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Bioterrorism: Legislation to Improve Public Health Preparedness and Response Capacity

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C. Stephen Redhead
Donna U. Vogt
Domestic Social Policy Division
Mary E. Tiemann
Resources, Science, & Industry Division

Bioterrorism: Legislation to Improve Public Health Preparedness and Response Capacity

Summary

The recent anthrax attacks, though small in scale compared to the scenarios envisioned by bioterrorism experts, strained the public health system and raised concern that the nation is insufficiently prepared to respond to bioterrorist attacks. Improving public health preparedness and response capacity offers protection not only from bioterrorist attacks, but also from naturally occurring public health emergencies.

In December 2001, the House and Senate each passed legislation (H.R. 3448, S. 1765) to improve the public health system's capacity to respond to bioterrorism. This legislation builds on the programs and authorities established in Title III of the Public Health Service (PHS) Act by the Public Health Threats and Emergencies Act of 2000 (P.L. 106-505, Title I). While the two bills are similar in many respects, there are several key differences that will be addressed in conference.

The Senate bill (S. 1765) would authorize a total of $3.25 billion in FY2002 to increase the public health system's bioterrorism preparedness and response capability, including $640 million to expand the National Pharmaceutical Stockpile (NPS), $509 million to purchase smallpox vaccine, and $1.46 billion for grants to state and local health departments and hospitals. S. 1765 would also strengthen regulation of domestic and imported food by the Food and Drug Administration (FDA) and give the U.S. Department of Agriculture (USDA) new authority to safeguard the nation's agricultural industry from the threat of bioterrorism.

The House bill (H.R. 3448) would authorize almost $3 billion in FY2002 for bioterrorism preparedness, including $646 million to expand the NPS, $509 million to purchase smallpox vaccine, and $1 billion for grants to states and localities. H.R. 3448 does not include any of the agricultural provisions that appear in S. 1765. Unlike the Senate bill, however, H.R. 3448 includes provisions to protect community drinking water supplies from bioterrorism and it places more emphasis on upgrading facilities at the Centers for Disease Control and Prevention (CDC).

While lawmakers work towards final passage of new authorizing legislation, Congress has appropriated more than $3 billion to the Dept. of Health and Human Services (HHS) to increase bioterrorism preparedness at the federal, state, and local levels. HHS anti-bioterrorism funding was included in the FY2002 Labor-HHS-Education appropriations bill and in the $20 billion emergency spending package that was attached to the FY2002 Defense appropriations bill. Until the new authorizing legislation is enacted, HHS is dispersing the funds according to existing authorities and the broad parameters set out in the appropriations bills.

The following analysts may be contacted for additional information:

Stephen Redhead (7-2261)	HHS/CDC programs and policies
Donna Vogt (7-7285)	Food safety (FDA)
Jean Rawson (7-7283)	Agriculture safety and security (USDA)
Mary Tiemann (7-5937)	Drinking water safety and security

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Introduction

The September 11, 2001 terrorist attacks and the subsequent deliberate release of anthrax spores in the mail have focused policymakers' attention on the preparedness and response capability of the U.S. public health system. Though small in scale compared to the scenarios envisioned by bioterrorism experts and played out in recent government exercises, the recent anthrax attacks strained the public health system and exposed weaknesses at the federal, state, and local levels. Many bioterrorism experts believe that had those responsible for the anthrax attacks employed a more sophisticated delivery mechanism or released a deadly communicable biological agent such as smallpox, the health care system may have been overwhelmed.

Bioterrorism poses a unique challenge to the medical care and public health systems. Unlike an explosion or chemical attack, which results in immediate and visible casualties, the public health impact of a biological attack can unfold gradually over time. Until a sufficient number of people arrive at emergency rooms and doctors' offices complaining of similar illnesses, there may be no sign that an attack has taken place. The speed and accuracy with which doctors and laboratories reach the correct diagnoses and report their findings to public health authorities has a direct impact on the number of people who become ill and the number that die. The nation's ability to respond to a bioterrorist attack, therefore, depends crucially on the state of preparedness of its medical care systems and public health infrastructure.

Public health experts have for years complained about the deterioration of the public health system through neglect and lack of funding. They warn that the nation is ill-equipped and insufficiently prepared to respond to a bioterrorist attack. For example, they point out that there are too few medical personnel trained to spot biological attacks, a shortage of sophisticated laboratories to identify the agents, and inadequate supplies of drugs and vaccines to counteract the threat. They also contend that inadequate plans exist for setting up quarantines and emergency facilities to handle the sick and infectious victims. Improving public health preparedness and response capacity offers protection not only from bioterrorist attacks, but also from naturally occurring public health emergencies. Public health officials are increasingly concerned about our exposure and susceptibility to infectious disease and food-borne illness because of global travel, ubiquitous food imports, and the evolution of antibiotic-resistant pathogens.

In December 2001, the House and Senate each passed comprehensive bioterrorism preparedness legislation (H.R. 3448, S. 1765) with broad bipartisan support. This report summarizes H.R. 3448 and S. 1765 and provides a side-by-side comparison of the provisions in each bill and in current law. Lawmakers also appropriated more than $3 billion to the Dept. of Health and Human Services (HHS) for bioterrorism preparedness: $336 million in the FY2002 Labor-HHS-Education appropriations bill (P.L. 107-116, H.R. 3061), and $2.8 billion in the anti-terrorism emergency supplemental appropriations bill (P.L. 107-117, H.R. 3338). Details of the FY2002 HHS bioterrorism funding are provided in Appendix A. In the weeks following the anthrax attacks, several congressional committees held hearings on bioterrorism preparedness. Appendix B lists all the bioterrorism-related hearings in the 107th Congress. In most cases, hearing testimony is available on the committee's Web site.

For a discussion of bioterrorism preparedness issues, see CRS Report RL31225, *Bioterrorism: Summary of a CRS/National Health Policy Forum Seminar on Federal, State, and Local Public Health Preparedness.*

House and Senate Bioterrorism Legislation

Bioterrorism Preparedness Act (S. 1765)

Senators Frist and Kennedy introduced the Bioterrorism Preparedness Act (S. 1715) on November 15, 2001. In a procedural move aimed at bypassing committee consideration and allowing prompt floor consideration, the legislation's sponsors reintroduced the bill (S. 1765) with 74 cosponsors on December 4, 2001. On December 20, 2001, the Senate took up the House bioterrorism bill (H.R. 3448, see below), substituted the text of S. 1765, and passed H.R. 3448, as amended.

The Bioterrorism Preparedness Act builds on the programs and authorities established in Title III of the Public Health Service (PHS) Act by the Public Health Threats and Emergencies Act of 2000 (P.L. 106-505, Title I). S. 1765 incorporates ideas and objectives from a number of other Senate bioterrorism bills introduced in the wake of the anthrax attacks.[1] It is intended to improve the health system's

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[1] Senate bioterrorism preparedness bills introduced in response to the September 11 attacks and the anthrax incidents include: the Biological and Chemical Weapons Preparedness Act of 2001 (S. 1486) introduced by Senator Edwards on Oct. 3, 2001; the Biological and Chemical Attack Preparedness Act (S. 1508) introduced by Senator Corzine on Oct. 4, 2001; the State Bioterrorism Preparedness Act (S. 1520) introduced by Senator Bayh on Oct. 9, 2001; the Protecting America's Children Against Terrorism Act (S. 1539) introduced by Senator Clinton on Oct. 11, 2001; the Bioterrorism Awareness Act (S. 1548) introduced by Senator Carnahan on Oct. 15, 2001; the Protecting the Food Supply from Bioterrorism Act (S. 1551) introduced by Senator Clinton on Oct. 15, 2001; the Agricultural Bioterrorism Countermeasures Act of 2001 (S. 1563) introduced by Senator Hutchison on Oct. 17, 2001; the Public Health Emergency Planning and Information Act of 2001 (S. 1574) introduced by Senator Rockefeller on Oct. 25, 2001; the Pathogen Research, Emergency Preparedness and

(continued...)

capacity to respond to bioterrorism, protect the nation's food supply from bioterrorist attacks, speed the development and production of new drug treatments and vaccines, improve coordination of federal anti-bioterrorism activities, and increase investment in state and local preparedness. S. 1765 is a 5-year authorization bill, which calls for a total of $3.25 billion in funding for FY2002 and such sums as may be necessary for the remaining years. Key provisions of the bill are summarized in the text box below, including the authorized appropriations for FY2002 (in parentheses).

Bioterrorism Preparedness Act of 2001 (S. 1765)

I. Federal Bioterrorism Preparedness and Response Capability:
- Expand the National Pharmaceutical Stockpile ($640 million).
- Upgrade CDC's bioterrorism response capability ($60 million).
- Improve public health laboratories ($59.5 million).
- Tighten controls on the possession and use of biological agents and toxins.

II. State and Local Bioterrorism Preparedness and Response Capability:
- Authorize block grants to states ($667 million).
- Expand existing discretionary grant programs ($420 million).
- Authorize grants to improve hospital response capability ($370 million).

III. Anti-Bioterrorism Drugs and Vaccines:
- Purchase smallpox vaccine ($509 million).
- Authorize long-term contracts for vaccine and drug development and provide limited exemption from federal antitrust laws.

IV. Food Supply and Agriculture ($525.5 million):
- Strengthen FDA regulation of domestic and imported food.
- Expand and upgrade the safety and security of the nation's food supply, livestock, and crops.

Public Health Security and Bioterrorism Response Act (H.R. 3448)

Representatives Tauzin (R-LA) and Dingell (D-MI) introduced the Public Health Security and Bioterrorism Response Act (H.R. 3448) on December 11, 2001. The bill was immediately considered under suspension of the rules and passed by the House the following day on a vote of 418–2 In many respects, H.R. 3448, which authorizes $3 billion in FY2002 to improve bioterrorism preparedness and response capacity, resembles the Senate-passed bill. Both bills would authorize funds to expand the National Pharmaceutical Stockpile, purchase smallpox vaccine, develop and produce anthrax vaccine, and provide grants to state and local governments and public health departments. However, there are a number of key differences between the House and Senate bills that will be addressed in conference.

S. 1765 contains several provisions aimed at combating agricultural terrorism, including one that would authorize the creation of a surveillance and response system

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[1] (...continued)
Response Efforts (PREPARE) Act of 2001 (S. 1635) introduced by Senator Hutchinson on Nov. 6, 2001; and the Deadly Biological Agent Control Act of 2001 (S. 1661) introduced by Senator Feinstein on Nov. 8, 2001.

to detect biological threats to animals and plants. Another provision would authorize the Secretary of Agriculture to award grants to universities to conduct research on improving the security of facilities at which hazardous biological agents and toxins are stored for agricultural research purposes. H.R. 3448 does not include any agricultural provisions. The Senate bill also provides a limited exemption from federal antitrust law that would enable drug companies to collaborate to develop vaccines. The House version has no such provision.

H.R. 3448 includes a set of provisions aimed at protecting the nation's drinking water supply, which are not included in S. 1765. The House bill would authorize a total of $170 million in FY2002 to assess the vulnerability of community drinking water systems, help communities develop emergency response plans, and take other steps to protect the water supply from acts of terrorism. H.R. 3448 also contains language that would strengthen FDA regulation of imported drugs, which is not present in S. 1765, and it places more emphasis on upgrading CDC's facilities and capacities. Key provisions of the House bill are summarized in the text box below, including the authorized appropriations for FY2002 (in parentheses).

Public Health Security and Bioterrorism Response Act of 2001 (H.R. 3448)

I. Federal Bioterrorism Preparedness and Response Capacity:
- Expand the National Pharmaceutical Stockpile ($646 million).
- Upgrade CDC's bioterrorism response capacity ($450 million).
- Tighten controls on the possession and use of biological agents and toxins.

II. State and Local Bioterrorism Preparedness and Response Capacity:
- Expand existing discretionary grant programs ($910 million).
- Relieve shortages of critical health care professionals ($40 million).

III. Anti-Bioterrorism Drugs and Vaccines:
- Purchase smallpox vaccine ($509 million).
- Stockpile potassium iodide near nuclear power plants.

IV. Food and Drug Supply:
- Strengthen FDA regulation of domestic and imported food ($100 million).
- Strengthen FDA regulation of imported drugs.

V. Drinking Water:
- Upgrade safety and security of drinking water supplies ($170 million).

Table 1 below provides a side-by-side comparison of H.R. 3448, S. 1765, and, where applicable, current law. All the PHS Act Title III provisions relating to public health emergencies that were established by P.L. 106-505 (i.e., Sections 319, 319A–319G) are included in the table, regardless of whether they are amended by S. 1765 or H.R. 3448.

Table 1. Side-by-Side Comparison of Legislation on Public Health Preparedness for Bioterrorism

Topic	Current Law	S. 1765 Frist/Kennedy	H.R. 3448 Tauzin/Dingell
Establishing National Goals and Public Health Capacities, Assessing Public Health Needs			
Establishing National Goals, Reports to Congress	No statutory provisions.	Adds a new Title XXVIII to the Public Health Service (PHS) Act setting out the following national goals for bioterrorism preparedness: (i) provide federal assistance to states and localities in the event of an attack; (ii) improve public health preparedness and response; (iii) develop new vaccines and therapies; (iv) protect the food supply and agriculture. [Section 101] Adds a new Section 2811 to the PHS Act to require the Secretary to report to Congress within 1 year, and biennially thereafter, on progress made toward meeting the objectives of the Act, including recommendations for new legislative authority needed to protect public health. Requires the Secretary to report to Congress within 1 year on the vulnerability of rural communities to bioterrorism and recommend any new legislative authority needed to strengthen the preparedness of such communities. [Section 201]	Adds a new Title XXVIII to the Public Health Service (PHS) Act that requires the Secretary, building on existing authority in PHS Act Section 319A, to develop and implement a bioterrorism preparedness and response plan, in consultation with other federal agencies. The plan would coordinate the activities of state and local governments and meet the preparedness goals in the bill (e.g., effective assistance to state and local governments, laboratory readiness, effective communications networks, training, and surveillance). Requires the Secretary to evaluate the feasibility of utilizing the Dept. of Veterans Affairs' research capabilities. Similar reporting requirements to those in S. 1765. [Section 101]
Establishing Public Health Capacities	Public Health Service (PHS) Act Section 319A requires the Secretary, together with state and local health officials, to establish what capacities are needed for national, state, and local public health systems to be able to detect, diagnose, and contain outbreaks of infectious disease, drug-resistant pathogens, or acts of bioterrorism. Authorizes $4 million for FY2001 and such sums as may be necessary for FY2002–FY2006.	No provisions.	No provisions.

Topic	Current Law	S. 1765 Frist/Kennedy	H.R. 3448 Tauzin/Dingell
Assessing Public Health Needs	PHS Act Section 319B authorizes grants to states and local public health departments to evaluate the extent to which they can achieve the capacities identified pursuant to Section 319A. Requires the Secretary to develop a national framework for the evaluations. Authorizes $45 million for FY2001, and such sums as may be necessary for FY2002–FY2003.	No provisions.	No provisions.
Federal (HHS) Preparedness and Response Capacity			
Assistant Secretary for Emergency Preparedness	No statutory provisions.	Adds a new Section 2813 to the PHS Act authorizing the appointment of an Assistant Secretary for Emergency Preparedness to head the Office of Emergency Preparedness and coordinate all HHS bioterrorism activities. [Section 211]	Adds a new Section 2811 to the PHS Act authorizing the appointment of an Assistant Secretary for Emergency Preparedness to coordinate all HHS bioterrorism-related activities under the Act and interface with other federal agencies. [Section 102]
Public Health Emergencies	PHS Act Section 319 authorizes the Secretary to respond to public health emergencies, including diseases, disorders, or bioterrorist attacks, by supporting grants, contracts, and investigations. Establishes the Public Health Emergency Fund and authorizes such sums as may be necessary. Requires an annual report to Congress on expenditures from the Fund.	Amends PHS Act Section 319 to require the Secretary to notify Congress within 48 hours of declaring a public health emergency. Allows such a declaration to remain in effect for 180 days and permits the Secretary to extend that period, provided Congress is notified within 48 hours of the extension. Allows the Secretary, as a result of public health emergencies, to waive deadlines for the submission of data and reports by individuals or public or private entities pursuant to any law administered by the Secretary. [Section 212]	Amends PHS Act Section 319 as follows: (i) permits the Secretary during a public health emergency to transfer funds between appropriations accounts administered under this Act, without lengthy waiting periods, and requires the Secretary to notify Congress of the intent to make such a transfer; and (ii) provides that public health emergencies expire by announcement of the Secretary or after 90 days, whichever comes first, and permits the Secretary to renew emergency declarations. Similar waiver authority to S. 1765. [Section 131, 134]

Topic	Current Law	S. 1765 Frist/Kennedy	H.R. 3448 Tauzin/Dingell
Quarantine and Inspection	PHS Act Section 361 authorizes the Surgeon General, in consultation with the Secretary, to develop quarantine, inspection, fumigation, sanitation, and pest extermination regulations to prevent the introduction, transmission, or spread of communicable diseases. Section 363 authorizes the development of regulations for the apprehension and examination of infected individuals in times of war.	No provisions.	Amends PHS Act Secs. 361 and 363 by eliminating the prerequisite for a National Advisory Health Council recommendation before issuing a quarantine rule or a rule providing for the apprehension of individuals during wartime. Permits federal regulations under Secs. 361 & 363, as amended, to preempt state laws that conflict with the exercise of federal authority. [Section 132]
Federal Working Groups and Advisory Committees	PHS Act Section 319F requires the Secretary to: (i) establish, with the Secretary of Defense, an interagency working group on bioterrorism preparedness, and (ii) establish, in collaboration with the Director of FEMA, the Attorney General, and the Secretary of Agriculture, an interagency working group to address the public health and medical consequences of a bioterrorist attack.	Amends PHS Act Section 319F by eliminating the two existing working groups and replacing them with a single interagency working group on the prevention, preparedness, and response to bioterrorism, to be established by the Secretary in coordination with the Director of FEMA, the Attorney General, and the Secretaries of Agriculture, Defense, Labor, and Veterans Affairs (VA), and with other federal officials as appropriate. Creates two advisory committees to the Secretary: (i) the National Task Force on Children and Terrorism; and (ii) the Emergency Public Information and Communications Task Force. Both Task Forces sunset after 1 year. [Section 213]	Amends PHS Act Section 319F by expanding the composition and responsibilities of the two existing interagency working groups. Requires the Secretary to establish the preparedness working group in coordination with the Director of FEMA, the Attorney General, the Secretaries of Agriculture, Defense, Energy, and the VA, and the EPA Administrator. Requires the Secretary to establish the public health and medical working group in coordination with the Director of FEMA, the Attorney General, the Secretaries of Agriculture, Defense, Labor, and the VA, and the EPA Administrator. Creates two advisory committees to the Secretary: (i) the National Advisory Committee on Children and Terrorism; and (ii) the Emergency Public Information and Communications Advisory Committee. Both committees sunset after 1 year. Requires a coordinated strategy on public health communications during a bioterrorist attack. [Section 104, 108]

Topic	Current Law	S. 1765 Frist/Kennedy	H.R. 3448 Tauzin/Dingell
National Disaster Medical System (NDMS)	No statutory provisions. The NDMS was established in 1984 as a partnership of four federal agencies (HHS, FEMA, DOD, VA), state and local governments, and the private sector to provide medical assistance and hospitalization for mass casualties in the event of a natural or man-made disaster. It consists of more than 7,000 volunteer health professionals and support personnel. For more information, go to [http://ndms.dhhs.gov].	Adds a new Section 2814 to the PHS Act providing statutory authorization for the NDMS, to be coordinated by the Secretary in collaboration with FEMA, DOD, and the VA. Appoints activated NDMS volunteers as temporary federal employees and establishes employment and reemployment rights for NDMS volunteers. [Section 211]	Adds a new Section 2811 to the PHS Act containing similar provisions to S. 1765, but with the following additional requirements and authorizations: requires the Secretary to collaborate with states and other public and private entities, and, within 1 year and periodically thereafter, to conduct exercises to test the capability and timeliness of the NDMS. Requires the Secretary to establish education and training criteria for NDMS personnel. Authorizes such sums as may be necessary for FY2002–FY2006 for NDMS and to provide for the Assistant Secretary of Emergency Preparedness. [Section 102]
National Pharmaceutical Stockpile (NPS)	No statutory provisions. The NPS, which was established and is managed by the CDC, includes pharmaceuticals, vaccines, and medical supplies that can be deployed anywhere in the country in response to a public health emergency. For more information, go to [http://www.cdc.gov/nceh/nps/default.htm].	Adds a new Section 2812 to the PHS Act requiring the Secretary, in coordination with the VA Secretary, to maintain a National Pharmaceutical Stockpile of vaccines, drugs, medical devices and supplies to meet the nation's emergency public health needs. Authorizes $640 million for FY2002, and such sums as may be necessary for FY2003–FY2006. [Section 201]	Similar provisions to S. 1765, but with additional requirements for periodic review of the stockpile and the development of a distribution plan. Requires the Secretary to consult with the Director of FEMA, the Attorney General, the Secretaries of Agriculture, DOD, Energy, and the VA, the EPA Administrator, and state and local agencies. Authorizes $1.155 billion for FY2002, of which $509 million is for purchasing smallpox vaccine, and such sums as may be necessary for FY2003–FY2006. [Section 121, 151]
Upgrading CDC	PHS Act Section 319D authorizes funds for the construction and renovation of CDC facilities, and to support the agency's activities to combat threats to public health. Authorizes $180 million for FY2001, and such sums as may be necessary for FY2002–FY2010.	Amends PHS Act Section 319D to clarify CDC's role in responding to bioterrorism. Authorizes $60 million for FY2002, and such sums as may be necessary for FY2003–FY2006, to upgrade CDC's facilities and capacities. [Section 202]	Amends PHS Act Section 319D to clarify CDC's role in responding to bioterrorism. Requires the Secretary to upgrade CDC's facilities and capacities. Provides authorization and multi-year contracting authority for renovation, development, and security at CDC facilities. Authorizes $450 million for FY2002, of which $300 million is for upgrading facilities, $300 million for FY2003 to upgrade facilities, and such sums as may be necessary for FY2004–FY2006. [Section 103, 151]

Topic	Current Law	S. 1765 Frist/Kennedy	H.R. 3448 Tauzin/Dingell
Public Health Laboratories Network, National Public Health Communications and Surveillance Network	No statutory provisions. Over the past 3 years, CDC has awarded grants to all 50 states and some metropolitan health departments to enhance state and local laboratory capacity and to help build an national electronic communications network connecting all the components of the public health community. For more information, go to [http://www.bt.cdc.gov].	Amends PHS Act Section 319D to provide grants to establish a coordinated network of public health labs. Authorizes $59.5 million for FY2002, and such sums as may be necessary for FY2003–FY2006. [Section 202]	Amends PHS Act Section 319D to provide grants to establish a coordinated network of public health labs and to develop a national public health communications and surveillance network. Authorizes such sums as necessary for FY2002–FY2006. [Section 103] Requires that all the FY2003 and FY2004 infrastructure grants provided by the National Telecommunications and Information Administration be awarded to health providers to facilitate participation in the national public health communications and surveillance network. [Section 139]
Education and Training of Health Care Personnel: Children and Other Vulnerable Populations	PHS Act 319F requires the Secretary to develop programs to educate health professionals in recognizing and caring for victims of bioterrorist attacks and programs to train laboratory personnel in identifying bioweapons.	Amends PHS Act Section 319F to require the interagency working group on the public health and medical consequences of bioterrorism, in collaboration with professional organizations, to develop education programs that recognize the special needs of children and other vulnerable populations during public health emergencies. [Section 313; Note: The interagency working group to which this subsection of the Act refers would be replaced by two advisory committees under S. 1765, see above.]	Amends PHS Act Section 319F by requiring the Secretary, in collaboration with the interagency working group and professional organizations, to award grants for the development of education materials to teach health officials and other emergency personnel to identify potential bioweapons and care for victims, recognizing the special needs of children and other vulnerable populations during public health emergencies. [Section 105]
GAO Report	PHS Act 319F requires a GAO report to Congress, within 6 months, on federal bioterrorism-related activities, including research, preparedness, and response. [This report, GAO-01-915, was issued by GAO on September 28, 2001.]	Amends PHS Act Section 319F to require a new GAO report to Congress on federal bioterrorism-related activities, including the development of public health lab capacity. [Section 314]	No provisions.
Occupational Safety and Health	Section 22 of the Occupational Safety and Health Act of 1970 (29 U.S.C. 671) created the National Institute for Occupational Safety and Health (NIOSH) as the federal agency responsible for conducting research and making recommendations for the prevention of work-related disease and injury. NIOSH is part of the CDC.	Amends OSH Act Section 22 to expand NIOSH research on bioterrorism threats and attacks in the workplace. [Section 315]	Requires the Secretary, acting through the Director of NIOSH, to expand research on bioterrorism threats and attacks in the workplace. [Section 138]

Topic	Current Law	S. 1765 Frist/Kennedy	H.R. 3448 Tauzin/Dingell
Agency for Toxic Substances and Disease Registry (ATSDR)	ATSDR, an agency within HHS, was created by the Superfund legislation to investigate and reduce the harmful effects of exposure to hazardous substances on human health.	No provisions.	Requires the Secretary to integrate ATSDR into plans for bioterrorism preparedness and response. Authorizes such sums as necessary for FY2002–FY2006 for ATSDR's bioterrorism-related activities. [Section 137]
Federal Bioterrorism Web Site	No statutory provisions.	Recommends establishing a federal Web site on bioterrorism with links to state and local government sites. [Section 214]	No provisions.
Miscellaneous Provisions	No applicable provisions.	No provisions.	Requires the Secretary, in consultation with other federal agencies, to conduct a study of the ability of local public health entities to maintain communications during a public health emergency. [Section 111] Adds a new Section 319J to the PHS Act allowing the Secretary to provide supplies, equipment, or services instead of, or in conjunction with, grants awarded under Sections 319 through 319I, or Section 319K. [Section 112] Requires the Secretary to conduct a study of best practices in local emergency response and report to Congress within 180 days. [Section 114]

Topic	Current Law	S. 1765 Frist/Kennedy	H.R. 3448 Tauzin/Dingell
Medicare, Medicaid, and the State Children's Health Insurance Program (SCHIP)			
Emergency Waivers	Medicare covers medically necessary acute care and follow-up services (hospital, short-term nursing home care, physician services, home health and a variety of outpatient services) for all persons age 65 and over, as well as certain disabled persons. Medicaid covers acute and long-term care services for low-income persons who are aged, blind, disabled, members of families with dependent children, and certain other pregnant women and children. The State Children's Health Insurance Program (SCHIP) covers uninsured children living in families with income above applicable Medicaid standards, typically up to or above 200% of the federal poverty level. In all three programs, providers must meet certain standards in order to participate and receive reimbursement for services rendered to program beneficiaries. For example, hospitals and other facilities must meet established conditions of participation, and laboratories must be certified under the Clinical Laboratories Improvement Act (CLIA). Physicians must be licensed to provide medical services in the state where medical care is rendered, and must follow established rules for obtaining prior approval to deliver certain types of services. Also, physicians must not refer patients to medical entities with which they have a financial relationship. Other statutory provisions require hospitals to fully stabilize patients receiving emergency care prior to transfer to another medical facility.	No provisions.	Authorizes the Secretary to temporarily waive conditions of participation and other certification requirements for any entity that furnishes health care items or services to Medicare, Medicaid, or SCHIP beneficiaries in an emergency area during a declared disaster or public health emergency. In addition, during such an emergency, authorizes the Secretary to waive: (i) participation, state licensing (as long as equivalent licensure from another state is held), and pre-approval requirements for physicians and other practitioners; (ii) sanctions for failing to meet requirements for emergency transfers between hospitals; and (iii) sanctions for physician self-referral. Requires the Secretary to provide Congress with a detailed written notice at least 2 days prior to exercising this waiver authority. Provides for the waiver authority to continue for 90 days. Permits the Secretary to extend the waiver period. Requires the Secretary, within 1 year after the end of the emergency, to provide Congress with an evaluation of the success of this approach and recommendations for improvements under this waiver authority. [Section 133]

Topic	Current Law	S. 1765 Frist/Kennedy	H.R. 3448 Tauzin/Dingell
Regulation of Biological Agents and Toxins			
Use and Possession of Select Agents	The 1996 Antiterrorism and Effective Death Penalty Act (P.L. 104-132, Section 511) required the Secretary to establish a list of biological agents that could pose a severe threat to public health and safety, and establish safety procedures for transferring listed agents and toxins so as to protect public safety and prevent access by terrorists (see 42 C.F.R. 72).	Codifies and expands provisions of P.L. 104-132 in the PHS Act under a new Section 351A. Requires the Secretary to: (i) establish and, at least biennially, review and, if necessary, revise a list of biological agents and toxins that could pose a severe threat to public health and safety; (ii) establish safety procedures for transferring listed agents and toxins so as to protect public safety and prevent access by terrorists; (iii) establish standards and procedures for the possession and use of listed agents and toxins so as to protect public health and safety; and (iv) require registration for the possession, use, and transfer of listed agents and toxins and maintain a national database of the location of such agents and toxins. Requires the Secretary to establish security requirements for persons possessing, using, or transferring listed agents or toxins, as a condition of registration. Authorizes the Secretary to conduct compliance inspections. Authorizes the Secretary to establish exemptions from the requirements outlined in (ii) and (iii) above that are consistent with protecting public health and safety, including exemptions for the use of attenuated or inactive agents or toxins in research or for medical purposes. Exempts clinical labs presented with a listed agent or toxin for diagnosis, verification, or proficiency testing. Establishes civil penalties of up to $500,000 and criminal penalties of up to 5 years in prison for those in violation of the above requirements for the possession, use, and transfer of listed agents and toxins. Protects information collected under these regulations from mandatory disclosure under the Freedom of Information Act. Mandates a report to Congress within 1 year. Repeals current law. [Section 216]	Similar provisions to S. 1765, but with added security provisions: (i) requires the Secretary to consult with the Attorney General in establishing security requirements for persons possessing, using, or transferring listed agents or toxins; and (ii) requires the Secretary, in consultation with the Attorney General and other federal agencies, to establish a screening protocol to ensure that access to such agents and toxins is not permitted by certain specified types of individuals (e.g., those with criminal records, suspected terrorists, etc.). Requires the Secretary to coordinate regulations promulgated under these provisions with Dept. of Agriculture regulations governing use of biological agents in developing animal vaccines and treatments. Clarifies that the Secretary's new authorities do not limit existing authorities of the Secretary of Agriculture. Authorizes such sums as may be necessary for FY2002, and each subsequent fiscal year, to upgrade security at HHS facilities that contain listed agents and toxins. [Section 201]

Topic	Current Law	S. 1765 Frist/Kennedy	H.R. 3448 Tauzin/Dingell
State and Local Preparedness and Response Capacity			
Grants to States, Localities, and Health Care Facilities	PHS Act Section 319F(c) authorizes grants to states, localities, and health care facilities to increase their capacity to detect, diagnose, and respond to bioterrorist attacks, including training of personnel. [Note: For all activities under Section 319F, authorizes $215 million for FY2001, and such sums as may be necessary for FY2002–FY2006.]	Amends PHS Act Section 319F(c) by replacing the existing grant program with block grants to states based on population, but with each state guaranteed a minimum level of funding. Requires states to develop a detailed bioterrorism preparedness plan to be eligible for funding. Authorizes $667 million for FY2002, and such sums as may be necessary for FY2003. [Section 301]	Amends PHS Act Section 319F(c) by expanding the existing grant authorization to permit the use of funds for community-wide planning activities, training, and purchasing or upgrading equipment, supplies, pharmaceuticals, and other countermeasures. Authorizes $455 million for FY2002, and such sums as may be necessary for FY2003–FY2006. [Section 108, 151]
Grants to Improve State and Local Public Health Agencies	PHS Act Section 319C authorizes grants to states and local governments, after they have completed an evaluation, to address core public health capacity needs (identified pursuant to Section 319A). Requires the Secretary to report to Congress on activities carried out under Sections 319A, 319B, and 319C by January 1, 2005. Authorizes $50 million for FY2001, and such sums as may be necessary for FY2002–FY2006.	Amends PHS Act Section 319C by authorizing $420 million for FY2002, and such sums as may be necessary for FY2003–FY2006. [Section 215]	Amends PHS Act Section 319C by expanding the existing grant authorization to permit the use of funds for purchasing or upgrading equipment, supplies, pharmaceuticals, and other countermeasures. Authorizes $455 million for FY2002, and such sums as may be necessary for FY2003–FY2006. [Section 109, 151]
Demonstration Grants	PHS Act Section 319G authorizes up to three demonstration grants for up to 5 years to states, localities, or non-profit organizations to carry out programs to improve biopathogen detection, develop plans for responding to bioterrorist attacks, and train response personnel. Requires a GAO report to Congress at the conclusion of the demonstration programs describing the capabilities of the grantees. Authorizes $6 million for FY2001, and such sums as may be necessary for FY2002–FY2006.	No provisions.	No provisions.

Topic	Current Law	S. 1765 Frist/Kennedy	H.R. 3448 Tauzin/Dingell
Grants to Hospitals	No applicable provisions.	Amends PHS Act Section 319F by establishing a grant program for hospitals and other medical centers to improve bioterrorism preparedness and response capacity. To be eligible, a hospital must form a consortium with a public health agency and a local government, and its grant proposal must be consistent with the state's bioterrorism preparedness plan. Requires the Secretary to develop and publish technical guidelines relating to equipment, training, treatment, capacity, and personnel. Authorizes $370 million for FY2002, and such sums as may be necessary for FY2003–FY2006. [Section 301, 311]	No provisions.
Grants to Address National Shortages of Specific Types of Health Professionals	No applicable provisions, although PHS Act Titles VII (Health Professionals Education) and VIII (Nursing Workforce Development) authorize federal support for training of health professionals for specific purposes.	No provisions.	Adds a new Section 319H to the PHS Act establishing a grant program to provide financial assistance for the education and training of individuals in any category of the health professions where there is a shortage that the Secretary determines should be alleviated to improve emergency readiness. Authorizes $40 million for FY2002, and such sums as may be necessary for FY2003–FY2006. [Section 106, 151]
Health Professional Volunteers	No applicable provisions.	No provisions.	Adds a new Section 319I to the PHS Act requiring the Secretary to establish a national system to help verify the licenses, credentials, and hospital privileges of health professionals who volunteer to respond during public health emergencies. Authorizes $2 million for FY2002, and such sums as may be necessary for FY2003–FY2006. [Section 107]
State Public Emergency Announcements	The Stafford Act (42 U.S.C. 5121 et seq.) authorizes federal assistance when the President determines that a natural or man-made disaster has overwhelmed state and local resources. Stafford assistance is administered by the Federal Emergency Management Agency (FEMA).	Amends Section 613(b) of the Stafford Act by requiring states to include a plan for providing a coordinated public communications response in their submission for federal funds to help pay for state emergency preparedness personnel and administrative expenses. [Section 312]	Same provisions as S. 1765. [Section 135]

Topic	Current Law	S. 1765 Frist/Kennedy	H.R. 3448 Tauzin/Dingell
Countermeasures (Research, Development, and Production of New Vaccines, Drugs, and Technologies)			
Antitrust Exemption	The Clayton Act (15 U.S.C. 12 et seq.) is one of the federal antitrust laws that seek to promote fair competition and protect consumers and businesses from anti-competitive business practices. It enumerates specific practices that are anti-competitive and therefore forbidden.	Amends Section 2 of the Clayton Act to exempt from antitrust law meetings between the Secretary and parties involved in the development, manufacture, distribution, purchase and sale of new priority countermeasures against bioterrorism. Permits the Attorney General, in consultation with the Chairman of the Federal Trade Commission, to grant a limited antitrust exemption to agreements reached at such meetings. Limited exemptions expire after 3 years, but may be renewed. Terminates the Attorney General's authority to grant limited antitrust exemptions after 6 years. [Section 401]	No provisions.
Smallpox Vaccine	No statutory provisions. In November 2001, HHS awarded a $428 million contact to Acambis, Inc. and Baxter International Inc. to produce 155 million doses of smallpox vaccine by the end of 2002. This is in addition to an earlier contract with Acambis to produce 54 million doses of the vaccine.	Adds new Section 2841 to the PHS Act requiring the Secretary to ensure adequate supplies of smallpox and other vaccines in the National Pharmaceutical Stockpile. Authorizes $509 million for FY2002, and such sums as may be necessary for FY2003–FY2006, to purchase smallpox vaccine. Adds a new Section 2842 to the PHS Act authorizing the Secretary to enter into long-term contracts with companies to purchase specific quantities of priority countermeasures at an agreed price. [Section 402]	Authorizes $509 million for FY2002, and such sums as may be necessary for FY2003–FY2006, to purchase smallpox vaccine. [Section 151]
Research and Development	PHS Act Section 319F requires the Secretary, in consultation with the interagency working group, to conduct research on the epidemiology and pathogenesis of biopathogens, diagnostic tests for biopathogens, and vaccines and other therapeutics.	Amends PHS Act Section 319F to: (i) make the genetic sequencing of biopathogens a priority at NIH; and (ii) expand research on the epidemiology and detection of biological agents and toxins, and the development of new vaccines and therapies. [Section 403, 404]	Amends PHS Act Section 319F to expand research on countermeasures, including the epidemiology and detection of biological agents and toxins, and the development of new vaccines and therapies. Defines a priority countermeasure as any drug, device, biologic, or diagnostic test to treat, identify, or prevent infection by a listed biological agent or toxin, or prevent harm from any other agent that may cause a pubic health emergency. Directs the Secretary to consider research collaboration with the VA. [Section 125]

Topic	Current Law	S. 1765 Frist/Kennedy	H.R. 3448 Tauzin/Dingell
FDA Approval of Drugs and Biologics	Under the Federal Food, Drug, and Cosmetic Act (FFDCA; 21 U.S.C. 301 et seq.), manufacturers of drugs and biologics (e.g., vaccines) must provide clinical trial data to demonstrate that their product is safe and effective, in order to obtain FDA marketing approval. The FFDCA provides for the designation of products as fast track to expedite the approval process.	Authorizes the Secretary to designate a priority countermeasure (i.e., drug or device) as a fast-track product for accelerated approval by the FDA. Permits a drug seeking FDA approval on the basis of animal data to be designated a fast-track product. Requires the FDA, within 30 days, to issue as a final rule the October 5, 1999 proposed rule permitting the use of animal data for approving new drugs and vaccines, when ethical issues preclude conducting clinical trials. [Section 405, 406]	Authorizes the Secretary to designate a priority countermeasure (i.e., drug or biologic) as a fast-track product for accelerated approval by the FDA but does not permit a drug seeking FDA approval on the basis of animal data to be designated a fast-track product. Requires the FDA, within 180 days, to issue as a final rule the October 5, 1999 proposed rule permitting the use of animal data for approving new drugs and vaccines, when ethical issues preclude conducting clinical trials. [Section 122, 123]
Security at Research and Production Facilities	No applicable provisions.	Adds a new Section 2843 to the PHS Act authorizing the Secretary, in consultation with the Secretary of Defense and the Attorney General, to provide technical or other assistance to enhance security at research and production facilities. Requires the Secretary to develop guidelines and best practices. [Section 402]	Adds a new Section 319K to the PHS Act authorizing the Secretary, in consultation with the Secretary of Defense and the Attorney General, to provide technical or other assistance to enhance security at research and production facilities. [Section 124]
Detection, Identification, Diagnosis, and Surveillance Technologies	No applicable provisions.	No provisions.	Requires the Secretary to evaluate and prioritize new and emerging technologies for responding to a bioterrorism attack or other public health emergency. Requires the Secretary to report to Congress within 180 days on those technologies whose development should be accelerated. [Section 126] Requires the Secretary of Energy and the Administrator of the National Nuclear Safety Administration, in coordination with the interagency working group, to expand research on the rapid detection and identification of biopathogens. Authorizes such sums as may be necessary for FY2002–FY2006. [Section 136]

Topic	Current Law	S. 1765 Frist/Kennedy	H.R. 3448 Tauzin/Dingell
Potassium Iodide	No applicable provisions.	No provisions.	Requires the Secretary to make potassium iodide available from the national pharmaceutical stockpile to states and local governments that submit a plan for local stockpile and distribution to the population within 20 miles of a nuclear power plant. Requires the Secretary, within 6 months, to provide Congress with a progress report. [Section 127]
Antimicrobial Resistance			
Combating Antimicrobial Resistance	PHS Act 319E requires the Secretary to establish an Antimicrobial Resistance Task Force to coordinate federal programs on antimicrobial resistance and to work on surveillance plans and information systems for detection and control of drug-resistant pathogens. Authorizes research and development initiatives for new antimicrobial drugs and diagnostics. Directs the Secretary to conduct a nationwide campaign to educate the public and health care professionals about the appropriate use of antibiotics. Authorizes grants for public health agencies to combat antimicrobial resistance. Authorizes demonstration grants for hospitals, clinics, and other entities to promote the judicious use of antibiotics and to control the spread of resistant infections. Authorizes $40 million for FY2001, and such sums as may be necessary for FY2002–FY2006.	No provisions.	Amends PHS Act Section 319E to authorize additional research on priority pathogens. Authorizes $25 million for FY2002 and for FY2003, and such sums as may be necessary for FY2004–FY2006. [Section 110, 151]

Topic	Current Law	S. 1765 Frist/Kennedy	H.R. 3448 Tauzin/Dingell
Drug and Device Supply Safety and Security			
Drug and Device Importation	FFDCA Section 510(i) requires foreign drug and device manufacturers that import into the United States to register with the Secretary their name, place of business, and the name of their U.S. agent. Section 801 governs the import and export of food, drugs, devices, and other items, and specifies the circumstances under which imported articles are inspected, detained, or refused entry into the United States.	No provisions.	Amends Section 510(i) of the FFDCA by mandating annual registration of foreign manufacturers engaged in the import of drugs and devices into the United States. Requires registration to include the name of each importer and carrier used by the manufacturer. Amends Section 801 so that an imported drug or device may be refused entry if the importer fails to give the Secretary a statement identifying each foreign establishment that, under the law, must also be registered. [Section 311]

Topic	Current Law	S. 1765 Frist/Kennedy	H.R. 3448 Tauzin/Dingell
Import Components Intended for Export	FFDCA Section 301 is the prohibited acts and penalties section of the statute. Section 801 governs the import and export of food, drugs, devices, and other items, and specifies the circumstances under which imported articles are inspected, detained, or refused entry into the United States.	No provisions.	Amends Section 801 of the FFDCA mandating a chain-of-possession identification and a customs bond for firms seeking to import components of drugs, devices, food additives, color additives, or dietary supplements for further processing and export. Requires certificates of analysis for components containing any chemical or biological substance intended for export. Permits the Secretary to exclude from importation any article for which there is credible evidence or information indicating that the article presents a serious health threat or death to humans or animals. Amends Section 301 making it illegal to knowingly submit false statements, certificates, records, or reports required under Section 801, as amended. [Section 312]
Food Supply Safety and Security			
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.

Topic	Current Law	S. 1765 Frist/Kennedy	H.R. 3448 Tauzin/Dingell
U.S. Department of Agriculture (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.
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]

Topic	Current Law	S. 1765 Frist/Kennedy	H.R. 3448 Tauzin/Dingell
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	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.	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]	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]
Registration of Food Facilities	Currently, only States have records of food processing, packing and holding facilities. The federal government must ask the states for this information.	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]	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]

Topic	Current Law	S. 1765 Frist/Kennedy	H.R. 3448 Tauzin/Dingell
Prior Notice of Imported Food Shipments	Under FFDCA 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 FFDCA 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 FFDCA 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: *United States: Refused Entry* 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 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.	Amends FFDCA 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.
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.

Topic	Current Law	S. 1765 Frist/Kennedy	H.R. 3448 Tauzin/Dingell
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.

Topic	Current Law	S. 1765 Frist/Kennedy	H.R. 3448 Tauzin/Dingell
Drinking Water Security and Safety			
Vulnerability Assessments and Emergency Response Plans	PHS Act Title XIV, the Safe Drinking Water Act (SDWA), authorizes federal regulation of public water systems (including community water systems), particularly through a program that regulates contaminants in public water supplies. The Act defines a community water system as a public water system that serves at least 15 service connections served by year-round residents or that regularly serves at least 25 year-round residents. The SDWA is administered and enforced by the Environmental Protection Agency (EPA).	No provisions.	Adds a new Section 1433 to the SDWA to require each community water system serving more than 3,300 individuals to conduct a vulnerability assessment. Requires EPA, not later than March 1, 2002, to provide information to community water systems concerning probable threats. Establishes deadlines for systems to certify to EPA that they have conducted vulnerability assessments. Requires each community water system serving more than 3,300 individuals to prepare or revise an emergency response plan incorporating the results of the vulnerability assessment. Systems must certify to EPA, no later than 6 months after completing an assessment, that they have completed response plans. Directs EPA to provide guidance to community water systems serving fewer than 3,300 individuals on conducting vulnerability assessments, preparing emergency response plans, and addressing threats from terrorist attacks or other actions intended to disrupt the provision of safe drinking water. Authorizes $120 million for FY2002, and such sums as may be necessary for FY2003 and FY2004, to provide financial assistance to community water systems to conduct assessments and prepare response plans, and for expenses and contracts to address basic security enhancements and significant threats. [Section 401(1)]

Topic	Current Law	S. 1765 Frist/Kennedy	H.R. 3448 Tauzin/Dingell
Review of Methods to Prevent, Detect, and Respond to the Intentional Introduction of Contaminants into Community Water Supplies	No statutory provisions.	No provisions.	Adds new SDWA Section 1434 directing the EPA Administrator, in consultation with CDC, and after consultation with other federal departments and state and local governments, to review current and future methods to prevent, detect and respond to the intentional introduction of chemical, biological or radiological contaminants into community water systems and their source waters. Provides that funding is authorized under Section 1435. [Section 401(1)]
Supply Disruption: Prevention, Detection and Response	No statutory provisions.	No provisions.	Adds new SDWA Section 1435 directing the EPA Administrator, in coordination with appropriate federal departments and agencies, to review methods and means by which terrorists or others could disrupt the supply of safe drinking water or take actions that render water unsafe, including methods and means by which water systems could be destroyed, impaired, or made subject to cross-contamination. EPA must also review methods and means by which systems could be reasonably protected from attacks, and by which alternative drinking water supplies could be provided if a water system was destroyed, impaired or contaminated. Authorizes $15 million for FY2002, and such sums as may be necessary for FY2003 and FY2004 to carry out Sections 1434 and 1435. [Section 401(1)]
Enforceable Requirements	SDWA Section 1414(i)(1) identifies the sections of SDWA for which the Act's enforcement authorities apply.	No provisions.	Amends SDWA Section 1414(i)(1) to include new Section 1433, requiring community water systems to conduct vulnerability assessments and to prepare emergency response plans, as an applicable and enforceable requirement under the Act. [Section 401(2)]

Topic	Current Law	S. 1765 Frist/Kennedy	H.R. 3448 Tauzin/Dingell
Emergency Powers	SDWA Section 1431 grants the EPA Administrator emergency powers to take such actions as deemed necessary to protect persons served by a public water system upon receipt of information that a contaminant which is present in or is likely to enter a public water system or groundwater source may present an imminent and substantial endangerment to health of those persons.	No provisions.	Amends SDWA Section 1431 to specify that EPA's emergency powers include the authority to act when there is a threatened or potential terrorist attack or other intentional act to disrupt the provision of safe drinking water or to impact the safety of a community's drinking water supply. [Section 401(3)]
Penalties for Tampering with Public Water Systems	SDWA Section 1432 authorizes criminal and civil penalties for persons who tamper, attempt to tamper, or threaten to tamper with public water supplies.	No provisions.	Amends SDWA Section 1432 to increase criminal and civil penalties for tampering, attempting to tamper, or making threats to tamper with public water supplies. [Section 401(4)]
Technical Assistance	SDWA Section 1442(b) authorizes EPA to provide technical assistance and to make grants to states and public water systems to assist in responding to and alleviating emergency situations.	No provisions.	Amends SDWA Section 1442(d) to authorize appropriations to carry out Section 1442(b) of not more than $35 million for FY2002, and such sums as may be necessary for each fiscal year thereafter. [Section 401(5)]

Appendix A. FY2002 HHS Bioterrorism Funding

FY2002 Labor-HHS-Education Appropriations

The President's FY2002 budget request for HHS included $250.6 million for bioterrorism preparedness: $181.9 million for CDC to upgrade its lab facilities, expand the National Pharmaceutical Stockpile, and award grants to state and local public health agencies for improving communications and preparedness; and $68.7 million for the HHS Office of Emergency Preparedness (OEP) for bioterrorism-related activities. The conference agreement on the FY2002 Labor-HHS-Education appropriations bill (H.Rept. 107-342, to accompany H.R. 3061) provided CDC with $181.9 for bioterrorism preparedness, the same as the Administration's request, and $61.0 million for OEP's bioterrorism activities, $7.7 million less than the request. Based on its FY2002 budget request, NIH estimated that it would spend $92.7 million on bioterrorism-related research in FY2002 (see **Table 2**).

Table 2. FY2002 Labor-HHS-Education Appropriations for Bioterrorism Preparedness and Response

($ millions)

	FY2001 Actual	FY2002 Request	FY2002 Enacted[a]
Centers for Disease Control & Prevention	$180.9	$181.9	$181.9
HHS Office of Emergency Preparedness	60.0	68.7	61.0
National Institutes of Health	49.7[b]	92.7[c]	92.7
Total	**$290.6**	**$343.3**	**$335.6**

Source: H.Rept. 107-342.

[a] P.L. 107-116.

[b] Estimate of the amount NIH spent on bioterrorism-related research in FY2001, based on the agency's FY2001 appropriations.

[c] Estimate of the amount NIH will spend on bioterrorism-related research in FY2002, based on the agency's FY2002 budget request.

Emergency Supplemental Appropriations

Within days of the September 11 terrorist attacks, Congress passed a $40 billion emergency supplemental appropriations act (P.L. 107-38, H.R. 2888) to provide aid to the victims, repair damaged public facilities and transportation systems, expand law enforcement activities, and strengthen counter-terrorism capabilities. The act divided the $40 billion into three amounts. The first $10 billion was available immediately for allocation by the President. An additional $10 billion was available 15 days after the President notified Congress about how he would distribute the funds. The final $20 billion was made subject to the appropriations process and allocated within an enacted FY2002 appropriation bill.

In a series of notifications beginning on September 21, 2001, the Administration allocated all but $327 million of the first $20 billion before the 15-day prior notification period expired on November 25. Those allocations included $126.2 million for HHS to provide emergency assistance for health care and social services in the New York and Washington, DC, metropolitan areas.[2]

On October 16, the Administration submitted to Congress its proposed allocation of the remaining $20 billion. The Administration's request provided $1.6 billion for HHS to combat bioterrorism, including $643.6 million to expand the National Pharmaceutical Stockpile, and $509 million to purchase smallpox vaccine. Funding was also requested to expand HHS's bioterrorism response capabilities and increase state and local bioterrorism readiness. Congress included the $20 billion emergency spending package as an amendment to the FY2002 Defense Department appropriations bill (H.R. 3338). As enacted, H.R. 3338 provides $2.8 billion to the HHS Public Health and Social Services Emergency Fund (PHSSEF) for bioterrorism-related activities (see **Table 3**).

[2] The funds were used to provide emergency grants to health care providers, community health centers, and mental health and substance abuse centers, and to provide services for the disabled, home-delivered meals, and transportation for senior citizens in affected areas.

Table 3. FY2002 Emergency Supplemental Appropriations: HHS Funding for Bioterrorism Preparedness and Response

($ millions)

	President's Request	Enacted[a]
National Pharmaceutical Stockpile	$643.6	$593.0
Smallpox vaccine	509.0	512.0
State and local public health capacity	80.0	865.0
Hospital capacity	50.0	135.0
Metropolitan Medical Response Systems	50.0	0.0
Office of the Secretary/National Disaster Medical System	33.0	55.8
CDC capacity and research	50.0	100.0
CDC environmental hazard control	0.0	7.5
CDC/NIH lab security	38.8	71.0
NIH/Nat. Institute of Allergy and Infectious Diseases	0.0	155.0[b]
FDA vaccine approval, food inspections, and security	95.6	151.1[c]
SAMHSA (mental health services for youth)	0.0	10.0
Recovery and response (NYC, New Jersey, Virginia)	45.0	0.0
Emergency health care reimbursement	0.0	140.0[d]
Total	**$1,595.0**	**$2,795.4[e]**

Source: H.Rept. 107-350.

[a] P.L. 107-117.

[b] Includes $85.0 million for bioterrorism research, and $70.0 million for constructing biosafety labs.

[c] Allocated as follows: expedite vaccine/biologic approval ($40.8 million); increase imported food inspections ($97.1 million); and increase security at FDA facilities ($13.2 million).

[d] Grants to reimburse public entities, not-for-profit entities, and Medicare and Medicaid providers for health care expenses or lost revenues attributable to the Sept. 11 attacks.

[e] Does not include $12.0 million appropriated directly to CDC for screening emergency personnel and rescue and recovery personnel, or $10.5 million provided to the National Institute of Environmental Health Sciences for research.

For detailed information on the allocation of the $40 billion emergency supplemental appropriations, see CRS Report RL31187, *Terrorism Funding: Congressional Debate on Emergency Supplemental Allocations* by Amy Belasco and Larry Q. Nowels and CRS Report RL31173, *Terrorism Funding: Emergency Supplemental Appropriations — Distribution of Funds to Departments and Agencies* by James R. Riehl.

Appendix B. Bioterrorism-Related Hearings (107th Congress)

Senate Appropriations Subcommittee on Labor, HHS, and Education

Oct. 3, 2001	Bioterrorism: Public health preparedness and response
Oct. 23, 2001	Public health response to anthrax attacks
Nov. 2, 2001	Smallpox: Public health preparedness and response
Nov. 29, 2001	Funding for bioterrorism preparedness

Senate Appropriations Subcommittee on VA-HUD and Independent Agencies

Nov. 28, 2001	Anthrax decontamination

Senate Armed Services Subcommittee on Emerging Threats and Capabilities

Oct. 25, 2001	Bioterrorism and the Dark Winter exercise

Senate Environment and Public Works Committee

Dec. 4, 2001	Anthrax decontamination

Senate Foreign Relations Committee

Sept. 5, 2001	Bioterrorism threat and the spread of infectious diseases

Senate Governmental Affairs Committee

July 23, 2001	Bioterrorism: FEMA's role and public health preparedness (Subcommittee on National Security, Proliferation and Federal Services)
Oct. 17, 2001	Bioterrorism: Federal agency preparedness
Oct. 30/31, 2001	Anthrax in the mail: Protecting postal workers and the public

Senate Health, Education, Labor, and Pensions Committee

Sept. 26, 2001	Psychological trauma of terrorism
Oct. 9, 2001	Bioterrorism: Public health preparedness and response
Nov. 2, 2001	Kids and terrorism (Subcommittee on Children and Families)

Senate Judiciary Committee

Nov. 6, 2001	Law enforcement and the domestic bioterrorism threat (Subcommittee on Technology, Terrorism and Government Information)

House Energy and Commerce Committee

Oct. 10, 2001	Bioterrorism preparedness and response (Subcommittee on Oversight and Investigations)
Nov. 1, 2001	Public health early-warning surveillance systems (Subcommittee on Oversight and Investigations)
Nov. 7, 2001	Physical security at NIH and CDC facilities (Subcommittee on Oversight and Investigations)
Nov. 15, 2001	Bioterrorism: Public health preparedness and response

House Government Reform Committee

May 1, 2001	Management of medical stockpiles (Subcommittee on National Security, Veterans Affairs and International Relations)
July 23, 2001	Federal response to a bioterrorism attack: Dark Winter (Subcommittee on National Security, Veterans Affairs and International Relations)
Oct. 5, 2001	Bioterrorism: Federal, state, and local preparedness (Subcommittee on Government Efficiency, Financial Management and Intergovernmental Relations)
Oct. 12, 2001	Assessing the threat of bioterrorism (Subcommittee on National Security, Veterans Affairs and International Relations)
Oct. 23, 2001	Vaccine research and development (Subcommittee on National Security, Veterans Affairs and International Relations)
Oct. 30, 2001	Anthrax and postal worker safety
Nov. 7, 2001	DOD medical readiness for chemical and biological warfare (Subcommittee on National Security, Veterans Affairs and International Relations)
Nov. 14, 2001	Medical care for bioterrorism victims

Nov. 29, 2001	Risk communication: National security and public health (Subcommittee on National Security, Veterans Affairs and International Relations)
Dec. 14, 2001	Bioterrorism Response: Information sharing between local, state, and federal governments (Subcommittee on Technology and Procurement Policy)

House International Relations Committee

Dec. 5, 2001	Bioterrorism and potential sources of anthrax

House Science Committee

Nov. 8, 2001	Anthrax decontamination
Dec. 5, 2001	Bioterrorism: Federal preparedness and response