"(4) CERTAIN POLITICAL SUBDIVISIONS.—

"(A) IN GENERAL.—For fiscal year 2003, the Secretary may, before making awards pursuant to paragraph (3) for such year, reserve from the amount appropriated under paragraph (1)(A)(i)(I) for the year an amount determined necessary by the Secretary to make awards under subsection (a) to political subdivisions that have a substantial number of residents, have a substantial local infrastructure for responding to public health emergencies, and face a high degree of risk from bioterrorist attacks or other public health emergencies. Not more than three political subdivisions may receive awards pursuant to this subparagraph.

"(B) COORDINATION WITH STATEWIDE PLANS.—An award pursuant to subparagraph (A) may not be made unless the application of the political subdivision involved is in coordination with, and consistent with, applicable Statewide plans described in subsection (c).

"(C) RELATIONSHIP TO FORMULA GRANTS.—In the case of a State that will receive an award pursuant to paragraph (3), and in which there is located a political subdivision that will receive an award pursuant to subparagraph (A), the Secretary shall, in determining the amount under paragraph (3)(C) for the State, subtract from the population of the State an amount equal to the population of such political subdivision.

"(D) CONTINUITY OF FUNDING.—In determining whether to make an award pursuant to subparagraph (A) to a political subdivision, the Secretary may consider, as a factor indicating that the award should be made, that the political subdivision received public health funding from the Secretary for fiscal year 2002.

"(5) SIGNIFICANT UNMET NEEDS; DEGREE OF RISK.—

"(A) IN GENERAL.—For fiscal year 2003, the Secretary may, before making awards pursuant to paragraph (3) for such year, reserve from the amount appropriated under paragraph (1)(A)(i)(I) for the year an amount determined necessary by the Secretary to make awards under subsection (a) to eligible entities that—

"(i) have a significant need for funds to build capacity to identify, detect, monitor, and respond to a bioterrorist or other threat to the public health, which need will not be met by awards pursuant to paragraph (3); and

"(ii) face a particularly high degree of risk of such a threat.

"(B) RECIPIENTS OF GRANTS.—Awards pursuant to subparagraph (A) may be supplemental awards to States that receive awards pursuant to paragraph (3), or may be awards to eligible entities described in subsection (b)(1)(B) within such States.

"(C) FINDING WITH RESPECT TO DISTRICT OF COLUMBIA.—The Secretary shall consider the District of Columbia to have a significant unmet need for purposes of subparagraph (A), and to face a particularly high degree of risk for such purposes, on the basis of the concentration of entities of national significance located within the District.

"(6) FUNDING OF LOCAL ENTITIES.—For fiscal year 2003, the Secretary shall in making awards under this section ensure that appropriate portions of such awards are made available to political subdivisions, local departments of public health, hospitals (including children's hospitals), clinics, health centers, or primary care facilities, or consortia of such entities.

42 USC 247d–3b.

"SEC. 319C–2. PARTNERSHIPS FOR COMMUNITY AND HOSPITAL PREPAREDNESS.

"(a) GRANTS.—The Secretary shall make awards of grants or cooperative agreements to eligible entities to enable such entities to improve community and hospital preparedness for bioterrorism and other public health emergencies.

"(b) ELIGIBILITY.—To be eligible for an award under subsection (a), an entity shall—

"(1) be a partnership consisting of—

"(A) one or more hospitals (including children's hospitals), clinics, health centers, or primary care facilities; and

"(B)(i) one or more political subdivisions of States;

"(ii) one or more States; or

"(iii) one or more States and one or more political subdivisions of States; and

"(2) prepare, in consultation with the Chief Executive Officer of the State, District, or territory in which the hospital, clinic, health center, or primary care facility described in paragraph (1)(A) is located, and submit to the Secretary, an application at such time, in such manner, and containing such information as the Secretary may require.

"(c) REGIONAL COORDINATION.—In making awards under subsection (a), the Secretary shall give preference to eligible entities that submit applications that, in the determination of the Secretary, will—

"(1) enhance coordination—

"(A) among the entities described in subsection (b)(1)(A); and

"(B) between such entities and the entities described in subsection (b)(1)(B); and

"(2) serve the needs of a defined geographic area.

"(d) CONSISTENCY OF PLANNED ACTIVITIES.—An entity described in subsection (b)(1) shall utilize amounts received under an award under subsection (a) in a manner that is coordinated and consistent, as determined by the Secretary, with an applicable State Bioterrorism and Other Public Health Emergency Preparedness and Response Plan.

"(e) USE OF FUNDS.—An award under subsection (a) may be expended for activities that may include the following and similar activities—

"(1) planning and administration for such award;

"(2) preparing a plan for triage and transport management in the event of bioterrorism or other public health emergencies;

"(3) enhancing the training of health care professionals to improve the ability of such professionals to recognize the symptoms of exposure to a potential bioweapon, to make appropriate diagnosis, and to provide treatment to those individuals so exposed;

"(4) enhancing the training of health care professionals to recognize and treat the mental health consequences of bioterrorism or other public health emergencies;

"(5) enhancing the training of health care professionals to assist in providing appropriate health care for large numbers of individuals exposed to a bioweapon;

"(6) enhancing training and planning to protect the health and safety of personnel involved in responding to a biological attack;

"(7) developing and implementing the trauma care and burn center care components of the State plans for the provision of emergency medical services; or

"(8) conducting such activities as are described in section 319C–1(d) that are appropriate for hospitals (including children's hospitals), clinics, health centers, or primary care facilities.

"(f) LIMITATION ON AWARDS.—A political subdivision of a State shall not participate in more than one partnership described in subsection (b)(1).

"(g) PRIORITIES IN USE OF GRANTS.—

"(1) IN GENERAL.—

"(A) PRIORITIES.—Except as provided in subparagraph (B), the Secretary shall, in carrying out the activities described in this section, address the following hazards in the following priority:

"(i) Bioterrorism or acute outbreaks of infectious diseases.

"(ii) Other public health threats and emergencies.

"(B) DETERMINATION OF THE SECRETARY.—In the case of the hazard involved, the degree of priority that would apply to the hazard based on the categories specified in clauses (i) and (ii) of subparagraph (A) may be modified by the Secretary if the following conditions are met:

"(i) The Secretary determines that the modification is appropriate on the basis of the following factors:

"(I) The extent to which eligible entities are adequately prepared for responding to hazards within the category specified in clause (i) of subparagraph (A).

"(II) There has been a significant change in the assessment of risks to the public health posed by hazards within the category specified in clause (ii) of such subparagraph.

"(ii) Prior to modifying the priority, the Secretary notifies the appropriate committees of the Congress of the determination of the Secretary under clause (i) of this subparagraph.

"(2) AREAS OF EMPHASIS WITHIN CATEGORIES.—The Secretary shall determine areas of emphasis within the category of hazards specified in clause (i) of paragraph (1)(A), and shall determine areas of emphasis within the category of hazards specified in clause (ii) of such paragraph, based on an assessment of the risk and likely consequences of such hazards and on an evaluation of Federal, State, and local needs, and may also take into account the extent to which receiving an award under subsection (a) will develop capacities that can be used for public health emergencies of varying types.

"(h) COORDINATION WITH LOCAL MEDICAL RESPONSE SYSTEM.—An eligible entity and local Metropolitan Medical Response Systems shall, to the extent practicable, ensure that activities carried out under an award under subsection (a) are coordinated with activities that are carried out by local Metropolitan Medical Response Systems.

"(i) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary for each of fiscal years 2004 through 2006.".

(b) CERTAIN GRANTS.—Section 319C of the Public Health Service Act (42 U.S.C. 247d–3) is amended by striking subsection (f).

Subtitle D—Emergency Authorities; Additional Provisions

SEC. 141. REPORTING DEADLINES.

Section 319 of the Public Health Service Act (42 U.S.C. 247d) is amended by adding at the end the following:

"(d) DATA SUBMITTAL AND REPORTING DEADLINES.—In any case in which the Secretary determines that, wholly or partially as a result of a public health emergency that has been determined pursuant to subsection (a), individuals or public or private entities are unable to comply with deadlines for the submission to the Secretary of data or reports required under any law administered by the Secretary, the Secretary may, notwithstanding any other provision of law, grant such extensions of such deadlines as the circumstances reasonably require, and may waive, wholly or partially, any sanctions otherwise applicable to such failure to comply. Before or promptly after granting such an extension or waiver, the Secretary shall notify the Congress of such action and publish in the Federal Register a notice of the extension or waiver.".

Federal Register, publication.

SEC. 142. STREAMLINING AND CLARIFYING COMMUNICABLE DISEASE QUARANTINE PROVISIONS.

(a) ELIMINATION OF PREREQUISITE FOR NATIONAL ADVISORY HEALTH COUNCIL RECOMMENDATION BEFORE ISSUING QUARANTINE RULES.—

(1) EXECUTIVE ORDERS SPECIFYING DISEASES SUBJECT TO INDIVIDUAL DETENTIONS.—Section 361(b) of the Public Health Act (42 U.S.C. 264(b)) is amended by striking "Executive orders of the President upon the recommendation of the National Advisory Health Council and the Surgeon General" and inserting "Executive orders of the President upon the recommendation of the Secretary, in consultation with the Surgeon General,".

(2) REGULATIONS PROVIDING FOR APPREHENSION OF INDIVIDUALS.—Section 361(d) of the Public Health Act (42 U.S.C. 264(d)) is amended by striking "On recommendation of the National Advisory Health Council, regulations" and inserting "Regulations".

(3) REGULATIONS PROVIDING FOR APPREHENSION OF INDIVIDUALS IN WARTIME.—Section 363 of the Public Health Act (42 U.S.C. 266) is amended by striking "the Surgeon General, on recommendation of the National Advisory Health Council," and

inserting "the Secretary, in consultation with the Surgeon General,".

(b) APPREHENSION AUTHORITY TO APPLY IN CASES OF EXPOSURE TO DISEASE.—

(1) REGULATIONS PROVIDING FOR APPREHENSION OF INDIVIDUALS.—Section 361(d) of the Public Health Act (42 U.S.C. 264(d)), as amended by subsection (a)(2), is further amended—

(A) by striking "(1)" and "(2)" and inserting "(A)" and "(B)", respectively;

(B) by striking "(d)" and inserting "(d)(1)";

(C) in paragraph (1) (as designated by subparagraph (B) of this paragraph), in the first sentence, by striking "in a communicable stage" each place such term appears and inserting "in a qualifying stage"; and

(D) by adding at the end the following paragraph:

"(2) For purposes of this subsection, the term 'qualifying stage', with respect to a communicable disease, means that such disease—

"(A) is in a communicable stage; or

"(B) is in a precommunicable stage, if the disease would be likely to cause a public health emergency if transmitted to other individuals.".

(2) REGULATIONS PROVIDING FOR APPREHENSION OF INDIVIDUALS IN WARTIME.—Section 363 of the Public Health Act (42 U.S.C. 266), as amended by subsection (a)(3), is further amended by striking "in a communicable stage".

(c) STATE AUTHORITY.—Section 361 of the Public Health Act (42 U.S.C. 264) is amended by adding at the end the following:

"(e) Nothing in this section or section 363, or the regulations promulgated under such sections, may be construed as superseding any provision under State law (including regulations and including provisions established by political subdivisions of States), except to the extent that such a provision conflicts with an exercise of Federal authority under this section or section 363.".

SEC. 143. EMERGENCY WAIVER OF MEDICARE, MEDICAID, AND SCHIP REQUIREMENTS.

(a) WAIVER AUTHORITY.—Title XI of the Social Security Act (42 U.S.C. 1301 et seq.) is amended by inserting after section 1134 the following new section:

"AUTHORITY TO WAIVE REQUIREMENTS DURING NATIONAL EMERGENCIES

"SEC. 1135. (a) PURPOSE.—The purpose of this section is to enable the Secretary to ensure to the maximum extent feasible, in any emergency area and during an emergency period (as defined in subsection (g)(1))— 42 USC 1320b–5.

"(1) that sufficient health care items and services are available to meet the needs of individuals in such area enrolled in the programs under titles XVIII, XIX, and XXI; and

"(2) that health care providers (as defined in subsection (g)(2)) that furnish such items and services in good faith, but that are unable to comply with one or more requirements described in subsection (b), may be reimbursed for such items and services and exempted from sanctions for such noncompliance, absent any determination of fraud or abuse.

"(b) SECRETARIAL AUTHORITY.—To the extent necessary to accomplish the purpose specified in subsection (a), the Secretary

is authorized, subject to the provisions of this section, to temporarily waive or modify the application of, with respect to health care items and services furnished by a health care provider (or classes of health care providers) in any emergency area (or portion of such an area) during any portion of an emergency period, the requirements of titles XVIII, XIX, or XXI, or any regulation thereunder (and the requirements of this title other than this section, and regulations thereunder, insofar as they relate to such titles), pertaining to—

"(1)(A) conditions of participation or other certification requirements for an individual health care provider or types of providers,

"(B) program participation and similar requirements for an individual health care provider or types of providers, and

"(C) pre-approval requirements;

"(2) requirements that physicians and other health care professionals be licensed in the State in which they provide such services, if they have equivalent licensing in another State and are not affirmatively excluded from practice in that State or in any State a part of which is included in the emergency area;

"(3) sanctions under section 1867 (relating to examination and treatment for emergency medical conditions and women in labor) for a transfer of an individual who has not been stabilized in violation of subsection (c) of such section if the transfer arises out of the circumstances of the emergency;

"(4) sanctions under section 1877(g) (relating to limitations on physician referral);

"(5) deadlines and timetables for performance of required activities, except that such deadlines and timetables may only be modified, not waived; and

"(6) limitations on payments under section 1851(i) for health care items and services furnished to individuals enrolled in a Medicare+Choice plan by health care professionals or facilities not included under such plan.

Insofar as the Secretary exercises authority under paragraph (6) with respect to individuals enrolled in a Medicare+Choice plan, to the extent possible given the circumstances, the Secretary shall reconcile payments made on behalf of such enrollees to ensure that the enrollees do not pay more than would be required had they received services from providers within the network of the plan and may reconcile payments to the organization offering the plan to ensure that such organization pays for services for which payment is included in the capitation payment it receives under part C of title XVIII.

"(c) AUTHORITY FOR RETROACTIVE WAIVER.—A waiver or modification of requirements pursuant to this section may, at the Secretary's discretion, be made retroactive to the beginning of the emergency period or any subsequent date in such period specified by the Secretary.

"(d) CERTIFICATION TO CONGRESS.—The Secretary shall provide a certification and advance written notice to the Congress at least two days before exercising the authority under this section with respect to an emergency area. Such a certification and notice shall include—

"(1) a description of—

"(A) the specific provisions that will be waived or modified;

"(B) the health care providers to whom the waiver or modification will apply;

"(C) the geographic area in which the waiver or modification will apply; and

"(D) the period of time for which the waiver or modification will be in effect; and

"(2) a certification that the waiver or modification is necessary to carry out the purpose specified in subsection (a).

"(e) DURATION OF WAIVER.—

"(1) IN GENERAL.—A waiver or modification of requirements pursuant to this section terminates upon—

"(A) the termination of the applicable declaration of emergency or disaster described in subsection (g)(1)(A);

"(B) the termination of the applicable declaration of public health emergency described in subsection (g)(1)(B); or

"(C) subject to paragraph (2), the termination of a period of 60 days from the date the waiver or modification is first published (or, if applicable, the date of extension of the waiver or modification under paragraph (2)).

"(2) EXTENSION OF 60-DAY PERIODS.—The Secretary may, by notice, provide for an extension of a 60-day period described in paragraph (1)(C) (or an additional period provided under this paragraph) for additional period or periods (not to exceed, except as subsequently provided under this paragraph, 60 days each), but any such extension shall not affect or prevent the termination of a waiver or modification under subparagraph (A) or (B) of paragraph (1).

"(f) REPORT TO CONGRESS.—Within one year after the end of the emergency period in an emergency area in which the Secretary exercised the authority provided under this section, the Secretary shall report to the Congress regarding the approaches used to accomplish the purposes described in subsection (a), including an evaluation of such approaches and recommendations for improved approaches should the need for such emergency authority arise in the future.

"(g) DEFINITIONS.—For purposes of this section:

"(1) EMERGENCY AREA; EMERGENCY PERIOD.—An 'emergency area' is a geographical area in which, and an 'emergency period' is the period during which, there exists—

"(A) an emergency or disaster declared by the President pursuant to the National Emergencies Act or the Robert T. Stafford Disaster Relief and Emergency Assistance Act; and

"(B) a public health emergency declared by the Secretary pursuant to section 319 of the Public Health Service Act.

"(2) HEALTH CARE PROVIDER.—The term 'health care provider' means any entity that furnishes health care items or services, and includes a hospital or other provider of services, a physician or other health care practitioner or professional, a health care facility, or a supplier of health care items or services.".

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall be effective on and after September 11, 2001.

42 USC 1320b–5 note.

SEC. 144. PROVISION FOR EXPIRATION OF PUBLIC HEALTH EMERGENCIES.

(a) IN GENERAL.—Section 319(a) of the Public Health Service Act (42 U.S.C. 247d(a)), is amended by adding at the end the following new sentence: "Any such determination of a public health emergency terminates upon the Secretary declaring that the emergency no longer exists, or upon the expiration of the 90-day period beginning on the date on which the determination is made by the Secretary, whichever occurs first. Determinations that terminate under the preceding sentence may be renewed by the Secretary (on the basis of the same or additional facts), and the preceding sentence applies to each such renewal. Not later than 48 hours after making a determination under this subsection of a public health emergency (including a renewal), the Secretary shall submit to the Congress written notification of the determination.".

42 USC 247d note.

(b) APPLICABILITY.—The amendment made by subsection (a) applies to any public health emergency under section 319(a) of the Public Health Service Act, including any such emergency that was in effect as of the day before the date of the enactment of this Act. In the case of such an emergency that was in effect as of such day, the 90-day period described in such section with respect to the termination of the emergency is deemed to begin on such date of enactment.

Subtitle E—Additional Provisions

SEC. 151. DESIGNATED STATE PUBLIC EMERGENCY ANNOUNCEMENT PLAN.

Section 613(b) of the Robert T. Stafford Disaster Relief and Emergency Assistance Act (42 U.S.C. 5196b(b)) is amended—

(1) in paragraph (5), by striking "and" at the end;

(2) in paragraph (6), by striking the period and inserting "; and"; and

(3) by adding at the end the following:

"(7) include a plan for providing information to the public in a coordinated manner.".

42 USC 7257d.

SEC. 152. EXPANDED RESEARCH BY SECRETARY OF ENERGY.

(a) DETECTION AND IDENTIFICATION RESEARCH.—

(1) IN GENERAL.—In conjunction with the working group under section 319F(a) of the Public Health Service Act, the Secretary of Energy and the Administrator of the National Nuclear Security Administration shall expand, enhance, and intensify research relevant to the rapid detection and identification of pathogens likely to be used in a bioterrorism attack or other agents that may cause a public health emergency.

(2) AUTHORIZED ACTIVITIES.—Activities carried out under paragraph (1) may include—

(A) the improvement of methods for detecting biological agents or toxins of potential use in a biological attack and the testing of such methods under variable conditions;

(B) the improvement or pursuit of methods for testing, verifying, and calibrating new detection and surveillance tools and techniques; and

(C) carrying out other research activities in relevant areas.

(3) REPORT.—Not later than 180 days after the date of the enactment of this Act, the Administrator of the National Nuclear Security Administration shall submit to the Committee on Energy and Natural Resources and the Committee on Armed Services of the Senate, and the Committee on Energy and Commerce and the Committee on Armed Services of the House of Representatives, a report setting forth the programs and projects that will be funded prior to the obligation of funds appropriated under subsection (b). Deadline.

(b) AUTHORIZATION.—For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary in each of fiscal years 2002 through 2006.

SEC. 153. EXPANDED RESEARCH ON WORKER HEALTH AND SAFETY. 29 USC 669a.

The Secretary of Health and Human Services (referred to in this section as the "Secretary"), acting through the Director of the National Institute of Occupational Safety and Health, shall enhance and expand research as deemed appropriate on the health and safety of workers who are at risk for bioterrorist threats or attacks in the workplace, including research on the health effects of measures taken to treat or protect such workers for diseases or disorders resulting from a bioterrorist threat or attack. Nothing in this section may be construed as establishing new regulatory authority for the Secretary or the Director to issue or modify any occupational safety and health rule or regulation.

SEC. 154. ENHANCEMENT OF EMERGENCY PREPAREDNESS OF DEPARTMENT OF VETERANS AFFAIRS. 38 USC note prec. 8101.

(a) READINESS OF DEPARTMENT MEDICAL CENTER.—(1) The Secretary of Veterans Affairs shall take appropriate actions to enhance the readiness of Department of Veterans Affairs medical centers to protect the patients and staff of such centers from chemical or biological attack or otherwise to respond to such an attack and so as to enable such centers to fulfil their obligations as part of the Federal response to public health emegencies.

(2) Actions under paragraph (1) shall include—

(A) the provision of decontamination equipment and personal protection equipment at Department medical centers; and

(B) the provision of training in the use of such equipment to staff of such centers.

(b) SECURITY AT DEPARTMENT MEDICAL AND RESEARCH FACILITIES.—(1) Not later than 180 days after the date of the enactment of this Act, the Secretary shall carry out an evaluation of the security needs at Department medical centers and research facilities. The evaluation shall address the following needs: Deadline.

(A) Needs for the protection of patients and medical staff during emergencies, including a chemical or biological attack or other terrorist attack.

(B) Needs, if any, for screening personnel engaged in research relating to biological pathogens or agents, including work associated with such research.

(C) Needs for securing laboratories or other facilities engaged in research relating to biological pathogens or agents.

(D) Any other needs the Secretary considers appropriate.

(2) The Secretary shall take appropriate actions to enhance the security of Department medical centers and research facilities, including staff and patients at such centers and facilities. In taking such actions, the Secretary shall take into account the results of the evaluation required by paragraph (1).

(c) TRACKING OF PHARMACEUTICALS AND MEDICAL SUPPLIES AND EQUIPMENT.—The Secretary shall develop and maintain a centralized system for tracking the current location and availability of pharmaceuticals, medical supplies, and medical equipment throughout the Department health care system in order to permit the ready identification and utilization of such pharmaceuticals, supplies, and equipment for a variety of purposes, including response to a chemical or biological attack or other terrorist attack.

(d) TRAINING.—The Secretary shall ensure that the Department medical centers, in consultation with the accredited medical school affiliates of such medical centers, develop and implement curricula to train resident physicians and health care personnel in medical matters relating to biological, chemical, or radiological attacks.

(e) PARTICIPATION IN NATIONAL DISASTER MEDICAL SYSTEM.—(1) The Secretary shall, in consultation with the Secretary of Defense, the Secretary of Health and Human Services, and the Director of the Federal Emergency Management Agency, establish and maintain a training program to facilitate the participation of the staff of Department medical centers, and of the community partners of such centers, in the National Disaster Medical System.

(2) The Secretary shall establish and maintain the training program under paragraph (1) in accordance with the recommendations of the working group under section 319F(a) of the Public Health Service Act.

(f) MENTAL HEALTH COUNSELING.—(1) With respect to activities conducted by personnel serving at Department medical centers, the Secretary shall, in consultation with the Secretary of Health and Human Services, the American Red Cross, and the working group under section 319F(a) of the Public Health Service Act, develop and maintain various strategies for providing mental health counseling and assistance, including counseling and assistance for post-traumatic stress disorder, to local and community emergency response providers, veterans, active duty military personnel, and individuals seeking care at Department medical centers following a bioterrorist attack or other public health emergency.

(2) The strategies under paragraph (1) shall include the following:

(A) Training and certification of providers of mental health counseling and assistance.

(B) Mechanisms for coordinating the provision of mental health counseling and assistance to emergency response providers referred to in that paragraph.

(g) AUTHORIZATION OF APPROPRIATIONS.—There is hereby authorized to be appropriated for the Department of Veterans Affairs amounts as follows:

(1) To carry out activities required by subsection (a)—

(A) $100,000,000 for fiscal year 2002; and

(B) such sums as may be necessary for each of fiscal years 2003 through 2006.

(2) To carry out activities required by subsections (b) through (f)—

(A) $33,000,000 for fiscal year 2002; and

(B) such sums as may be necessary for each of fiscal years 2003 through 2006.

SEC. 155. REAUTHORIZATION OF EXISTING PROGRAM.

Section 582(f) of the Public Health Service Act (42 U.S.C. 290hh-1(f)) is amended by striking "2002 and 2003" and inserting "2003 through 2006".

SEC. 156. SENSE OF CONGRESS.

It is the sense of the Congress that—

(1) many excellent university-based programs are already functioning and developing important biodefense products and solutions throughout the United States;

(2) accelerating the crucial work done at university centers and laboratories will contribute significantly to the United States capacity to defend against any biological threat or attack;

(3) maximizing the effectiveness of, and extending the mission of, established university programs would be one appropriate use of the additional resources provided for in this Act and the amendments made by this Act; and

(4) the Secretary of Health and Human Services should, as appropriate, recognize the importance of existing public and private university-based research, training, public awareness, and safety related biological defense programs when the Secretary makes awards of grants and contracts in accordance with this Act and the amendments made by this Act.

SEC. 157. GENERAL ACCOUNTING OFFICE REPORT.

42 USC 300hh note.

(a) IN GENERAL.—The Comptroller General shall submit to the Committee on Health, Education, Labor, and Pensions and the Committee on Appropriations of the Senate, and to the Committee on Energy and Commerce and the Committee on Appropriations of the House of Representatives, a report that describes—

(1) Federal activities primarily related to research on, preparedness for, and the management of the public health and medical consequences of a bioterrorist attack against the civilian population;

(2) the coordination of the activities described in paragraph (1);

(3) the effectiveness of such efforts in preparing national, State, and local authorities to address the public health and medical consequences of a potential bioterrorist attack against the civilian population;

(4) the activities and costs of the Civil Support Teams of the National Guard in responding to biological threats or attacks against the civilian population;

(5) the activities of the working group under subsection (a) and the efforts made by such group to carry out the activities described in such subsection; and

(6) the ability of private sector contractors to enhance governmental responses to biological threats or attacks.

SEC. 158. CERTAIN AWARDS.

Section 319(a) of the Public Health Service Act (42 U.S.C. 247d(a)) is amended in the matter after and below paragraph (2) by striking "grants and" and inserting "grants, providing awards for expenses, and".

Community Access to Emergency Defibrillation Act of 2002.
42 USC 201 note.
42 USC 244 note.

SEC. 159. PUBLIC ACCESS DEFIBRILLATION PROGRAMS AND PUBLIC ACCESS DEFIBRILLATION DEMONSTRATION PROJECTS.

(a) SHORT TITLE.—This section may be cited as the "Community Access to Emergency Defibrillation Act of 2002".

(b) FINDINGS.—Congress makes the following findings:

(1) Over 220,000 Americans die each year from cardiac arrest. Every 2 minutes, an individual goes into cardiac arrest in the United States.

(2) The chance of successfully returning to a normal heart rhythm diminishes by 10 percent each minute following sudden cardiac arrest.

(3) Eighty percent of cardiac arrests are caused by ventricular fibrillation, for which defibrillation is the only effective treatment.

(4) Sixty percent of all cardiac arrests occur outside the hospital. The average national survival rate for out-of-hospital cardiac arrest is only 5 percent.

(5) Communities that have established and implemented public access defibrillation programs have achieved average survival rates for out-of-hospital cardiac arrest as high as 50 percent.

(6) According to the American Heart Association, wide use of defibrillators could save as many as 50,000 lives nationally each year.

(7) Successful public access defibrillation programs ensure that cardiac arrest victims have access to early 911 notification, early cardiopulmonary resuscitation, early defibrillation, and early advanced care.

(c) PUBLIC ACCESS DEFIBRILLATION PROGRAMS AND PROJECTS.—Part B of title III of the Public Health Service Act (42 U.S.C. 243 et seq.), as amended by Public Law 106–310, is amended by adding after section 311 the following:

42 USC 244.

"SEC. 312. PUBLIC ACCESS DEFIBRILLATION PROGRAMS.

Grants.

"(a) IN GENERAL.—The Secretary shall award grants to States, political subdivisions of States, Indian tribes, and tribal organizations to develop and implement public access defibrillation programs—

"(1) by training and equipping local emergency medical services personnel, including firefighters, police officers, paramedics, emergency medical technicians, and other first responders, to administer immediate care, including cardiopulmonary resuscitation and automated external defibrillation, to cardiac arrest victims;

"(2) by purchasing automated external defibrillators, placing the defibrillators in public places where cardiac arrests are likely to occur, and training personnel in such places to administer cardiopulmonary resuscitation and automated external defibrillation to cardiac arrest victims;

"(3) by setting procedures for proper maintenance and testing of such devices, according to the guidelines of the manufacturers of the devices;

"(4) by providing training to members of the public in cardiopulmonary resuscitation and automated external defibrillation;

"(5) by integrating the emergency medical services system with the public access defibrillation programs so that emergency

medical services personnel, including dispatchers, are informed about the location of automated external defibrillators in their community; and

"(6) by encouraging private companies, including small businesses, to purchase automated external defibrillators and provide training for their employees to administer cardiopulmonary resuscitation and external automated defibrillation to cardiac arrest victims in their community.

"(b) PREFERENCE.—In awarding grants under subsection (a), the Secretary shall give a preference to a State, political subdivision of a State, Indian tribe, or tribal organization that—

"(1) has a particularly low local survival rate for cardiac arrests, or a particularly low local response rate for cardiac arrest victims; or

"(2) demonstrates in its application the greatest commitment to establishing and maintaining a public access defibrillation program.

"(c) USE OF FUNDS.—A State, political subdivision of a State, Indian tribe, or tribal organization that receives a grant under subsection (a) may use funds received through such grant to—

"(1) purchase automated external defibrillators that have been approved, or cleared for marketing, by the Food and Drug Administration;

"(2) provide automated external defibrillation and basic life support training in automated external defibrillator usage through nationally recognized courses;

"(3) provide information to community members about the public access defibrillation program to be funded with the grant;

"(4) provide information to the local emergency medical services system regarding the placement of automated external defibrillators in public places;

"(5) produce materials to encourage private companies, including small businesses, to purchase automated external defibrillators; and

"(6) further develop strategies to improve access to automated external defibrillators in public places.

"(d) APPLICATION.—

"(1) IN GENERAL.—To be eligible to receive a grant under subsection (a), a State, political subdivision of a State, Indian tribe, or tribal organization shall prepare and submit an application to the Secretary at such time, in such manner, and containing such information as the Secretary may reasonably require.

"(2) CONTENTS.—An application submitted under paragraph (1) shall—

"(A) describe the comprehensive public access defibrillation program to be funded with the grant and demonstrate how such program would make automated external defibrillation accessible and available to cardiac arrest victims in the community;

"(B) contain procedures for implementing appropriate nationally recognized training courses in performing cardiopulmonary resuscitation and the use of automated external defibrillators;

"(C) contain procedures for ensuring direct involvement of a licensed medical professional and coordination with the local emergency medical services system in the oversight of training and notification of incidents of the use of the automated external defibrillators;

"(D) contain procedures for proper maintenance and testing of the automated external defibrillators, according to the labeling of the manufacturer;

"(E) contain procedures for ensuring notification of local emergency medical services system personnel, including dispatchers, of the location and type of devices used in the public access defibrillation program; and

"(F) provide for the collection of data regarding the effectiveness of the public access defibrillation program to be funded with the grant in affecting the out-of-hospital cardiac arrest survival rate.

"(e) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated $25,000,000 for fiscal year 2003, and such sums as may be necessary for each of the fiscal years 2004 through 2006. Not more than 10 percent of amounts received under a grant awarded under this section may be used for administrative expenses.

42 USC 245.

"SEC. 313. PUBLIC ACCESS DEFIBRILLATION DEMONSTRATION PROJECTS.

"(a) IN GENERAL.—The Secretary shall award grants to political subdivisions of States, Indian tribes, and tribal organizations to develop and implement innovative, comprehensive, community-based public access defibrillation demonstration projects that—

"(1) provide cardiopulmonary resuscitation and automated external defibrillation to cardiac arrest victims in unique settings;

"(2) provide training to community members in cardiopulmonary resuscitation and automated external defibrillation; and

"(3) maximize community access to automated external defibrillators.

"(b) USE OF FUNDS.—A recipient of a grant under subsection (a) shall use the funds provided through the grant to—

"(1) purchase automated external defibrillators that have been approved, or cleared for marketing, by the Food and Drug Administration;

"(2) provide basic life training in automated external defibrillator usage through nationally recognized courses;

"(3) provide information to community members about the public access defibrillation demonstration project to be funded with the grant;

"(4) provide information to the local emergency medical services system regarding the placement of automated external defibrillators in the unique settings; and

"(5) further develop strategies to improve access to automated external defibrillators in public places.

"(c) APPLICATION.—

"(1) IN GENERAL.—To be eligible to receive a grant under subsection (a), a political subdivision of a State, Indian tribe, or tribal organization shall prepare and submit an application to the Secretary at such time, in such manner, and containing such information as the Secretary may reasonably require.

"(2) CONTENTS.—An application submitted under paragraph (1) may—

"(A) describe the innovative, comprehensive, community-based public access defibrillation demonstration project to be funded with the grant;

"(B) explain how such public access defibrillation demonstration project represents innovation in providing public access to automated external defibrillation; and

"(C) provide for the collection of data regarding the effectiveness of the demonstration project to be funded with the grant in—

"(i) providing emergency cardiopulmonary resuscitation and automated external defibrillation to cardiac arrest victims in the setting served by the demonstration project; and

"(ii) affecting the cardiac arrest survival rate in the setting served by the demonstration project.

"(d) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section $5,000,000 for each of fiscal years 2002 through 2006. Not more than 10 percent of amounts received under a grant awarded under this section may be used for administrative expenses.".

TITLE II—ENHANCING CONTROLS ON DANGEROUS BIOLOGICAL AGENTS AND TOXINS

Subtitle A—Department of Health and Human Services

SEC. 201. REGULATION OF CERTAIN BIOLOGICAL AGENTS AND TOXINS.

(a) BIOLOGICAL AGENTS PROVISIONS OF THE ANTITERRORISM AND EFFECTIVE DEATH PENALTY ACT OF 1996; CODIFICATION IN THE PUBLIC HEALTH SERVICE ACT, WITH AMENDMENTS.—Subpart 1 of part F of title III of the Public Health Service Act (42 U.S.C. 262 et seq.) is amended by inserting after section 351 the following:

"SEC. 351A. ENHANCED CONTROL OF DANGEROUS BIOLOGICAL AGENTS AND TOXINS. 42 USC 262a.

"(a) REGULATORY CONTROL OF CERTAIN BIOLOGICAL AGENTS AND TOXINS.—

"(1) LIST OF BIOLOGICAL AGENTS AND TOXINS.—

"(A) IN GENERAL.—The Secretary shall by regulation establish and maintain a list of each biological agent and each toxin that has the potential to pose a severe threat to public health and safety.

"(B) CRITERIA.—In determining whether to include an agent or toxin on the list under subparagraph (A), the Secretary shall—

"(i) consider—

"(I) the effect on human health of exposure to the agent or toxin;

"(II) the degree of contagiousness of the agent or toxin and the methods by which the agent or toxin is transferred to humans;

"(III) the availability and effectiveness of pharmacotherapies and immunizations to treat and prevent any illness resulting from infection by the agent or toxin; and

"(IV) any other criteria, including the needs of children and other vulnerable populations, that the Secretary considers appropriate; and

"(ii) consult with appropriate Federal departments and agencies and with scientific experts representing appropriate professional groups, including groups with pediatric expertise.

"(2) BIENNIAL REVIEW.—The Secretary shall review and republish the list under paragraph (1) biennially, or more often as needed, and shall by regulation revise the list as necessary in accordance with such paragraph.

"(b) REGULATION OF TRANSFERS OF LISTED AGENTS AND TOXINS.—The Secretary shall by regulation provide for—

"(1) the establishment and enforcement of safety procedures for the transfer of listed agents and toxins, including measures to ensure—

"(A) proper training and appropriate skills to handle such agents and toxins; and

"(B) proper laboratory facilities to contain and dispose of such agents and toxins;

"(2) the establishment and enforcement of safeguard and security measures to prevent access to such agents and toxins for use in domestic or international terrorism or for any other criminal purpose;

"(3) the establishment of procedures to protect the public safety in the event of a transfer or potential transfer of such an agent or toxin in violation of the safety procedures established under paragraph (1) or the safeguard and security measures established under paragraph (2); and

"(4) appropriate availability of biological agents and toxins for research, education, and other legitimate purposes.

"(c) POSSESSION AND USE OF LISTED AGENTS AND TOXINS.—The Secretary shall by regulation provide for the establishment and enforcement of standards and procedures governing the possession and use of listed agents and toxins, including the provisions described in paragraphs (1) through (4) of subsection (b), in order to protect the public health and safety.

"(d) REGISTRATION; IDENTIFICATION; DATABASE.—

"(1) REGISTRATION.—Regulations under subsections (b) and (c) shall require registration with the Secretary of the possession, use, and transfer of listed agents and toxins, and shall include provisions to ensure that persons seeking to register under such regulations have a lawful purpose to possess, use, or transfer such agents and toxins, including provisions in accordance with subsection (e)(6).

"(2) IDENTIFICATION; DATABASE.—Regulations under subsections (b) and (c) shall require that registration include (if available to the person registering) information regarding the characterization of listed agents and toxins to facilitate their

identification, including their source. The Secretary shall maintain a national database that includes the names and locations of registered persons, the listed agents and toxins such persons are possessing, using, or transferring, and information regarding the characterization of such agents and toxins.

"(e) SAFEGUARD AND SECURITY REQUIREMENTS FOR REGISTERED PERSONS.—

"(1) IN GENERAL.—Regulations under subsections (b) and (c) shall include appropriate safeguard and security requirements for persons possessing, using, or transferring a listed agent or toxin commensurate with the risk such agent or toxin poses to public health and safety (including the risk of use in domestic or international terrorism). The Secretary shall establish such requirements in consultation with the Attorney General, and shall ensure compliance with such requirements as part of the registration system under such regulations.

"(2) LIMITING ACCESS TO LISTED AGENTS AND TOXINS.—Requirements under paragraph (1) shall include provisions to ensure that registered persons—

"(A) provide access to listed agents and toxins to only those individuals whom the registered person involved determines have a legitimate need to handle or use such agents and toxins;

"(B) submit the names and other identifying information for such individuals to the Secretary and the Attorney General, promptly after first determining that the individuals need access under subparagraph (A), and periodically thereafter while the individuals have such access, not less frequently than once every five years;

"(C) deny access to such agents and toxins by individuals whom the Attorney General has identified as restricted persons; and

"(D) limit or deny access to such agents and toxins by individuals whom the Attorney General has identified as within any category under paragraph (3)(B)(ii), if limiting or denying such access by the individuals involved is determined appropriate by the Secretary, in consultation with the Attorney General.

"(3) SUBMITTED NAMES; USE OF DATABASES BY ATTORNEY GENERAL.—

"(A) IN GENERAL.—Upon the receipt of names and other identifying information under paragraph (2)(B), the Attorney General shall, for the sole purpose of identifying whether the individuals involved are within any of the categories specified in subparagraph (B), promptly use criminal, immigration, national security, and other electronic databases that are available to the Federal Government and are appropriate for such purpose.

"(B) CERTAIN INDIVIDUALS.—For purposes of subparagraph (A), the categories specified in this subparagraph regarding an individual are that—

"(i) the individual is a restricted person; or

"(ii) the individual is reasonably suspected by any Federal law enforcement or intelligence agency of—

"(I) committing a crime set forth in section 2332b(g)(5) of title 18, United States Code;

"(II) knowing involvement with an organization that engages in domestic or international terrorism (as defined in section 2331 of such title 18) or with any other organization that engages in intentional crimes of violence; or

"(III) being an agent of a foreign power (as defined in section 1801 of title 50, United States Code).

"(C) NOTIFICATION BY ATTORNEY GENERAL REGARDING SUBMITTED NAMES.—After the receipt of a name and other identifying information under paragraph (2)(B), the Attorney General shall promptly notify the Secretary whether the individual is within any of the categories specified in subparagraph (B).

"(4) NOTIFICATIONS BY SECRETARY.—The Secretary, after receiving notice under paragraph (3) regarding an individual, shall promptly notify the registered person involved of whether the individual is granted or denied access under paragraph (2). If the individual is denied such access, the Secretary shall promptly notify the individual of the denial.

"(5) EXPEDITED REVIEW.—Regulations under subsections (b) and (c) shall provide for a procedure through which, upon request to the Secretary by a registered person who submits names and other identifying information under paragraph (2)(B) and who demonstrates good cause, the Secretary may, as determined appropriate by the Secretary—

"(A) request the Attorney General to expedite the process of identification under paragraph (3)(A) and notification of the Secretary under paragraph (3)(C); and

"(B) expedite the notification of the registered person by the Secretary under paragraph (4).

"(6) PROCESS REGARDING PERSONS SEEKING TO REGISTER.—

"(A) INDIVIDUALS.—Regulations under subsections (b) and (c) shall provide that an individual who seeks to register under either of such subsections is subject to the same processes described in paragraphs (2) through (4) as apply to names and other identifying information submitted to the Attorney General under paragraph (2)(B). Paragraph (5) does not apply for purposes of this subparagraph.

"(B) OTHER PERSONS.—Regulations under subsections (b) and (c) shall provide that, in determining whether to deny or revoke registration by a person other than an individual, the Secretary shall submit the name of such person to the Attorney General, who shall use criminal, immigration, national security, and other electronic databases available to the Federal Government, as appropriate for the purpose of promptly notifying the Secretary whether the person, or, where relevant, the individual who owns or controls such person, is a restricted person or is reasonably suspected by any Federal law enforcement or intelligence agency of being within any category specified in paragraph (3)(B)(ii) (as applied to persons, including individuals). Such regulations shall provide that a person who seeks to register under either of such subsections is subject to the same processes described in paragraphs

(2) and (4) as apply to names and other identifying information submitted to the Attorney General under paragraph (2)(B). Paragraph (5) does not apply for purposes of this subparagraph. The Secretary may exempt Federal, State, or local governmental agencies from the requirements of this subparagraph.

"(7) REVIEW.—

"(A) ADMINISTRATIVE REVIEW.—

"(i) IN GENERAL.—Regulations under subsections (b) and (c) shall provide for an opportunity for a review by the Secretary—

"(I) when requested by the individual involved, of a determination under paragraph (2) to deny the individual access to listed agents and toxins; and

"(II) when requested by the person involved, of a determination under paragraph (6) to deny or revoke registration for such person.

"(ii) EX PARTE REVIEW.—During a review under clause (i), the Secretary may consider information relevant to the review ex parte to the extent that disclosure of the information could compromise national security or an investigation by any law enforcement agency.

"(iii) FINAL AGENCY ACTION.—The decision of the Secretary in a review under clause (i) constitutes final agency action for purposes of section 702 of title 5, United States Code.

"(B) CERTAIN PROCEDURES.—

"(i) SUBMISSION OF EX PARTE MATERIALS IN JUDICIAL PROCEEDINGS.—When reviewing a decision of the Secretary under subparagraph (A), and upon request made ex parte and in writing by the United States, a court, upon a sufficient showing, may review and consider ex parte documents containing information the disclosure of which could compromise national security or an investigation by any law enforcement agency. If the court determines that portions of the documents considered ex parte should be disclosed to the person involved to allow a response, the court shall authorize the United States to delete from such documents specified items of information the disclosure of which could compromise national security or an investigation by any law enforcement agency, or to substitute a summary of the information to which the person may respond. Any order by the court authorizing the disclosure of information that the United States believes could compromise national security or an investigation by any law enforcement agency shall be subject to the processes set forth in subparagraphs (A) and (B)(i) of section 2339B(f)(5) of title 18, United States Code (relating to interlocutory appeal and expedited consideration).

"(ii) DISCLOSURE OF INFORMATION.—In a review under subparagraph (A), and in any judical proceeding conducted pursuant to such review, neither the Secretary nor the Attorney General may be required to disclose to the public any information that under subsection (h) shall not be disclosed under section 552 of title 5, United States Code.

"(8) NOTIFICATIONS REGARDING THEFT OR LOSS OF AGENTS.—Requirements under paragraph (1) shall include the prompt notification of the Secretary, and appropriate Federal, State, and local law enforcement agencies, of the theft or loss of listed agents and toxins.

"(9) TECHNICAL ASSISTANCE FOR REGISTERED PERSONS.—The Secretary, in consultation with the Attorney General, may provide technical assistance to registered persons to improve security of the facilities of such persons.

"(f) INSPECTIONS.—The Secretary shall have the authority to inspect persons subject to regulations under subsection (b) or (c) to ensure their compliance with such regulations, including prohibitions on restricted persons and other provisions of subsection (e).

"(g) EXEMPTIONS.—

"(1) CLINICAL OR DIAGNOSTIC LABORATORIES.—Regulations under subsections (b) and (c) shall exempt clinical or diagnostic laboratories and other persons who possess, use, or transfer listed agents or toxins that are contained in specimens presented for diagnosis, verification, or proficiency testing, provided that—

"(A) the identification of such agents or toxins is reported to the Secretary, and when required under Federal, State, or local law, to other appropriate authorities; and

"(B) such agents or toxins are transferred or destroyed in a manner set forth by the Secretary by regulation.

"(2) PRODUCTS.—

"(A) IN GENERAL.—Regulations under subsections (b) and (c) shall exempt products that are, bear, or contain listed agents or toxins and are cleared, approved, licensed, or registered under any of the Acts specified in subparagraph (B), unless the Secretary by order determines that applying additional regulation under subsection (b) or (c) to a specific product is necessary to protect public health and safety.

"(B) RELEVANT LAWS.—For purposes of subparagraph (A), the Acts specified in this subparagraph are the following:

"(i) The Federal Food, Drug, and Cosmetic Act.

"(ii) Section 351 of this Act.

"(iii) The Act commonly known as the Virus-Serum-Toxin Act (the eighth paragraph under the heading 'Bureau of Animal Industry' in the Act of March 4, 1913; 21 U.S.C. 151–159).

"(iv) The Federal Insecticide, Fungicide, and Rodenticide Act.

"(C) INVESTIGATIONAL USE.—

"(i) IN GENERAL.—The Secretary may exempt an investigational product that is, bears, or contains a listed agent or toxin from the applicability of provisions of regulations under subsection (b) or (c) when such product is being used in an investigation authorized under any Federal Act and the Secretary determines that applying additional regulation under subsection

(b) or (c) to such product is not necessary to protect public health and safety.

"(ii) CERTAIN PROCESSES.—Regulations under subsections (b) and (c) shall set forth the procedures for applying for an exemption under clause (i). In the case of investigational products authorized under any of the Acts specified in subparagraph (B), the Secretary shall make a determination regarding a request for an exemption not later than 14 days after the first date on which both of the following conditions have been met by the person requesting the exemption: Deadline.

"(I) The person has submitted to the Secretary an application for the exemption meeting the requirements established by the Secretary.

"(II) The person has notified the Secretary that the investigation has been authorized under such an Act.

"(3) PUBLIC HEALTH EMERGENCIES.—The Secretary may temporarily exempt a person from the applicability of the requirements of this section, in whole or in part, if the Secretary determines that such exemption is necessary to provide for the timely participation of the person in a response to a domestic or foreign public health emergency (whether determined under section 319(a) or otherwise) that involves a listed agent or toxin. With respect to the emergency involved, such exemption for a person may not exceed 30 days, except that the Secretary, after review of whether such exemption remains necessary, may provide one extension of an additional 30 days.

"(4) AGRICULTURAL EMERGENCIES.—Upon request of the Secretary of Agriculture, after the granting by such Secretary of an exemption under section 212(g)(1)(D) of the Agricultural Bioterrorism Protection Act of 2002 pursuant to a finding that there is an agricultural emergency, the Secretary of Health and Human Services may temporarily exempt a person from the applicability of the requirements of this section, in whole or in part, to provide for the timely participation of the person in a response to the agricultural emergency. With respect to the emergency involved, the exemption under this paragraph for a person may not exceed 30 days, except that upon request of the Secretary of Agriculture, the Secretary of Health and Human Services may, after review of whether such exemption remains necessary, provide one extension of an additional 30 days.

"(h) DISCLOSURE OF INFORMATION.—

"(1) NONDISCLOSURE OF CERTAIN INFORMATION.—No Federal agency specified in paragraph (2) shall disclose under section 552 of title 5, United States Code, any of the following:

"(A) Any registration or transfer documentation submitted under subsections (b) and (c) for the possession, use, or transfer of a listed agent or toxin; or information derived therefrom to the extent that it identifies the listed agent or toxin possessed, used, or transferred by a specific registered person or discloses the identity or location of a specific registered person.

"(B) The national database developed pursuant to subsection (d), or any other compilation of the registration or transfer information submitted under subsections (b) and (c) to the extent that such compilation discloses site-specific registration or transfer information.

"(C) Any portion of a record that discloses the site-specific or transfer-specific safeguard and security measures used by a registered person to prevent unauthorized access to listed agents and toxins.

"(D) Any notification of a release of a listed agent or toxin submitted under subsections (b) and (c), or any notification of theft or loss submitted under such subsections.

"(E) Any portion of an evaluation or report of an inspection of a specific registered person conducted under subsection (f) that identifies the listed agent or toxin possessed by a specific registered person or that discloses the identity or location of a specific registered person if the agency determines that public disclosure of the information would endanger public health or safety.

"(2) COVERED AGENCIES.—For purposes of paragraph (1) only, the Federal agencies specified in this paragraph are the following:

"(A) The Department of Health and Human Services, the Department of Justice, the Department of Agriculture, and the Department of Transportation.

"(B) Any Federal agency to which information specified in paragraph (1) is transferred by any agency specified in subparagraph (A) of this paragraph.

"(C) Any Federal agency that is a registered person, or has a sub-agency component that is a registered person.

"(D) Any Federal agency that awards grants or enters into contracts or cooperative agreements involving listed agents and toxins to or with a registered person, and to which information specified in paragraph (1) is transferred by any such registered person.

"(3) OTHER EXEMPTIONS.—This subsection may not be construed as altering the application of any exemptions to public disclosure under section 552 of title 5, United States Code, except as to subsection 552(b)(3) of such title, to any of the information specified in paragraph (1).

"(4) RULE OF CONSTRUCTION.—Except as specifically provided in paragraph (1), this subsection may not be construed as altering the authority of any Federal agency to withhold under section 552 of title 5, United States Code, or the obligation of any Federal agency to disclose under section 552 of title 5, United States Code, any information, including information relating to—

"(A) listed agents and toxins, or individuals seeking access to such agents and toxins;

"(B) registered persons, or persons seeking to register their possession, use, or transfer of such agents and toxins;

"(C) general safeguard and security policies and requirements under regulations under subsections (b) and (c); or

"(D) summary or statistical information concerning registrations, registrants, denials or revocations of registrations, listed agents and toxins, inspection evaluations and reports, or individuals seeking access to such agents and toxins.

"(5) DISCLOSURES TO CONGRESS; OTHER DISCLOSURES.—This subsection may not be construed as providing any authority—

"(A) to withhold information from the Congress or any committee or subcommittee thereof; or

"(B) to withhold information from any person under any other Federal law or treaty.

"(i) CIVIL MONEY PENALTY.—

"(1) IN GENERAL.—In addition to any other penalties that may apply under law, any person who violates any provision of regulations under subsection (b) or (c) shall be subject to the United States for a civil money penalty in an amount not exceeding $250,000 in the case of an individual and $500,000 in the case of any other person.

"(2) APPLICABILITY OF CERTAIN PROVISIONS.—The provisions of section 1128A of the Social Security Act (other than subsections (a), (b), (h), and (i), the first sentence of subsection (c), and paragraphs (1) and (2) of subsection (f)) shall apply to a civil money penalty under paragraph (1) in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a) of such Act. The Secretary may delegate authority under this subsection in the same manner as provided in section 1128A(j)(2) of the Social Security Act, and such authority shall include all powers as contained in section 6 of the Inspector General Act of 1978 (5 U.S.C. App.).

"(j) NOTIFICATION IN EVENT OF RELEASE.—Regulations under subsections (b) and (c) shall require the prompt notification of the Secretary by a registered person whenever a release, meeting criteria established by the Secretary, of a listed agent or toxin has occurred outside of the biocontainment area of a facility of the registered person. Upon receipt of such notification and a finding by the Secretary that the release poses a threat to public health or safety, the Secretary shall take appropriate action to notify relevant State and local public health authorities, other relevant Federal authorities, and, if necessary, other appropriate persons (including the public). If the released listed agent or toxin is an overlap agent or toxin (as defined in subsection (l)), the Secretary shall promptly notify the Secretary of Agriculture upon notification by the registered person.

"(k) REPORTS.—The Secretary shall report to the Congress annually on the number and nature of notifications received under subsection (e)(8) (relating to theft or loss) and subsection (j) (relating to releases).

"(l) DEFINITIONS.—For purposes of this section:

"(1) The terms 'biological agent' and 'toxin' have the meanings given such terms in section 178 of title 18, United States Code.

"(2) The term 'listed agents and toxins' means biological agents and toxins listed pursuant to subsection (a)(1).

"(3) The term 'listed agents or toxins' means biological agents or toxins listed pursuant to subsection (a)(1).

"(4) The term 'overlap agents and toxins' means biological agents and toxins that—

"(A) are listed pursuant to subsection (a)(1); and

"(B) are listed pursuant to section 212(a)(1) of the Agricultural Bioterrorism Protection Act of 2002.

"(5) The term 'overlap agent or toxin' means a biological agent or toxin that—

"(A) is listed pursuant to subsection (a)(1); and

"(B) is listed pursuant to section 212(a)(1) of the Agricultural Bioterrorism Protection Act of 2002.

"(6) The term 'person' includes Federal, State, and local governmental entities.

"(7) The term 'registered person' means a person registered under regulations under subsection (b) or (c).

"(8) The term 'restricted person' has the meaning given such term in section 175b of title 18, United States Code.

"(m) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2002 through 2007.".

Deadline. 42 USC 262a note.

(b) REPORT TO CONGRESS.—Not later than one year after the date of the enactment of this Act, the Secretary of Health and Human Services, after consultation with other appropriate Federal agencies, shall submit to the Congress a report that—

(1) describes the extent to which there has been compliance by governmental and private entities with applicable regulations under section 351A of the Public Health Service Act (as added by subsection (a) of this section), including the extent of compliance before the date of the enactment of this Act, and including the extent of compliance with regulations promulgated after such date of enactment;

(2) describes the actions to date and future plans of the Secretary for updating the list of biological agents and toxins under such section 351A;

(3) describes the actions to date and future plans of the Secretary for determining compliance with regulations under such section 351A and for taking appropriate enforcement actions;

(4) evaluates the impact of such section 351A on research on biological agents and toxins listed pursuant to such section; and

(5) provides any recommendations of the Secretary for administrative or legislative initiatives regarding such section 351A.

Deadlines. 42 USC 262a note.

SEC. 202. IMPLEMENTATION BY DEPARTMENT OF HEALTH AND HUMAN SERVICES.

(a) DATE CERTAIN FOR NOTICE OF POSSESSION.—Not later than 90 days after the date of the enactment of this Act, all persons (unless exempt under subsection (g) of section 351A of the Public Health Service Act, as added by section 201 of this Act) in possession of biological agents or toxins listed under such section 351A of the Public Health Service Act shall notify the Secretary of Health and Human Services of such possession. Not later than 30 days after such date of enactment, the Secretary shall provide written guidance on how such notice is to be provided to the Secretary.

Guidelines.

(b) DATE CERTAIN FOR PROMULGATION; EFFECTIVE DATE REGARDING CRIMINAL AND CIVIL PENALTIES.—Not later than 180 days after the date of the enactment of this Act, the Secretary of Health and Human Services shall promulgate an interim final rule for carrying out section 351A of the Public Health Service Act, subject to subsection (c). Such interim final rule shall take effect 60 days after the date on which such rule is promulgated, including for purposes of—

Rules.

(1) section 175b(c) of title 18, United States Code (relating to criminal penalties), as added by section 231(a)(5) of this Act; and

(2) section 351A(i) of the Public Health Service Act (relating to civil penalties).

(c) TRANSITIONAL PROVISION REGARDING CURRENT RESEARCH AND EDUCATION.—The interim final rule under subsection (b) shall include time frames for the applicability of the rule that minimize disruption of research or educational projects that involve biological agents and toxins listed pursuant to section 351A(a)(1) of the Public Health Service Act and that were underway as of the effective date of such rule.

SEC. 203. EFFECTIVE DATES.

42 USC 262a note.

(a) IN GENERAL.—Regulations promulgated by the Secretary of Health and Human Services under section 511 of the Antiterrorism and Effective Death Penalty Act of 1996 are deemed to have been promulgated under section 351A of the Public Health Service Act, as added by section 201 of this Act. Such regulations, including the list under subsection (d)(1) of such section 511, that were in effect on the day before the date of the enactment of this Act remain in effect until modified by the Secretary in accordance with such section 351A and with section 202 of this Act.

(b) EFFECTIVE DATE REGARDING DISCLOSURE OF INFORMATION.—Subsection (h) of section 351A of the Public Health Service Act, as added by section 201 of this Act, is deemed to have taken effect on the effective date of the Antiterrorism and Effective Death Penalty Act of 1996.

SEC. 204. CONFORMING AMENDMENT.

Subsections (d), (e), (f), and (g) of section 511 of the Antiterrorism and Effective Death Penalty Act of 1996 (42 U.S.C. 262 note) are repealed.

Subtitle B—Department of Agriculture

SEC. 211. SHORT TITLE.

Agricultural Bioterrorism Protection Act of 2002.
7 USC 8401 note.

This subtitle may be cited as the "Agricultural Bioterrorism Protection Act of 2002".

SEC. 212. REGULATION OF CERTAIN BIOLOGICAL AGENTS AND TOXINS.

7 USC 8401.

(a) REGULATORY CONTROL OF CERTAIN BIOLOGICAL AGENTS AND TOXINS.—

(1) LIST OF BIOLOGICAL AGENTS AND TOXINS.—

(A) IN GENERAL.—The Secretary of Agriculture shall by regulation establish and maintain a list of each biological agent and each toxin that the Secretary determines has the potential to pose a severe threat to animal or plant health, or to animal or plant products.

(B) CRITERIA.—In determining whether to include an agent or toxin on the list under subparagraph (A), the Secretary shall—

(i) consider—

(I) the effect of exposure to the agent or toxin on animal or plant health, and on the production and marketability of animal or plant products;

(II) the pathogenicity of the agent or the toxicity of the toxin and the methods by which the agent or toxin is transferred to animals or plants;

(III) the availability and effectiveness of pharmacotherapies and prophylaxis to treat and prevent any illness caused by the agent or toxin; and

(IV) any other criteria that the Secretary considers appropriate to protect animal or plant health, or animal or plant products; and

(ii) consult with appropriate Federal departments and agencies and with scientific experts representing appropriate professional groups.

Publication.

(2) BIENNIAL REVIEW.—The Secretary shall review and republish the list under paragraph (1) biennially, or more often as needed, and shall by regulation revise the list as necessary in accordance with such paragraph.

Safety.

(b) REGULATION OF TRANSFERS OF LISTED AGENTS AND TOXINS.—The Secretary shall by regulation provide for—

(1) the establishment and enforcement of safety procedures for the transfer of listed agents and toxins, including measures to ensure—

(A) proper training and appropriate skills to handle such agents and toxins; and

(B) proper laboratory facilities to contain and dispose of such agents and toxins;

(2) the establishment and enforcement of safeguard and security measures to prevent access to such agents and toxins for use in domestic or international terrorism or for any other criminal purpose;

(3) the establishment of procedures to protect animal and plant health, and animal and plant products, in the event of a transfer or potential transfer of such an agent or toxin in violation of the safety procedures established under paragraph (1) or the safeguard and security measures established under paragraph (2); and

(4) appropriate availability of biological agents and toxins for research, education, and other legitimate purposes.

(c) POSSESSION AND USE OF LISTED AGENTS AND TOXINS.—The Secretary shall by regulation provide for the establishment and enforcement of standards and procedures governing the possession and use of listed agents and toxins, including the provisions described in paragraphs (1) through (4) of subsection (b), in order to protect animal and plant health, and animal and plant products.

(d) REGISTRATION; IDENTIFICATION; DATABASE.—

(1) REGISTRATION.—Regulations under subsections (b) and (c) shall require registration with the Secretary of the possession, use, and transfer of listed agents and toxins, and shall include provisions to ensure that persons seeking to register under such regulations have a lawful purpose to possess, use, or transfer such agents and toxins, including provisions in accordance with subsection (e)(6).

(2) IDENTIFICATION; DATABASE.—Regulations under subsections (b) and (c) shall require that registration include (if available to the person registering) information regarding the characterization of listed agents and toxins to facilitate their

identification, including their source. The Secretary shall maintain a national database that includes the names and locations of registered persons, the listed agents and toxins such persons are possessing, using, or transferring, and information regarding the characterization of such agents and toxins. Records.

(e) SAFEGUARD AND SECURITY REQUIREMENTS FOR REGISTERED PERSONS.—

(1) IN GENERAL.—Regulations under subsections (b) and (c) shall include appropriate safeguard and security requirements for persons possessing, using, or transferring a listed agent or toxin commensurate with the risk such agent or toxin poses to animal and plant health, and animal and plant products (including the risk of use in domestic or international terrorism). The Secretary shall establish such requirements in consultation with the Attorney General, and shall ensure compliance with such requirements as part of the registration system under such regulations.

(2) LIMITING ACCESS TO LISTED AGENTS AND TOXINS.—Requirements under paragraph (1) shall include provisions to ensure that registered persons—

(A) provide access to listed agents and toxins to only those individuals whom the registered person involved determines have a legitimate need to handle or use such agents and toxins;

(B) submit the names and other identifying information for such individuals to the Secretary and the Attorney General, promptly after first determining that the individuals need access under subparagraph (A), and periodically thereafter while the individuals have such access, not less frequently than once every five years; and

(C)(i) in the case of listed agents and toxins that are not overlap agents and toxins (as defined in subsection (g)(1)(A)(ii)), limit or deny access to such agents and toxins by individuals whom the Attorney General has identified as within any category under paragraph (3)(B), if limiting or denying such access by the individuals involved is determined appropriate by the Secretary, in consultation with the Attorney General; and

(ii) in the case of listed agents and toxins that are overlap agents—

(I) deny access to such agents and toxins by individuals whom the Attorney General has identified as within any category referred to in paragraph (3)(B)(i); and

(II) limit or deny access to such agents and toxins by individuals whom the Attorney General has identified as within any category under paragraph (3)(B)(ii), if limiting or denying such access by the individuals involved is determined appropriate by the Secretary, in consultation with the Attorney General.

(3) SUBMITTED NAMES; USE OF DATABASES BY ATTORNEY GENERAL.—

(A) IN GENERAL.—Upon the receipt of names and other identifying information under paragraph (2)(B), the Attorney General shall, for the sole purpose of identifying whether the individuals involved are within any of the categories specified in subparagraph (B), promptly use criminal, immigration, national security, and other electronic databases that are available to the Federal Government and are appropriate for such purpose.

(B) CERTAIN INDIVIDUALS.—For purposes of subparagraph (A), the categories specified in this subparagraph regarding an individual are that—

(i) the individual is within any of the categories described in section 175b(d)(1) of title 18, United States Code (relating to restricted persons); or

(ii) the individual is reasonably suspected by any Federal law enforcement or intelligence agency of—

(I) committing a crime set forth in section 2332b(g)(5) of title 18, United States Code;

(II) knowing involvement with an organization that engages in domestic or international terrorism (as defined in section 2331 of such title 18) or with any other organization that engages in international crimes of violence; or

(III) being an agent of a foreign power (as defined in section 1801 of title 50, United States Code).

(C) NOTIFICATION BY ATTORNEY GENERAL REGARDING SUBMITTED NAMES.—After the receipt of a name and other identifying information under paragraph (2)(B), the Attorney General shall promptly notify the Secretary whether the individual is within any of the categories specified in subparagraph (B).

(4) NOTIFICATIONS BY SECRETARY.—The Secretary, after receiving notice under paragraph (3) regarding an individual, shall promptly notify the registered person involved of whether the individual is granted or denied access under paragraph (2). If the individual is denied such access, the Secretary shall promptly notify the individual of the denial.

(5) EXPEDITED REVIEW.—Regulations under subsections (b) and (c) shall provide for a procedure through which, upon request to the Secretary by a registered person who submits names and other identifying information under paragraph (2)(B) and who demonstrates good cause, the Secretary may, as determined appropriate by the Secretary—

(A) request the Attorney General to expedite the process of identification under paragraph (3)(A) and notification of the Secretary under paragraph (3)(C); and

(B) expedite the notification of the registered person by the Secretary under paragraph (4).

(6) PROCESS REGARDING PERSONS SEEKING TO REGISTER.—

(A) INDIVIDUALS.—Regulations under subsections (b) and (c) shall provide that an individual who seeks to register under either of such subsections is subject to the same processes described in paragraphs (2) through (4) as apply to names and other identifying information submitted to the Attorney General under paragraph (2)(B). Paragraph (5) does not apply for purposes of this subparagraph.

(B) OTHER PERSONS.—Regulations under subsections (b) and (c) shall provide that, in determining whether to deny or revoke registration by a person other than an

individual, the Secretary shall submit the name of such person to the Attorney General, who shall use criminal, immigration, national security, and other electronic databases available to the Federal Government, as appropriate for the purpose of promptly notifying the Secretary whether the person, or, where relevant, the individual who owns or controls such person, is within any of the categories described in section 175b(d)(1) of title 18, United States Code (relating to restricted persons), or is reasonably suspected by any Federal law enforcement or intelligence agency of being within any category specified in paragraph (3)(B)(ii) (as applied to persons, including individuals). Such regulations shall provide that a person who seeks to register under either of such subsections is subject to the same processes described in paragraphs (2) and (4) as apply to names and other identifying information submitted to the Attorney General under paragraph (2)(B). Paragraph (5) does not apply for purposes of this subparagraph. The Secretary may exempt Federal, State, or local governmental agencies from the requirements of this subparagraph.

(7) REVIEW.—

(A) ADMINISTRATIVE REVIEW.—

(i) IN GENERAL.—Regulations under subsections (b) and (c) shall provide for an opportunity for a review by the Secretary—

(I) when requested by the individual involved, of a determination under paragraph (2) to deny the individual access to listed agents and toxins; and

(II) when requested by the person involved, of a determination under under paragraph (6) to deny or revoke registration for such person.

(ii) EX PARTE REVIEW.—During a review under clause (i), the Secretary may consider information relevant to the review ex parte to the extent that disclosure of the information could compromise national security or an investigation by any law enforcement agency.

(iii) FINAL AGENCY ACTION.—The decision of the Secretary in a review under clause (i) constitutes final agency action for purposes of section 702 of title 5, United States Code.

(B) CERTAIN PROCEDURES.—

(i) SUBMISSION OF EX PARTE MATERIALS IN JUDICIAL PROCEEDINGS.—When reviewing a decision of the Secretary under subparagraph (A), and upon request made ex parte and in writing by the United States, a court, upon a sufficient showing, may review and consider ex parte documents containing information the disclosure of which could compromise national security or an investigation by any law enforcement agency. If the court determines that portions of the documents considered ex parte should be disclosed to the person involved to allow a response, the court shall authorize the United States to delete from such documents specified items of information the disclosure of which could compromise national security or an investigation by

any law enforcement agency, or to substitute a summary of the information to which the person may respond. Any order by the court authorizing the disclosure of information that the United States believes could compromise national security or an investigation by any law enforcement agency shall be subject to the processes set forth in subparagraphs (A) and (B)(i) of section 2339B(f)(5) of title 18, United States Code (relating to interlocutory appeal and expedited consideration).

(ii) DISCLOSURE OF INFORMATION.—In a review under subparagraph (A), and in any judical proceeding conducted pursuant to such review, neither the Secretary nor the Attorney General may be required to disclose to the public any information that under subsection (h) shall not be disclosed under section 552 of title 5, United States Code.

(8) NOTIFICATIONS REGARDING THEFT OR LOSS OF AGENTS.—Requirements under paragraph (1) shall include the prompt notification of the Secretary, and appropriate Federal, State, and local law enforcement agencies, of the theft or loss of listed agents and toxins.

(9) TECHNICAL ASSISTANCE FOR REGISTERED PERSONS.—The Secretary, in consultation with the Attorney General, may provide technical assistance to registered persons to improve security of the facilities of such persons.

(f) INSPECTIONS.—The Secretary shall have the authority to inspect persons subject to regulations under subsection (b) or (c) to ensure their compliance with such regulations, including prohibitions on restricted persons and other provisions of subsection (e).

(g) EXEMPTIONS.—

(1) OVERLAP AGENTS AND TOXINS.—

(A) IN GENERAL.—

(i) LIMITATION.—In the case of overlap agents and toxins, exemptions from the applicability of provisions of regulations under subsection (b) or (c) may be granted only to the extent provided in this paragraph.

(ii) DEFINITIONS.—For purposes of this section:

(I) The term "overlap agents and toxins" means biological agents and toxins that—

(aa) are listed pursuant to subsection (a)(1); and

(bb) are listed pursuant to section 315A(a)(1) of the Public Health Service Act.

(II) The term "overlap agent or toxin" means a biological agent or toxin that—

(aa) is listed pursuant to subsection (a)(1); and

(bb) is listed pursuant to section 315A(a)(1) of the Public Health Service Act.

(B) CLINICAL OR DIAGNOSTIC LABORATORIES.—Regulations under subsections (b) and (c) shall exempt clinical or diagnostic laboratories and other persons who possess, use, or transfer overlap agents or toxins that are contained in specimens presented for diagnosis, verification, or proficiency testing, provided that—

(i) the identification of such agents or toxins is reported to the Secretary, and when required under Federal, State, or local law, to other appropriate authorities; and

(ii) such agents or toxins are transferred or destroyed in a manner set forth by the Secretary by regulation.

(C) PRODUCTS.—

(i) IN GENERAL.—Regulations under subsections (b) and (c) shall exempt products that are, bear, or contain overlap agents or toxins and are cleared, approved, licensed, or registered under any of the Acts specified in clause (ii), unless the Secretary by order determines that applying additional regulation under subsection (b) or (c) to a specific product is necessary to protect animal or plant health, or animal or plant products.

(ii) RELEVANT LAWS.—For purposes of clause (i), the Acts specified in this clause are the following:

(I) The Federal Food, Drug, and Cosmetic Act.

(II) Section 351 of the Public Health Service Act.

(III) The Act commonly known as the Virus-Serum-Toxin Act (the eighth paragraph under the heading "Bureau of Animal Industry" in the Act of March 4, 1913; 21 U.S.C. 151–159).

(IV) The Federal Insecticide, Fungicide, and Rodenticide Act.

(iii) INVESTIGATIONAL USE.—

(I) IN GENERAL.—The Secretary may exempt an investigational product that is, bears, or contains an overlap agent or toxin from the applicability of provisions of regulations under subsection (b) or (c) when such product is being used in an investigation authorized under any Federal Act and the Secretary determines that applying additional regulation under subsection (b) or (c) to such product is not necessary to protect animal and plant health, and animal and plant products.

(II) CERTAIN PROCESSES.—Regulations under subsections (b) and (c) shall set forth the procedures for applying for an exemption under subclause (I). In the case of investigational products authorized under any of the Acts specified in clause (ii), the Secretary shall make a determination regarding a request for an exemption not later than 14 days after the first date on which both of the following conditions have been met by the person requesting the exemption:

(aa) The person has submitted to the Secretary an application for the exemption meeting the requirements established by the Secretary.

(bb) The person has notified the Secretary that the investigation has been authorized under such an Act.

(D) AGRICULTURAL EMERGENCIES.—The Secretary may temporarily exempt a person from the applicability of the requirements of this section with respect to an overlap agent or toxin, in whole or in part, if the Secretary determines that such exemption is necessary to provide for the timely participation of the person in a response to a domestic or foreign agricultural emergency that involves such an agent or toxin. With respect to the emergency involved, the exemption under this subparagraph for a person may not exceed 30 days, except that the Secretary, after review of whether such exemption remains necessary, may provide one extension of an additional 30 days.

(E) PUBLIC HEALTH EMERGENCIES.—Upon request of the Secretary of Health and Human Services, after the granting by such Secretary of an exemption under 351A(g)(3) of the Public Health Service Act pursuant to a finding that there is a public health emergency, the Secretary of Agriculture may temporarily exempt a person from the applicability of the requirements of this section with respect to an overlap agent or toxin, in whole or in part, to provide for the timely participation of the person in a response to the public health emergency. With respect to the emergency involved, such exemption for a person may not exceed 30 days, except that upon request of the Secretary of Health and Human Services, the Secretary of Agriculture may, after review of whether such exemption remains necessary, provide one extension of an additional 30 days.

(2) GENERAL AUTHORITY FOR EXEMPTIONS NOT INVOLVING OVERLAP AGENTS OR TOXINS.—In the case of listed agents or toxins that are not overlap agents or toxins, the Secretary may grant exemptions from the applicability of provisions of regulations under subsection (b) or (c) if the Secretary determines that such exemptions are consistent with protecting animal and plant health, and animal and plant products.

(h) DISCLOSURE OF INFORMATION.—

(1) NONDISCLOSURE OF CERTAIN INFORMATION.—No Federal agency specified in paragraph (2) shall disclose under section 552 of title 5, United States Code, any of the following:

(A) Any registration or transfer documentation submitted under subsections (b) and (c), or permits issued prior to the date of the enactment of this Act, for the possession, use or transfer of a listed agent or toxin; or information derived therefrom to the extent that it identifies the listed agent or toxin possessed, used or transferred by a specific person or discloses the identity or location of a specific person.

(B) The national database developed pursuant to subsection (d), or any other compilation of the registration or transfer information submitted under subsections (b) and (c) to the extent that such compilation discloses site-specific registration or transfer information.

(C) Any portion of a record that discloses the site-specific or transfer-specific safeguard and security measures used by a registered person to prevent unauthorized access to listed agents and toxins.

(D) Any notification of a release of a listed agent or toxin submitted under subsections (b) and (c), or any

notification of theft or loss submitted under such subsections.

(E) Any portion of an evaluation or report of an inspection of a specific registered person conducted under subsection (f) that identifies the listed agent or toxin possessed by a specific registered person or that discloses the identity or location of a specific registered person if the agency determines that public disclosure of the information would endanger animal or plant health, or animal or plant products.

(2) COVERED AGENCIES.—For purposes of paragraph (1) only, the Federal agencies specified in this paragraph are the following:

(A) The Department of Health and Human Services, the Department of Justice, the Department of Agriculture, and the Department of Transportation.

(B) Any Federal agency to which information specified in paragraph (1) is transferred by any agency specified in subparagraph (A) of this paragraph.

(C) Any Federal agency that is a registered person, or has a sub-agency component that is a registered person.

(D) Any Federal agency that awards grants or enters into contracts or cooperative agreements involving listed agents and toxins to or with a registered person, and to which information specified in paragraph (1) is transferred by any such registered person.

(3) OTHER EXEMPTIONS.—This subsection may not be construed as altering the application of any exemptions to public disclosure under section 552 of title 5, United States Code, except as to subsection 552(b)(3) of such title, to any of the information specified in paragraph (1).

(4) RULE OF CONSTRUCTION.—Except as specifically provided in paragraph (1), this subsection may not be construed as altering the authority of any Federal agency to withhold under section 552 of title 5, United States Code, or the obligation of any Federal agency to disclose under section 552 of title 5, United States Code, any information, including information relating to—

(A) listed agents and toxins, or individuals seeking access to such agents and toxins;

(B) registered persons, or persons seeking to register their possession, use, or transfer of such agents and toxins;

(C) general safeguard and security policies and requirements under regulations under subsections (b) and (c); or

(D) summary or statistical information concerning registrations, registrants, denials or revocations of registrations, listed agents and toxins, inspection evaluations and reports, or individuals seeking access to such agents and toxins.

(5) DISCLOSURES TO CONGRESS; OTHER DISCLOSURES.—This subsection may not be construed as providing any authority—

(A) to withhold information from the Congress or any committee or subcommittee thereof; or

(B) to withhold information from any person under any other Federal law or treaty.

(i) CIVIL MONEY PENALTY.—

(1) IN GENERAL.—In addition to any other penalties that may apply under law, any person who violates any provision of regulations under subsection (b) or (c) shall be subject to the United States for a civil money penalty in an amount not exceeding $250,000 in the case of an individual and $500,000 in the case of any other person.

(2) APPLICABILITY OF CERTAIN PROVISIONS.—The provisions of sections 423 and 425(2) of the Plant Protection Act (7 U.S.C. 7733 and 7735(2)) shall apply to a civil money penalty or activity under paragraph (1) in the same manner as such provisions apply to a penalty or activity under the Plant Protection Act.

(j) NOTIFICATION IN EVENT OF RELEASE.—Regulations under subsections (b) and (c) shall require the prompt notification of the Secretary by a registered person whenever a release, meeting criteria established by the Secretary, of a listed agent or toxin has occurred outside of the biocontainment area of a facility of the registered person. Upon receipt of such notification and a finding by the Secretary that the release poses a threat to animal or plant health, or animal or plant products, the Secretary shall take appropriate action to notify relevant Federal, State, and local authorities, and, if necessary, other appropriate persons (including the public). If the released listed agent or toxin is an overlap agent or toxin, the Secretary shall promptly notify the Secretary of Health and Human Services upon notification by the registered person.

(k) REPORTS.—The Secretary shall report to the Congress annually on the number and nature of notifications received under subsection (e)(8) (relating to theft or loss) and subsection (j) (relating to releases).

(l) DEFINITIONS.—For purposes of this section:

(1) The terms "biological agent" and "toxin" have the meanings given such terms in section 178 of title 18, United States Code.

(2) The term "listed agents and toxins" means biological agents and toxins listed pursuant to subsection (a)(1).

(3) The term "listed agents or toxins" means biological agents or toxins listed pursuant to subsection (a)(1).

(4) The terms "overlap agents and toxins" and "overlap agent or toxin" have the meaning given such terms in subsection (g)(1)(A)(ii).

(5) The term "person" includes Federal, State, and local governmental entities.

(6) The term "registered person" means a person registered under regulations under subsection (b) or (c).

(7) The term "Secretary" means the Secretary of Agriculture.

(m) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2002 through 2007, in addition to other funds that may be available.

Deadlines.

SEC. 213. IMPLEMENTATION BY DEPARTMENT OF AGRICULTURE.

Rules.
7 USC 8401 note.

(a) DATE CERTAIN FOR PROMULGATION OF LIST.—Not later than 60 days after the date of the enactment of this Act, the Secretary of Agriculture (referred to in this section as the "Secretary") shall promulgate an interim final rule that establishes the initial list

under section 212(a)(1). In promulgating such rule, the Secretary shall provide written guidance on the manner in which the notice required in subsection (b) is to be provided to the Secretary. Guidelines.

(b) DATE CERTAIN FOR NOTICE OF POSSESSION.—Not later than 60 days after the date on which the Secretary promulgates the interim final rule under subsection (a), all persons (unless exempt under section 212(g)) in possession of biological agents or toxins included on the list referred to in subsection (a) shall notify the Secretary of such possession.

(c) DATE CERTAIN FOR PROMULGATION; EFFECTIVE DATE REGARDING CRIMINAL AND CIVIL PENALTIES.—Not later than 180 days after the date of the enactment of this Act, the Secretary shall promulgate an interim final rule for carrying out section 212, other than for the list referred to in subsection (a) of this section (but such rule may incorporate by reference provisions promulgated pursuant to subsection (a)). Such interim final rule shall take effect 60 days after the date on which such rule is promulgated, including for purposes of— Rules.

(1) section 175b(c) of title 18, United States Code (relating to criminal penalties), as added by section 231(a)(5) of this Act; and

(2) section 212(i) of this Act (relating to civil penalties).

(d) TRANSITIONAL PROVISION REGARDING CURRENT RESEARCH AND EDUCATION.—The interim final rule under subsection (c) shall include time frames for the applicability of the rule that minimize disruption of research or educational projects that involve biological agents and toxins listed pursuant to section 212(a)(1) and that were underway as of the effective date of such rule.

Subtitle C—Interagency Coordination Regarding Overlap Agents and Toxins

SEC. 221. INTERAGENCY COORDINATION. 7 USC 8411.

(a) IN GENERAL.—

(1) COORDINATION.—The Secretary of Agriculture and the Secretary of Health and Human Services shall in accordance with this section coordinate activities regarding overlap agents and toxins.

(2) OVERLAP AGENTS AND TOXINS; OTHER TERMS.—For purposes of this section:

(A) The term "overlap agent or toxin" means a biological agent or toxin that—

(i) is listed pursuant to section 315A(a)(1) of the Public Health Service Act, as added by section 201 of this Act; and

(ii) is listed pursuant to section 212(a)(1) of this Act.

(B) The term "section 351A program" means the program under section 351A of the Public Health Service Act.

(C) The term "section 212 program" means the program under section 212 of this Act.

(b) CERTAIN MATTERS.—In carrying out the section 351A program and the section 212 program, the Secretary of Health and Human Services and the Secretary of Agriculture shall, to the

greatest extent practicable, coordinate activities to achieve the following purposes:

(1) To minimize any conflicts between the regulations issued under, and activities carried out under, such programs.

(2) To minimize the administrative burden on persons subject to regulation under both of such programs.

(3) To ensure the appropriate availability of biological agents and toxins for legitimate biomedical, agricultural or veterinary research, education, or other such purposes.

(4) To ensure that registration information for overlap agents and toxins under the section 351A and section 212 programs is contained in both the national database under the section 351A program and the national database under the section 212 program.

(c) MEMORANDUM OF UNDERSTANDING.—

(1) IN GENERAL.—Promptly after the date of the enactment of this Act, the Secretary of Agriculture and the Secretary of Health and Human Services shall enter into a memorandum of understanding regarding overlap agents and toxins that is in accordance with paragraphs (2) through (4) and contains such additional provisions as the Secretary of Agriculture and the Secretary of Health and Human Services determine to be appropriate.

(2) SINGLE REGISTRATION SYSTEM REGARDING REGISTERED PERSONS.—The memorandum of understanding under paragraph (1) shall provide for the development and implementation of a single system of registration for persons who possess, use, or transfer overlap agents or toxins and are required to register under both the section 351A program and the section 212 program. For purposes of such system, the memorandum shall provide for the development and implementation of the following:

(A) A single registration form through which the person submitting the form provides all information that is required for registration under the section 351A program and all information that is required for registration under the section 212 program.

(B) A procedure through which a person may choose to submit the single registration form to the agency administering the section 351A program (in the manner provided under such program), or to the agency administering the section 212 program (in the manner provided under such program).

(C) A procedure through which a copy of a single registration form received pursuant to subparagraph (B) by the agency administering one of such programs is promptly provided to the agency administering the other program.

(D) A procedure through which the agency receiving the single registration form under one of such programs obtains the concurrence of the agency administering the other program that the requirements for registration under the other program have been met.

(E) A procedure through which—

(i) the agency receiving the single registration form under one of such programs informs the agency administering the other program whether the receiving agency has denied the registration; and

(ii) each of such agencies ensures that registrations are entered into the national database of registered persons that is maintained by each such agency.

(3) PROCESS OF IDENTIFICATION.—With respect to the process of identification under the section 351A program and the section 212 program for names and other identifying information submitted to the Attorney General (relating to certain categories of individuals and entities), the memorandum of understanding under paragraph (1) shall provide for the development and implementation of the following:

(A) A procedure through which a person who is required to submit information pursuant to such process makes (in addition to the submission to the Attorney General) a submission, at the option of the person, to either the agency administering the section 351A program or the agency administering the section 212 program, but not both, which submission satisfies the requirement of submission for both of such programs.

(B) A procedure for the sharing by both of such agencies of information received from the Attorney General by one of such agencies pursuant to the submission under subparagraph (A).

(C) A procedure through which the agencies administering such programs concur in determinations that access to overlap agents and toxins will be granted.

(4) COORDINATION OF INSPECTIONS AND ENFORCEMENT.—The memorandum of understanding under paragraph (1) shall provide for the development and implementation of procedures under which Federal personnel under the section 351A program and the section 212 program may share responsibilities for inspections and enforcement activities under such programs regarding overlap agents and toxins. Activities carried out under such procedures by one of such programs on behalf of the other may be carried out with or without reimbursement by the agency that administers the other program.

(5) DATE CERTAIN FOR IMPLEMENTATION.—The memorandum of understanding under paragraph (1) shall be implemented not later than 180 days after the date of the enactment of this Act. Until the single system of registration under paragraph (2) is implemented, persons who possess, use, or transfer overlap agents or toxins shall register under both the section 351A program and the section 212 program. Deadline.

(d) JOINT REGULATIONS.—Not later than 18 months after the date on which the single system of registration under subsection (c)(2) is implemented, the Secretary of Health and Human Services and the Secretary of Agriculture shall jointly issue regulations for the possession, use, and transfer of overlap agents and toxins that meet the requirements of both the section 351A program and the section 212 program. Deadline.

Subtitle D—Criminal Penalties Regarding Certain Biological Agents and Toxins

SEC. 231. CRIMINAL PENALTIES.

(a) IN GENERAL.—Section 175b of title 18, United States Code, as added by section 817 of Public Law 107–56, is amended—

(1) by striking "(a)" and inserting "(a)(1)";

(2) by transferring subsection (c) from the current placement of the subsection and inserting the subsection before subsection (b);

(3) by striking "(c)" and inserting "(2);

(4) by redesignating subsection (b) as subsection (d); and

(5) by inserting before subsection (d) (as so redesignated) the following subsections:

"(b) TRANSFER TO UNREGISTERED PERSON.—

"(1) SELECT AGENTS.—Whoever transfers a select agent to a person who the transferor knows or has reasonable cause to believe is not registered as required by regulations under subsection (b) or (c) of section 351A of the Public Health Service Act shall be fined under this title, or imprisoned for not more than 5 years, or both.

"(2) CERTAIN OTHER BIOLOGICAL AGENTS AND TOXINS.—Whoever transfers a biological agent or toxin listed pursuant to section 212(a)(1) of the Agricultural Bioterrorism Protection Act of 2002 to a person who the transferor knows or has reasonable cause to believe is not registered as required by regulations under subsection (b) or (c) of section 212 of such Act shall be fined under this title, or imprisoned for not more than 5 years, or both.

"(c) UNREGISTERED FOR POSSESSION.—

"(1) SELECT AGENTS.—Whoever knowingly possesses a biological agent or toxin where such agent or toxin is a select agent for which such person has not obtained a registration required by regulations under section 351A(c) of the Public Health Service Act shall be fined under this title, or imprisoned for not more than 5 years, or both.

"(2) CERTAIN OTHER BIOLOGICAL AGENTS AND TOXINS.—Whoever knowingly possesses a biological agent or toxin where such agent or toxin is a biological agent or toxin listed pursuant to section 212(a)(1) of the Agricultural Bioterrorism Protection Act of 2002 for which such person has not obtained a registration required by regulations under section 212(c) of such Act shall be fined under this title, or imprisoned for not more than 5 years, or both.".

(b) CONFORMING AMENDMENTS.—Chapter 10 of title 18, United States Code, is amended—

(1) in section 175b (as added by section 817 of Public Law 107–56 and amended by subsection (a) of this section)—

(A) in subsection (d)(1), by striking "The term" and all that follows through "does not include" and inserting the following: "The term 'select agent' means a biological agent or toxin to which subsection (a) applies. Such term (including for purposes of subsection (a)) does not include"; and

(B) in the heading for the section, by striking "**Possession by restricted persons**" and inserting "**Select agents; certain other agents**"; and

(2) in the chapter analysis, in the item relating to section 175b, by striking "Possession by restricted persons." and inserting "Select agents; certain other agents.".

(c) TECHNICAL CORRECTIONS.—Chapter 10 of title 18, United States Code, as amended by section 817 of Public Law 107–56 and subsections (a) and (b) of this section, is amended—

(1) in section 175(c), by striking "protective" and all that follows and inserting "protective, bona fide research, or other peaceful purposes.";

(2) in section 175b—

(A) in subsection (a)(1), by striking "described in subsection (b)" and all that follows and inserting the following: "shall ship or transport in or affecting interstate or foreign commerce, or possess in or affecting interstate or foreign commerce, any biological agent or toxin, or receive any biological agent or toxin that has been shipped or transported in interstate or foreign commerce, if the biological agent or toxin is listed as a select agent in Appendix A of part 72 of title 42, Code of Federal Regulations, pursuant to section 351A of the Public Health Service Act, and is not exempted under subsection (h) of section 72.6, or Appendix A of part 72, of title 42, Code of Federal Regulations."; and

(B) in subsection (d)(3), by striking "section 1010(a)(3)" and inserting "section 101(a)(3)";

(3) in section 176(a)(1)(A), by striking "exists by reason of" and inserting "pertains to"; and

(4) in section 178—

(A) in paragraph (1), by striking "means any microorganism" and all that follows through "product, capable of" and inserting the following: "means any microorganism (including, but not limited to, bacteria, viruses, fungi, rickettsiae or protozoa), or infectious substance, or any naturally occurring, bioengineered or synthesized component of any such microorganism or infectious substance, capable of";

(B) in paragraph (2), by striking "means the toxic" and all that follows through "including—" and inserting the following: "means the toxic material or product of plants, animals, microorganisms (including, but not limited to, bacteria, viruses, fungi, rickettsiae or protozoa), or infectious substances, or a recombinant or synthesized molecule, whatever their origin and method of production, and includes—"; and

(C) in paragraph (4), by striking "recombinant molecule," and all that follows through "biotechnology," and inserting "recombinant or synthesized molecule,".

(d) ADDITIONAL TECHNICAL CORRECTION.—Section 2332a of title 18, United States Code, is amended—

(1) in subsection (a), in the matter preceding paragraph (1), by striking "section 229F)" and all that follows through "section 178)—" and inserting "section 229F)—"; and

(2) in subsection (c)(2)(C), by striking "a disease organism" and inserting "a biological agent, toxin, or vector (as those terms are defined in section 178 of this title)".

TITLE III—PROTECTING SAFETY AND SECURITY OF FOOD AND DRUG SUPPLY

Subtitle A—Protection of Food Supply

21 USC 341 note.

SEC. 301. FOOD SAFETY AND SECURITY STRATEGY.

(a) IN GENERAL.—The President's Council on Food Safety (as established by Executive Order No. 13100) shall, in consultation with the Secretary of Transportation, the Secretary of the Treasury, other relevant Federal agencies, the food industry, consumer and producer groups, scientific organizations, and the States, develop a crisis communications and education strategy with respect to bioterrorist threats to the food supply. Such strategy shall address threat assessments; technologies and procedures for securing food processing and manufacturing facilities and modes of transportation; response and notification procedures; and risk communications to the public.

(b) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of implementing the strategy developed under subsection (a), there are authorized to be appropriated $750,000 for fiscal year 2002, and such sums as may be necessary for each subsequent fiscal year.

SEC. 302. PROTECTION AGAINST ADULTERATION OF FOOD.

(a) INCREASING INSPECTIONS FOR DETECTION OF ADULTERATION OF FOOD.—Section 801 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381) is amended by adding at the end the following subsection:

"(h)(1) The Secretary shall give high priority to increasing the number of inspections under this section for the purpose of enabling the Secretary to inspect food offered for import at ports of entry into the United States, with the greatest priority given to inspections to detect the intentional adulteration of food.".

(b) IMPROVEMENTS TO INFORMATION MANAGEMENT SYSTEMS.—Section 801(h) of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a) of this section, is amended by adding at the end the following paragraph:

"(2) The Secretary shall give high priority to making necessary improvements to the information management systems of the Food and Drug Administration that contain information related to foods imported or offered for import into the United States for purposes of improving the ability of the Secretary to allocate resources, detect the intentional adulteration of food, and facilitate the importation of food that is in compliance with this Act.".

(c) LINKAGES WITH APPROPRIATE PUBLIC ENTITIES.—Section 801(h) of the Federal Food, Drug, and Cosmetic Act, as amended by subsection (b) of this section, is amended by adding at the end the following paragraph:

"(3) The Secretary shall improve linkages with other regulatory agencies of the Federal Government that share responsibility for food safety, and shall with respect to such safety improve linkages