETY FROM FARM TO TABLE: REGULATORY FRAGMENTATION AND INCONSISTENCY

Monitoring the nation's vast food-production network, ports of entry, and food-processing plants is a monumental endeavor; one that has been made more complicated by a variety of factors. These include the global marketplace for food, the emergence of new strains of foodborne bacteria, the growing number of people (that is, the elderly, the very young, and the immunosuppressed) at high risk for severe or fatal foodborne illnesses, the increasing reliance on minimally processed fresh fruits and vegetables, the growing popularity of raw foods, and the centralization and growth of large food processors and distributors.

Legal Authority, Overlap, and Inconsistencies

Federal interest in food safety began in the late 1800s. By the early 1900s, the first federal food safety agency was established in the United States. Over the years, as new challenges emerged, new agencies were created, resulting in the layers of complexity and fragmentation that exist today. There are at least 12 different federal agencies (see Appendix I)⁷ that

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administer 35 different laws that govern food safety, in addition to 28 House and Senate subcommittees with food safety oversight. In addition, state and local governments, health departments, and public health laboratories all play an active role in ensuring the safety of food. As a result of President Clinton's Food Safety Initiative of 1997, efforts to streamline the process have been made. The President's Council on Food Safety, for example, was established in August 1998 to provide a comprehensive national food safety strategic plan facilitating improved coordination between government agencies.⁸ Despite this and other sweeping changes, most would agree that the system and the statutes under which it operates are still in need of refinement.

The Federal Food, Drug, and Cosmetic Act, the Federal Meat Inspection Act, the Poultry Products Inspection Act, the Egg Products Inspection Act, the Food Quality Protection Act, and the Public Health Service Act are the principal U.S. food safety authorizing statutes. In addition, food regulatory agencies abide by, as regulatory agencies must, procedural statutes such as the Administrative Procedure Act, the Federal Advisory Committee Act, and the Freedom of Information Act.

Of the 12 federal agencies involved in food safety, two account for the majority of federal food safety spending and regulatory responsibilities: the Food and Drug Administration (FDA) within the Department of Health and Human Services (DHHS) and the Food Safety and Inspection Service (FSIS) within the USDA. In addition to these two lead agencies, others—such as the CDC, the Environmental Protection Agency, and the U.S. Customs Service—also play a vital role.

Disparities between the two lead agencies exist in terms of both resources and mandates. The FDA, for example, has 770 inspectors for 57,000 food establishments and 132 ports,⁹ while the USDA employs 7,600 inspectors for 6,500 meat and poultry plants and has another 5,000 inspectors and veterinarians working at ports and in veterinary laboratories and crop fields. The USDA handles inspections of meat, poultry, and processed egg products, while the FDA is charged with handling the safety of most other foods. Table 1 (see page 5) highlights some of the inconsistencies and disparities in inspection.¹⁰

Much of this inconsistency results from a system that evolved piecemeal over time and reflects legal requirements rather than level of risk. For example, as GAO's Robinson testified:

The number of agencies involved in regulating a sandwich illustrates the fragmented nature of the current food safety system....The responsible regulatory agency as well as the frequency with which inspections occur depends on how the sandwich is presented. FSIS inspects manufacturers of packaged open-face meat or poultry sandwiches (e.g., those with one slice of bread), but FDA inspects manufacturers of packaged closed-faced meat or poultry sandwiches (e.g., those with two slices of bread). According to FSIS officials, the agency lacked the resources to inspect all meat

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and poultry sandwich manufacturers, so it was decided that FSIS would inspect manufacturers of the less common open-faced sandwich, leaving inspection of other sandwich manufacturers to the FDA. Although there are no differences in the risks posed by these products, wholesale manufacturers of open-face sandwiches sold in interstate commerce are inspected by FSIS daily, while wholesale manufacturers of closed-face sandwiches sold in interstate commerce are generally inspected by the FDA on average once every 5 years.

TABLE 1
Examples of Inconsistencies and Disparities
in FDA and FSIS Inspection

Manufacturing Plant Inspected Daily by FSIS	Manufacturing Plant Inspected, on Average, about Once Every 5 Years by FDA
Open-faced meat and poultry sandwiches	Closed-face (traditional) meat and poultry sandwiches
Hot dog in pastry dough	Hot dog in a roll
Corn dog	Bagel dog
Beef broth	Chicken broth
Spaghetti sauce with meat stock	Spaghetti sauce w/o meat stock
Beans with bacon (2% or more bacon)	Pork and beans (no limit on amount of pork)
Pizza with meat topping	Pizza without meat topping
Soups with more than 2% meat or poultry	Soups with less than 2% meat or poultry

Source: U.S. General Accounting Office, Food Safety and Quality: Uniform, Risk-Based Inspection System Needed to Ensure Safe Food Supply (GAO/RCED-92-152, June 26, 1992).

In addition to differences in their resources and areas of oversight, the FDA and the USDA have divergent food safety philosophies, cultures, and bureaucratic structures. The FDA's inspectors, for example, take a more science-based approach to food safety, evaluating the entire food production process within an establishment. They do not, however, conduct any type of microbial analyses on site. Rather, this type of research is done by headquarters scientists. FDA inspectors also check for adherence to good manufacturing practices, an essential component of food safety that involves checking and auditing such vital areas as sanitary design,

cross-contamination control, production flow, cleanliness, personal hygiene, pest control, and supplier control, which involves the use of hazard analysis and critical control point (HACCP) systems.¹¹

USDA inspectors, on the other hand, conduct frequent plant inspections, focusing on a variety of aspects, such as cleanliness, that are related to the numerous steps involved in food processing and distribution. The USDA has interpreted its mandates (the Federal Meat Inspection Act, the Poultry Products Inspection Act, the Egg Products Inspection Act, and the Food Quality Protection Act) to mean having inspectors in the plants, using sight, smell, and touch to detect problems. While USDA food safety inspectors are highly trained (receiving a great deal of on-the job training), many do not hold college degrees. This is relevant in that some experts believe that the increased threat of a biologic attack on the nation's food supply necessitates a stronger emphasis on science-based food safety inspections.

In a 1998 report, *Ensuring Safe Food: From Production to Consumption*, the Institute of Medicine noted: "A science base for ensuring safe food encompasses many elements. When utilized, these elements improve the ability to identify, reduce, and manage risks; minimize occurrence of foodborne hazards; gather and utilize information; enhance knowledge; and improve overall safety."

The report lists the following as examples of science-based actions that have been implemented in the U.S. food safety system:

- Implementation of low-acid canned food processing technology, which reduces the risk of botulism.
- Implementation of HACCP systems and risk assessment in decision making.
- Use of labeling as a device to warn consumers who are sensitive to potential food allergens.
- Estimation of maximum allowable exposure levels to pesticides.
- Prohibition of the use of lead-based paints on utensils that come in contact with food.

The report also emphasizes that "an effective food safety system also integrates science and risk analysis at all levels of the system, including food safety research, information and technology transfer, and consumer education."

FDA: The Center for Food Safety and Applied Nutrition

It has been estimated that consumers spend 25 cents of every consumer dollar on products regulated by the FDA. Of this amount, approximately 75 percent is spent on foods.¹² CFSAN, the Center for Food Safety and Applied Nutrition, is the FDA center that, together with the FDA's field staff and the FDA's Center for Veterinary Medicine, is responsible for the safety of the nation's food supply.¹³

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CFSAN regulates approximately \$240 billion worth of domestic food and \$15 billion worth of imported foods, in addition to \$15 billion worth of cosmetics sold across state lines.¹⁴ The FDA's regulatory authority for food comes from a myriad of acts, including the Federal Food and Drugs Act of 1906; the Federal Import Milk Act (1927); the Federal Food, Drug, and Cosmetic Act of 1938, as amended; the Public Health Service Act (1944); the Fair Packaging and Labeling Act (1966); the Infant Formula Act of 1980, as amended; the Nutrition Labeling and Education Act of 1990; and the Dietary Supplement Health and Education Act of 1994.

The FDA spent more than \$280 million in fiscal year (FY) 2000 on food (and cosmetic) safety activities. Among the responsibilities included in these activities are the following:

- The safety of substances added to food, such as food and color additives.
- The safety of foods and ingredients developed through biotechnology.
- Seafood HACCP regulations.
- Juice HACCP regulations.
- Regulations and research programs to address health risks associated with foodborne, chemical, and biological contaminants.
- Regulations and activities dealing with the proper labeling of foods.
- Regulations and policy governing the safety of dietary supplements, infant formulas, and medical foods.
- Food industry postmarket surveillance and compliance.
- Consumer education and industry outreach.
- Cooperative programs with state and local governments.
- International food standard and safety harmonization efforts.¹⁵

The FDA reports that some of CFSAN's areas of food safety concern are biological pathogens (such as bacteria, viruses, and parasites), naturally occurring toxins, food tampering, and decomposition and filth. In addition, CFSAN specifically and the FDA generally have added bioterrorism and deliberate acts of food contamination to their list of priority concerns.

In an effort to address those concerns, the FDA issued two sets of guidelines to safeguard the food supply in early January 2002.¹⁶ One set of guidelines is for importers and filers and the other is for domestic food producers, processors, transporters, and retailers. Although the guidelines are not legally binding, they have the effect of regulation, and companies typically adhere to them.

The following are among FDA guidelines for bolstering security at U.S. food facilities:

- Restricting access to laboratories.
- Tracking which employees are on what shifts and monitoring employees coming in unusually early or staying late.

- Conducting regular inspections of employee lockers, bags, or vehicles.
- Restricting access to computer control systems.

FSIS: The USDA's Food Safety and Inspection Service

The USDA Office of Food Safety, headed by the under secretary for food safety, provides oversight of FSIS, which operates under the authority of the Federal Meat Inspection Act, the Poultry Products Inspection Act, and the Egg Products Inspection Act. In FY 1999, FSIS reported that it had inspected over 8.3 billion poultry, 155 million head of livestock, and 3.4 billion pounds of egg products. Imported meat and poultry products are also subject to FSIS scrutiny and, during 1999, nearly 3 billion pounds of meat and poultry from 32 countries passed inspection for entry into the United States.¹⁷ To accomplish these tasks, FSIS employees are stationed in about 6,000 establishments, including approximately 140 import stations. In order to fully protect the food supply, FSIS coordinates its policies with other USDA agencies, as well as the FDA, the EPA, the CDC and international organizations.

Among FSIS activities are the following:

- Inspecting poultry and livestock, as well as carcasses and processed products made from them. (FSIS inspection begins at the slaughter facilities; it does not have on-farm jurisdiction.)
- Inspecting all liquid, frozen, and dried egg products.
- Setting standards for plant sanitation, process controls, product contents (standards of identity), packaging and labeling, and microbial and chemical contamination.
- Analyzing products for microbiological and chemical adulterants.
- Conducting risk assessments, as well as epidemiologic and other scientific studies.
- Educating consumers about foodborne illness via publications, educational campaigns, and a toll-free, nationwide USDA meat and poultry hotline (1-800-535-4555).¹⁸

In addition, FSIS has authority to approve state meat and poultry inspection programs for products traveling in intrastate commerce. In addition to training and technical assistance to state and local agencies, FSIS reviews meat and poultry plant inspection programs to make sure that the state standards are at least equal to the federal standards. Through its Grants to States program, the USDA contributes up to 50 percent of each state's costs for complying with federal inspection requirements. Twenty-seven states currently participate in this program.

USDA efforts related to food security also extend to covering on-farm issues as well as working closely with FSIS's sister agency, APHIS, the Animal and Plant Health Inspection Service, which is responsible for

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protecting the United States from pests and diseases of plants and animals. APHIS is the lead agency involved in safeguarding against bovine spongiform encephalopathy (BSE), also known as “mad cow disease,” a potential biosecurity risk.

The USDA’s FY 2003 budget request for food safety provides \$905 million (a \$28 million dollar increase from FY 2002) to FSIS to fund 7,600 inspectors, veterinarians, and other food safety officials who protect the country’s meat, poultry, and egg supply. The proposed increase of funds includes \$14.5 million to improve FSIS’s information technology infrastructure through the implementation of the FSIS Automated Corporate Technology Suite (FACTS). According to Elsa Murano, under secretary for food safety, “This budget request takes food safety to the next level.”

The next level of food safety involves preparing for unintentional as well as intentional outbreaks of foodborne diseases. In her testimony before Congress in March 2002, Murano articulated five goals USDA was pursuing in protecting the public’s health. These are (a) protect meat, poultry, and egg products against intentional harm; (b) improve upon the overall management and effectiveness of FSIS programs; (c) enhance coordination of food safety activities within and outside of the USDA; (d) use science to guide future policy decisions, and (e) significantly enhance outreach and public education efforts.

The first goal, protecting against intentional harm, involves several initiatives. For example, within the department, the USDA Homeland Security Council was established to serve as the lead group charged with coordinating all USDA-wide homeland security issues. Within FSIS, Murano explained, there is now an internal group known as F-BAT, the Food Biosecurity Action Team, which was formed to “coordinate and facilitate all activities pertaining to biosecurity, countering terrorism, and emergency preparedness within the agency. F-BAT also serves as FSIS’s voice with other government agencies, and internal and external constituents on biosecurity issues.”

FUNDING BIOSECURITY IN THE FOOD CHAIN

All of these efforts to insure food safety cost money. Funding for improved food safety and increased counterterrorism measures come from a variety of sources. Shortly after the September 11 attacks, for example, Congress passed the Emergency Supplemental Appropriations Act for Recovery from and Response to Terrorist Attacks on the United States (P.L. 107-38) authorizing \$40 billion for antiterrorism and disaster relief efforts. The law stipulated that the \$40 billion be divided in half—\$20 billion for the president to combat terrorism and \$20 billion for congressional action.

Of the first \$20 billion emergency relief monies, funds were allocated to both the FDA and the USDA to, among other things, improve homeland

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security through food safety enhancements. Similarly, the FY 2002 Department of Defense Appropriations Act (P.L. 107-117) included language allocating the remaining \$20 billion. A portion of those funds again went to the USDA and the FDA: \$15 million was allocated to the USDA's FSIS "for emergency expenses to respond to the September 11, 2001, terrorist attacks" and \$105 million to USDA's APHIS. Of the \$151.1 million designated for the FDA, \$97.1 million was to be used for food safety activities. The remaining \$54 million was divided among improving facilities and security (\$13.25 million) and ensuring the wider availability of drugs, vaccines, and medical devices (\$40.75 million).

Much of the FDA food safety money is to be used to enhance food safety by increasing inspections of imported food products. The new funding would enable the FDA to hire approximately 400 more inspectors, 150 laboratory analysts, and 84 compliance officers and domestic investigators, as well as 38 employees for assignments associated with regulatory compliance policy, risk assessments, and rapid analytical methods. In addition, a portion of the extra funding would allow for the expansion of the FDA's information systems used in monitoring imports and tracking disease.

The president's FY 2003 budget provides a total of \$4.3 billion for DHHS' bioterrorism preparedness programs and activities. This includes \$98 million for FDA food safety activities and \$7 million for the FDA's physical security.

In a January 31, 2002, news release, USDA Secretary Ann M. Veneman announced that "In his budget proposal for FY 2003, President Bush will include \$131 million in new spending to protect the nation's food supply from animal and plant pests and diseases, strengthen food safety programs and support specific research activities." Among the many initiatives outlined in the budget proposal, FSIS is slated to receive an additional \$28 million to support FSIS food safety activities. This funding earmarks \$14.5 million for enhancing the information technology infrastructure to improve risk management systems and \$2.7 million for epidemiological surveys of animal slaughter-related hazards and risk prevention activities.

ONGOING EFFORTS TO IMPROVE FOOD SAFETY AND SECURITY

Experts agree that money alone will not be enough. Despite the cooperation among agencies and several food safety achievements, many flaws, inconsistencies, and holes remain throughout the food safety net. Efforts are under way to close these safety gaps and mend the security holes.

Surveillance: Monitoring Foodborne Diseases

Preventing foodborne illnesses is the primary object of all the agencies—federal, state, and local. One of the most powerful tools available in

recognizing and identifying a foodborne disease outbreak—whether intentional or unintentional—are surveillance systems. As the September 2001 GAO report, “Food Safety: CDC Is Working to Address Limitations in Several of Its Foodborne Disease Surveillance Systems,” points out:

Surveillance of foodborne diseases allows public health officials to recognize trends, detect outbreaks, pinpoint the causes of these outbreaks, and develop effective prevention and control measures. Such surveillance presents a complex challenge. Many foods today are imported, prepared and/or eaten outside the home, and widely distributed after processing. As a result, an outbreak of foodborne disease can involve people in different localities, states, and even countries. The number and diversity of foodborne disease further complicate surveillance.¹⁹

Through the use of cooperative surveillance and monitoring efforts, many of the various agencies have partnered to share information and identify problems. The Foodborne Diseases Active Surveillance Network (FoodNet),²⁰ PulseNet,²¹ and eLEXNET²² are all examples of successful collaborative efforts.

Surveillance is one part of the overall public health infrastructure. The public health apparatus, with its laboratories, epidemiologists, and surveillance systems, has been a critical resource in preventing and identifying foodborne disease outbreaks. In their March 2002 article, “Threat of a Biological Terrorist Attack on the U.S. Food Supply: The CDC Perspective,” Jeremy Sobel, Ali S. Khan, and David L. Swerdlow write:

The adequacy of response will depend on the capacity of public-health officials to respond to all foodborne disease outbreaks. Hence, a cornerstone of preparedness is improvement of the public-health infrastructure for detection and response to unintentional outbreaks: ensuring robust surveillance, improving laboratory diagnostic capacity, increasing trained staff for rapid epidemiological investigations, and enhancing effective communications. Preparedness for such a situation also requires the capacity to respond to extraordinary demands on emergency services and medical resources.²³

A Single Food Safety Agency, A Single Food Safety Statute

The 1998 IOM report on food safety described an effective food safety system as a “dynamic interdependence” “aligned to the unified mission of improving food safety so as to maintain and improve the public’s health and well-being.” The system described in the report comprises three key, independent partners—government agencies at all levels, business and other private-sector organizations, and consumers—supported by other players, such as institutions of higher education, the news media, and focused special interest groups. These supportive players, said the report, are “critical to the integration of...research, education, and information.” While a certain degree of interdependence is necessary, however, critics of the current system are concerned with the level of

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fragmentation that exists in both the number of government agencies involved as well as in the number of food safety–related laws.

As a necessary component of the bioterrorism preparedness efforts, several experts have called for a re-examination of the fragmentation and inconsistency that exists in the food safety apparatus. Security specialists and food safety gurus are all anxious to provide a framework that will mend the holes in the food safety net. While they share the same goal, their means for reaching it differ. Some experts are calling for a single, unified food safety statute; others are pushing to consolidate the various food safety responsibilities into a single entity.²⁴

On the subject of a single food safety entity, Tom Ridge, White House director of homeland security, spoke at a national security conference on November 15, 2001: “We need to consider this in light of homeland security, whether or not we want to have multiple organizations basically tasked with the same responsibility, or if we couldn’t enhance our security, improve our efficiency and maybe save a few bucks and put them someplace else for enhanced security if we merged functions.”²⁵

At an industry-sponsored food safety conference held in March 2002, Lester Crawford, D.V.M., Ph.D., the FDA’s acting principal deputy commissioner (and previous head of the USDA’s FSIS), and Ridge both questioned whether the current division of food safety responsibilities made sense in today’s environment. Along with several consumer groups and the supermarket industry, Sen. Richard Durbin (D-Ill.) has, for a number of years, been campaigning for a single food agency. Although the food processors and grocery manufacturers are extremely concerned about the notion of a single food safety agency, believing it would be “very disruptive,” the idea is gaining momentum in and around Capitol Hill. Proponents of a single food agency are concerned, however, that chances of such a merger may grow slimmer as the shock of September 11 lessens.

Improving Food Safety and Security through Legislation

Other legislative and regulatory proposals concerned with improving food security, in light of September 11, have been floated in and around the Capitol. Two of these bills, S. 1765, introduced by Sens. William Frist (R-Tenn.) and Edward M. Kennedy (D-Mass.), and H.R. 3448, authored by Reps. W. J. Tauzin (R-La.) and John Dingell (D-Mich.) have been analyzed by the Congressional Research Service in a March 8, 2002, side-by-side analysis entitled “Bioterrorism: Legislation to Improve Public Health Preparedness and Response Capacity” (See Appendix II). These bills are currently in conference. The provisions in both bills span a variety of topics, including the development of a strategic plan for food safety and security, USDA activities, DHHS and FDA biosecurity, food detention, debarment from importing food, maintenance and inspection of records, registration of food facilities, prior notice of imported food shipments, authority to commission other federal officials to conduct

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inspections, prohibition against port shopping, grants to states for inspection, notices to states regarding imported food, and the surveillance of animal and human health. Capitol Hill staff are of the opinion that the timetable for the entire bioterrorism bill to be completed is on track for Memorial Day recess. As of this writing, the food safety section (Title III) is one of the sections that is furthest along in terms of negotiation. While the Senate bill contains more language on agricultural terrorism than the House bill, Senate staff point out that the Senate version is essentially a restatement of the existing agriculture authority and are hopeful that the negotiations which are currently underway will wrap up by the Memorial Day recess.

The post-September 11 atmosphere has triggered a heightened awareness and a palpable sense of urgency. Given the potential for the deliberate sabotage of the food supply, Congress, the FDA, the USDA, and all the state and federal agencies associated with food safety—and now with security as well—have acknowledged that they are on a heightened state of alert.

ENDNOTES

1. This paper does not address the issue of the vulnerability of the nation's water supply.
2. Robert A. Robinson, "Food Safety and Security: Fundamental Changes Needed to Ensure Safe Food," testimony before the Subcommittee on Oversight of Government Management, Restructuring and the District of Columbia, Committee on Governmental Affairs, U.S. Senate, October 10, 2001 (GAO-02-47T), U. S. General Accounting Office, Washington, D.C., 2.
3. Sen. Richard Durbin, statement on reintroduction of the Safe Food Act (S. 1501), October 4, 2001.
4. See Judith Miller, Stephen Engelberg, and William Broad, "Chapter 1—The Attack," in *Germs: Biological Weapons and America's Secret War* (New York: Simon & Schuster, 2001) for a detailed account of these incidents.
5. Miller, Engelberg, and Broad, *Germs*, 33.
6. Richard V. Lee, M.D., in Wes Allison, "Expert: Food Not Prone to Sabotage," *St. Petersburg Times*, November 30, 2001.
7. Robinson, "Food Safety," Appendix I.
8. Nick Littlefield and Nicole R. Hadas, "A Survey of Developments in Food and Drug Law from July 1998 to November 1999," *Food and Drug Law Journal*, 55: 56.
9. Currently, the Food and Drug Administration physically inspects less than 1 percent of food imports each year.
10. Robinson, "Food Safety," Appendix I, 20.
11. HACCP systems are a major and fairly new systematic approach to food safety via "the identification and control of the biological, chemical, and physical hazards that are reasonably likely to occur in a particular food in a particular production process....HACCP is a risk-based, food safety management system that helps food manufacturers determine which hazards are reasonably likely to affect their products and then to develop safety assurance programs targeted to the specific steps that must be controlled to safeguard consumers." HACCP systems are required of all meat and poultry plants, in addition to their use with seafood. (Bernard A. Schwetz, D.V.M., Ph.D., then acting principal deputy commissioner of

the FDA, testimony before the Committee on Governmental Affairs, Subcommittee on Oversight of Government Management, Restructuring and the District of Columbia, U.S. Senate, October 10, 2001; accessed April 8, 2001, at <http://www.fda.gov/ola/2001/foodsafety1010.html>.)

12. Food and Drug Law Institute, *2001 FDA Directory*, Issue 2, July–December 2001, Food and Drug Law Institute, Washington, D.C., 2001, 61.

13. The Center for Food Safety and Applied Nutrition is also responsible for ensuring that cosmetic products are safe and properly labeled.

14. Food and Drug Administration, “Center for Food Safety and Applied Nutrition—Overview”; accessed November 30, 2001, at <http://www.cfsan.fda.gov/~lrd/cfsan4.html>.

15. Food and Drug Administration, “Center.”

16. See Food and Drug Administration, “Guidance for Industry—Food Producers, Processors, Transporters, and Retailers: Food Security Preventive Measures Guidance,” at <http://www.cfsan.fda.gov/~dms/secguid.html>, and “Guidance for Industry—Importers and Filers: Food Security Preventive Measures Guidance,” at <http://www.cfsan.fda.gov/~dms/secguid2.html>.

17. U.S. Department of Agriculture, “Food Safety,” in *Agriculture Fact Book*, 139-140; accessed November 8, 2001, at <http://www.fsis.usda.gov/oa/pubs/fsisfact2000.pdf>.

18. Agriculture, “Food Safety,” 139.

19. U.S. General Accounting Office, “Food Safety: CDC Is Working to Address Limitations in Several of Its Foodborne Disease Surveillance Systems” (GAO-01-973), Washington, D.C., September 2001; accessed November 8, 2001, at <http://www.gao.gov/new.items/d01973.pdf>.

20. FoodNet is part of the CDC’s Emerging Infections Program, a collaborative project of the CDC, the USDA, the FDA, and nine states.

21. PulseNet, developed by the CDC, enables a national network of public health laboratories to “fingerprint” bacteria that may be foodborne and compare results through an electronic database maintained by the CDC. It is a collaborative effort of the CDC, the FDA, the USDA, and all 50 states.

22. eLEXNET, the electronic Laboratory Exchange Network, is a seamless, integrated, secure network developed by the FDA to provide access to critical food testing data in federal, state, and local food safety laboratories.

23. Jeremy Sobel, Ali S. Khan, and David L. Swerdlow, “Threat of a Biological Terrorist Attack on the U.S. Food Supply: The CDC Perspective,” *Lancet*, 359 no. 9309 (March 9, 2002); accessed April 10, 2002, at <http://www.thelancet.com/journal/vol359/iss9309/>.

24. Sen. Richard Durbin (D-Ill.) has been one of the most outspoken advocates of a single, independent agency, the Food Safety Administration, that he calls for in S. 1281, the Safe Food Act of 1999.

25. Julie Vorman, “Bush Admin Revives Idea of Single U.S. Food Agency,” Reuters, Washington, D.C., November 16, 2001; accessed November 16, 2001, at http://dailynews.yahoo.com/hx/nm/20011116/hl/food_2.html.

Appendix I: Food Safety Responsibilities and FY 2000 Funding and Staffing Levels at 12 Federal Agencies

Agency	FY 2000 Funding ^a (in millions)	FY 2000 Staffing
Food and Drug Administration (FDA), within the Department of Health and Human Services (HHS), is responsible for ensuring that domestic and imported food products (except meat, poultry, and processed egg products) are safe, wholesome, and properly labeled. The Federal Food, Drug, and Cosmetic Act, as amended, is the major law governing FDA's activities to ensure food safety and quality. The act also authorizes FDA to conduct surveillance of all animal drugs, feeds, and veterinary devices to ensure that drugs and feeds used in animals are safe, effective, and properly labeled and produce no human health hazards when used in food-producing animals.	\$323 ^b	2,828 ^b
Centers for Disease Control and Prevention (CDC), within HHS, is charged with protecting the nation's public health by leading and directing the prevention and control of diseases and responding to public health emergencies. CDC conducts surveillance for foodborne diseases; develops new epidemiological and laboratory tools to enhance surveillance and detection of outbreaks; and performs other activities to strengthen local, state, and national capacity to identify, characterize, and control foodborne hazards. CDC engages in public health activities related to food safety under the general authority of the Public Health Service Act, as amended.	29	66
Food Safety and Inspection Service (FSIS), within the U.S. Department of Agriculture (USDA), is responsible for ensuring that meat, poultry, and some eggs and egg products moving in interstate and foreign commerce are safe, wholesome, and correctly marked, labeled, and packaged. FSIS carries out its inspection responsibilities under the Federal Meat Inspection Act, as amended, the Poultry Products Inspection Act, as amended, and the Egg Products Inspection Act, as amended.	649 ^c	9,545
Animal and Plant Health Inspection Service (APHIS), within USDA, is responsible for ensuring the health and care of animals and plants. APHIS has no statutory authority for public health issues unless the concern to public health is also a concern to the health of animals or plants. APHIS identifies research and data needs and coordinates research programs to protect the animal industry against pathogens or diseases that are a risk to humans to improve food safety.	d	d
Grain Inspection, Packers and Stockyards Administration (GIPSA), within USDA, is responsible for establishing quality standards and providing for a national inspection system to facilitate the marketing of grain and other related products. Certain inspection services, such as testing corn for the presence of aflatoxin and starlink, enable the market to assess the value of a product on the basis of its compliance with contractual specifications and FDA requirements. GIPSA has no regulatory responsibility regarding food safety. Under a memorandum of understanding with FDA, GIPSA reports to FDA certain lots of grain, rice, pulses, or food products (which were officially inspected as part of GIPSA's service functions) that are considered objectionable under the Federal Food, Drug, and Cosmetic Act, as amended, the U.S. Grain Standards Act, as amended, and the Agriculture Marketing Act of 1946, as amended.	d	d
Agricultural Marketing Service (AMS), within USDA, is primarily responsible for establishing quality and condition standards and for grading the quality of dairy, fruit, vegetable, livestock, meat, poultry, and egg products. As part of this grading process, AMS considers safety factors, such as the cleanliness of the product. AMS also runs a voluntary pesticide data program and carries out a wide array of programs to facilitate marketing. It carries out these programs under more than 50 statutes, including the Agricultural Marketing Agreement Act of 1937, as amended; the Agricultural Marketing Act of 1946, as amended; the Egg Products Inspection Act, as amended; the Export Apple and Pear Act, as amended; the Export Grape and Plum Act, as amended; the Federal Seed Act; and the Food Quality Protection Act. AMS is largely funded with user fees.	13 ^e	26 ^e

Appendix 1 (cont.)

Agency	FY 2000 Funding ^a (in millions)	FY 2000 Staffing
Agricultural Research Service (ARS), within USDA, is responsible for conducting a wide range of research relating to the Department’s mission, including food safety research. ARS carries out its programs under the Department of Agriculture Organic Act of 1862; the Research and Marketing Act of 1946, as amended; and the National Agricultural Research, Extension, and Teaching Policy Act of 1977, as amended.	82	222
National Marine Fisheries Service (NMFS), within the Department of Commerce, conducts voluntary seafood safety and quality inspection programs under the Agricultural Marketing Act of 1946, as amended, and the Fish and Wildlife Act of 1956, as amended. NMFS provides inspection and certification services for fishery products for human consumption, as well as for animal feeds and pet foods containing a fish base.	^f	165 ^f
Environmental Protection Agency (EPA) is responsible for regulating all pesticide products sold or distributed in the United States and setting maximum allowed residue levels for pesticides on food commodities and animal feed. EPA conducts these activities under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, and the Federal Food, Drug, and Cosmetic Act, as amended.	171	1,076
Federal Trade Commission (FTC) enforces the Federal Trade Commission Act, which prohibits unfair or deceptive acts or practices. FTC’s food safety objective is to prevent consumer deception through the misrepresentation of food.	^g	^g
U.S. Customs Service, within the Department of the Treasury, is responsible for collecting revenues and enforcing various customs and related laws. Customs assists FDA and FSIS in carrying out their regulatory roles in food safety.	^g	^g
Bureau of Alcohol, Tobacco, and Firearms, within the Department of the Treasury, is responsible for administering and enforcing laws covering the production (including safety), use, and distribution of alcoholic beverages under the Federal Alcohol Administration Act and the Internal Revenue Code.	^g	^g
Total	\$1,267	13,928

^a Fiscal year 2000 appropriated funds.

^b FDA’s data includes funding and staffing for various programs across FDA that are involved with food safety activities, including the Center for Food Safety and Applied Nutrition, the Center for Veterinary Medicine, the National Center for Toxicological Research, and the field components for these centers.

^c FSIS’ total funding for fiscal year 2000 was \$751 million, which includes appropriated funds, reimbursements, and trust funds.

^d The agency did not specify its food safety resources.

^e AMS’ funding and staffing are for Food Quality Protection Act information gathering only.

^f NMFS’ activities were funded through \$12.4 million in user fees, not appropriated funds.

Funding and staffing levels are for both safety and quality inspection activities.

^g We [GAO] did not obtain these agencies’ food safety budgets due to the small amount of funds for these activities in previous years.

Source: U.S. General Accounting Office, Food Safety and Security: Fundamental Changes Needed to Ensure Safe Food (GAO-02-47T, October 10, 2001); federal agencies’ data.

Appendix II: Food Supply Safety and Security Side-by-Side

(Excerpted from C. Stephen Redhead, Donna U. Vogt, and Mary E. Tiemann, "Bioterrorism: Legislation to Improve Public Health Preparedness and Response Capacity," Congressional Research Service, Washington, D.C., updated March 8, 2002)

Topic	Current Law	S. 1765 Frist/Kennedy	H.R. 3448 Tauzin/Dingell
Strategic Plan for Food Safety and Security	Executive Order 13100 created the President's Council on Food Safety, headed by the Secretaries of Agriculture and Health and Human Services, the Administrator of the Environmental Protection Agency, and the Assistant to the President for Science and Technology. On January 18, 2001, the Council published a strategic plan for food safety which contained recommendations on making statutory changes to unify federal food safety regulations.	Requires the Council, along with the Secretaries of Commerce and Transportation, and in consultation with states, the food industry, and consumer and producer groups, to develop a crisis communications and education strategy for bioterrorist threats to the food supply that includes threat assessments, response and notification procedures, and public risk communication plans. Authorizes \$500,000 for FY2002, and such sums as may be necessary in each subsequent fiscal year, to implement the strategy. [Section 511]	No provisions.
USDA Activities	USDA's Food Safety and Inspection Service (FSIS) inspects meat, poultry, and processed egg products sold for human consumption for safety, wholesomeness, and proper labeling. The Animal and Plant Inspection Service (APHIS) inspects cargo and passengers at U.S. ports for animal and plant pests, quarantines some of these products, and responds to animal disease outbreaks. The Agricultural Research Service (ARS) conducts research on animal diseases and food safety to support other USDA regulatory responsibilities.	Authorizes \$15 million for enhanced FSIS inspections domestically and internationally and collaboration with other federal agencies; \$30 million for APHIS for increased inspections, cooperative agreements with state and private veterinarians, and an automated, integrated, interagency emergency warning, response, and record-keeping system; and \$180 million for upgrading biosecurity at ARS labs in New York and Iowa. Authorizes the Secretary of Agriculture to use \$20 million in FY2002 to award up to \$45,000 each to land grant universities to establish security at facilities, inventory hazardous toxins, develop a screening protocol for access to facilities, and develop industry-on-farm education program. Authorizes a total of \$245 million for FY2002 for USDA biosecurity efforts and such sums as necessary for each fiscal year thereafter. [Section 512, 513, 515, 527]	No provisions

Topic	Current Law	S. 1765 Frist/Kennedy	H.R. 3448 Tauzin/Dingell
HHS and FDA Biosecurity	FFDCA Chapter IV prohibits the entry into interstate commerce of adulterated or misbranded foods. FDA monitors through inspections whether food manufacturers adhere to their legal responsibility to produce food that is not defective, unsafe, filthy, or produced under unsanitary conditions.	Requires the Secretary of HHS to secure existing facilities where potential animal or plant pathogens are housed and researched. Authorizes \$59 million to expand FDA's inspections and collaboration with other federal, state, and tribal agencies. Authorizes \$500,000 for the Secretary to develop best practices for biosecurity for use by food manufacturers, processors, and distributors. Authorizes a total of \$59.5 million for FY2002 for HHS agencies and such sums as may be necessary for each fiscal year thereafter. [Section 514,516,518]	Authorizes a total of \$100 million for the Secretary of HHS to increase inspections for the detection of intentional adulteration of imported food; to give high priority to improving FDA's information management systems; to develop tests and sampling methods to rapidly detect intentionally adulterated food; and to complete an assessment of threats to food posed by intentional adulteration and report its findings on these protective activities to Congress.[Section 301]
Food Detention	FFDCA Section 304 allows for the seizure of food in interstate commerce under restricted circumstances.	Amends FFDCA Section 304 to authorize the detention of food for 20 days, and if needed for 30 days, if an officer or qualified employee of FDA has credible evidence (and the Secretary approves) showing the food violates the FFDCA and presents a threat of serious adverse health consequences or death to humans or animals. The detained food must be secured, and the responsible person can file an appeal within 15 days with expedited procedures for perishable foods. Adds a new definition to FFDCA Section 310 prohibiting removal of product or mark or label from the detained product. [Section 531]	Similar to provisions in S. 1765, except that it limits detention approval authority to the Secretary or the Secretary's designee. It also does not set a time limit on the appeal, but does require that FDA make a final decision within 72 hours on the appeal. Authorizes the Secretary to request the Treasury Secretary to temporarily hold imported food at a port for 24 hours, if FDA has credible evidence indicating that the food presents a threat, to allow FDA to determine whether to detain it. Requires that the Secretary notify the state in which the involved port is located. [Section 302]
Debarment for Food Imports	FFDCA Section 306 gives the Secretary of HHS authority to debar, temporarily deny approval, or suspend the rights of individuals who have been convicted of a felony to submit an application for approval of a drug.	Amends FFDCA Section 306 to debar from importing foods any person who is convicted of a felony related to the importation of food or who repeatedly imports, or knows, or should have known, that the imported food that was adulterated or misbranded. Amends FFDCA Section 402 to include in the definition of "adulterated food" any food imported by debarred persons. [Section 532]	Similar provisions. [Section 303]

Topic	Current Law	S. 1765 Frist/Kennedy	H.R. 3448 Tauzin/Dingell
Maintenance and Inspection of Records	<p>FFDCA Section 704 authorizes FDA to conduct factory inspections. Currently, FDA inspectors have access to company records but can only request access to copy, and verify records for restricted medical devices, prescription drugs, not for foods. Inspectors may not require that records be kept nor do officials have authority to copy records found during inspections.</p>	<p>Add a new Section 414 to the FFDCA allowing the Secretary, if a food is believed to be adulterated or misbranded and presents a threat of serious adverse health consequences or death to humans or animals, to have access to and to copy all records related to the food. Excludes restaurants and farms, and has reduced requirements for small businesses (less than 50 employees.) Requires records to be kept for 2 years so food can be investigated. Excludes records on USDA-regulated foods (meat, poultry, and egg products), and on trade secrets and/or confidential information on recipes, and financial, pricing, personnel, research, and sales data. Amends FFDCA Section 704 to add a clause to allow the inspection of all records and other information described in the new Section 414. Requires final rules to be issued on record keeping within 18 months. [Section 533]</p>	<p>Similar provisions to S. 1765, but includes language that requires the Secretary to put into effect procedures to prevent unauthorized disclosure of any trade secrets or confidential information. Also provides authority to the Secretary to take into account the size of the business when imposing any record keeping requirements. Does not impose a time limit for promulgation of rules. [Section 304]</p>
Registration of Food Facilities	<p>Currently, only States have records of food processing, packing and holding facilities. The federal government must ask the states for this information.</p>	<p>Creates a new Section 415 in the FFDCA requiring all facilities, domestic and foreign, that manufacture, process, and handle food to register with the Secretary all the identities (brand names) under which business is conducted, addresses of the facilities, and general food categories. Foreign registrations must name a U.S. agent. Requires the Secretary to give each facility a number and keep the list of registered facilities up to date. Exempts certain retail stores and farms from registration requirements. Registration does not imply a license. Requirements for registration would take effect 180 days after enactment. Amends Section 403 to prohibit interstate commerce of food from unregistered facilities. [Section 534]</p>	<p>Similar provisions to S. 1765, but applies requirements to facilities that manufacture, process, pack or hold food (excludes farms.) Adds that the Secretary may provide for and encourage the use of electronic submissions to register as long as there are authorization protocols used to identify the registrant and validate the data. Adds that the Secretary must within 60 days identify facilities required to register, and, as S. 1765, enforce the registration within 180 days of the Act's enactment. Exempts only retail establishments from registration requirements. Specifies that registration requirements would not apply to food products regulated by USDA. [Section 305]</p>

Topic	Current Law	S. 1765 Frist/Kennedy	H.R. 3448 Tauzin/Dingell
Prior Notice of Imported Food Shipments	Under FFDCCA Section 801, a food that (i) is found to be manufactured, processed, or packed under unsanitary conditions, (ii) is forbidden or restricted in the producing country or from where it was exported, or (iii) is adulterated or misbranded at the border, can have its admission deferred while the food is reconditioned, relabeled or destroyed.	Amends FFDCCA Section 801 to require a producer, manufacturer, or shipper of imported food, at least 4 hours before it is imported, to document its identity, country of origin, and quantity imported to FDA and the U.S. Customs or the import can be refused entry. Exempts all USDA-regulated foods (meat, poultry, and egg products.) Prohibits knowingly making a false statement in the import documentation. [Section 535]	Similar provisions to S. 1765, except the advance period for submission of documentation is to be not less than 24 hours nor more than 72 hours before importation of the food. The required information includes a description of the food, the identity of the manufacturer and shipper, if possible the grower, the country of origin of the food, the country from which the article is shipped, and the anticipated U.S. port of entry. Without a notice, the food will be refused admission or held until the required information is provided and a determination that the food is not a serious health threat to humans or animals. The Secretary can ask for more information. This provision excludes USDA regulated products. [Section 306]
Mark Articles Refused Admission	The FFDCCA Section 403 defines misbranded foods as food whose labeling or advertising is false or misleading. Section 801(a) gives the Secretary the general authority to refuse imports deemed adulterated or misbranded.	Amends both Sections 403 and 801(a) definitions of misbranded food to include food that has been refused admission to the United States and not destroyed and which presents a threat of serious adverse health consequences or death, unless the packaging is clearly and conspicuously labeled: <i>United States: Refused Entry</i> at the expense of the food's owner until the food is brought into compliance. [Section 536]	Similar provisions to S. 1765. [Section 307]
Authority to Commission Other Federal Officials to Conduct Inspections	The FFDCCA Section 702 states that the Secretary is authorized to conduct food inspections (examinations and investigations) through officers and employees of HHS, or any health, food, or drug officer of a state that has been duly commissioned by the Secretary as an officer of the Department.	Amends FFDCCA Section 702 to provide the authority to commission qualified federal officials from other departments or agencies to conduct inspections. This can only happen if there are no current laws restricting the use of a department or agency officers, employees, or funds. [Section 537]	No provisions.

Topic	Current Law	S. 1765 Frist/Kennedy	H.R. 3448 Tauzin/Dingell
Prohibition against Port Shopping	The FFDCa Section 402 defines “adulterated” food as any food that bears or contains any poisonous or deleterious substance which may render it injurious to health.	Amends FFDCa Section 402 to require that an importer offering food that has been refused admission prove at his own expense that the food is in compliance with the applicable requirements of the Act. [Section 538]	Similar provisions to S. 1765 except that importer, at his own expense, must prove that the article is not adulterated, as determined by the Secretary. [Section 308]
Grants to States for Inspections	The FFDCa Section 702 states that the Secretary is authorized to conduct food inspections (examinations and investigations) through officers and employees of HHS, or any health, food, or drug officer of a state that has been duly commissioned by the Secretary as an officer of the Department.	Creates a new Section 910 in the FFDCa authorizing \$10 million for FY2002, and such sums as may be necessary for subsequent fiscal years, to provide grants to states to increase food safety examinations, inspections and investigations under FFDCa Section 702. [Section 539]	Creates a new Section 909 in the FFDCa authorizing grants to states and territories to conduct food safety examinations, inspections, and investigations under Section 702, like S. 1765, but does not specify an amount. Also, allows grants to states to assist in costs when responding to adulterated food that might injure public health. [Section 310]
Notices to States Regarding Imported Food	No provisions.	No provisions.	Requires that the Secretary notify the state that holds the food when there is credible evidence that it presents a threat of serious adverse health consequences or death to humans or animals. [Section 309]
Rule of Construction	USDA regulates meat under the Federal Meat Inspection Act (21 U.S.C. 601 et seq.), poultry under the Poultry Products Inspection Act (21 U.S.C. 451 et seq.), and processed egg products under the Egg Products Inspection Act (21 U.S.C. 1031 et seq.)	Prohibits FDA from regulating any food under USDA’s jurisdiction. [Section 540]	No provisions.
Food Safety Grants	FoodNet, established in 1995 by USDA and FDA, tracks the incidence of illnesses caused by nine pathogens in nine geographic areas across the United States. PulseNet compares genetic patterns of bacteria isolated from patients with foodborne illness and/or contaminated food.	Amends PHS Act Title III to authorize \$19.5 million for FY2002 in grants to states to expand the number participating in FoodNet and PulseNet and other surveillance networks and to maintain technical and laboratory capacity. [Section 541]	No provisions.

Topic	Current Law	S. 1765 Frist/Kennedy	H.R. 3448 Tauzin/Dingell
Surveillance of Animal and Human Health	CDC has more than 20 surveillance programs that monitor outbreaks of food borne illness caused by specific pathogens.	Amends PHS Act Title III to authorize FDA, CDC, and USDA to develop and implement a plan for coordinating surveillance for zoonotic and human diseases. [Section 541]	No provisions.
Agricultural Bioterrorism Research and Development	Current research programs are in place in the Agricultural Research Service (ARS) and the Cooperative Research Service Education and Extension Service (CSREES).	Expands, with an authorization of \$190 million for FY2002 and such sums as may be necessary for subsequent fiscal years, the programs of USDA's agencies ARS and CSREES to protect the food supply and expand links with the intelligence community and international organizations. [Section 542]	No provisions