"**Public Health Security and Bioterrorism Preparedness and Response Act of 2002**".

SEC. 108. WORKING GROUP.	
(a)(1) … The Secretary, in coordination with the Secretary of Agriculture, the Attorney General, the Director of Central Intelligence, the Secretary of Defense, the Secretary of Energy, the Administrator of the Environmental Protection Agency, the Director of the Federal Emergency Management Agency, the Secretary of Labor, the Secretary of Veterans Affairs, and with other similar Federal officials as determined appropriate, shall establish a working group on the prevention, preparedness, and response to bioterrorism and other public health emergencies. Such joint working group, or subcommittees thereof, shall meet periodically for the purpose of consultation on, assisting in, and making recommendations on—	
SEC. 109. ANTIMICROBIAL RESISTANCE.	
(4) … the sequencing of the genomes, or other DNA analysis, or other comparative analysis, of priority pathogens (as determined by the Director of the National Institutes of Health in consultation with the task force established under subsection (a)), in collaboration and coordination with the activities of the Department of Defense and the Joint Genome Institute of the Department of Energy; and''; (2) in subsection (e)(2), by inserting after societies,'' the following: schools or programs that train medical laboratory personnel,''; and (3) in subsection (g), by striking and such sums'' and all that follows and inserting the following: $25,000,000 for each of the fiscal years 2002 and 2003, and such sums as may be necessary for each of the fiscal years 2004 through 2006.''.	
SEC. 125. ACCELERATED COUNTERMEASURE RESEARCH AND DEVELOPMENT.	
(h) ACCELERATED RESEARCH AND DEVELOPMENT ON PRIORITY PATHOGENS AND COUNTERMEASURES (1) …With respect to pathogens of potential use in a bioterrorist attack, and other agents that may cause a public health emergency, the Secretary, taking into consideration any recommendations of the working group under subsection (a), shall conduct, and award grants, contracts, or cooperative agreements for, research, investigations, experiments, demonstrations, and studies in the health sciences relating to— (B) the sequencing of the genomes, or other DNA analysis, or other comparative analysis, of	

priority pathogens (as determined by the Director of the National Institutes of Health in consultation with the working group established in subsection (a)), in collaboration and coordination with the activities of the Department of Defense and the Joint Genome Institute of the Department of Energy;	
Subtitle E—Additional Provisions **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 Ad ministration shall expand, enhance, and intensify research relevant to the rapid detection and identificatio n of pathogens likely to be used in a bioterrorism attack or other agents that may cause a public health emergency.	
(2) AUTHORIZED ACTIVITIES (1) may include—	
(A) the improvement of methods for detecting biological agents or toxins of potentia l 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).	
TITLE II—ENHANCING CONTROLS ON DANGEROUS BIOLOGICAL AGENTS AND TOXINS **Subtitle A—Department of Health and Human Services**	

SEC. 351A. ENHANCED CONTROL OF DANGEROUS BIOLOGICAL AGENTS AND TOXINS.	
(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) …Regulations under subsections (b) and (c) shall include appropriate safe guard 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	
(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.	
(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. (2) PRODUCTS. (C) INVESTIGATIONAL USE (i) …The Secretary may exempt an investigational product … (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: (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.	
(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 there from 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 per son if the agency determines that public disclosure of the information would endanger public health or safety.	
(i) **CIVIL MONEY PENALTY** (1)…In addition to any other penalties that may apply under law, any person who violates any provision of regulations under sub section (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.	
(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.	
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.	
(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,	
Subtitle B—Department of Agriculture	
SEC. 212. REGULATION OF CERTAIN BIOLOGICAL AGENTS AND TOXINS.	
(1) **LIST OF BIOLOGICAL AGENTS AND TOXINS** (A) …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) 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**	
(e) **SAFEGUARD AND SECURITY REQUIREMENTS FOR REGISTERED PERSONS**	
(2) **LIMITING ACCESS TO LISTED AGENTS AND TOXINS**	
(ii) **DISCLOSURE OF INFORMATION**	
(8) **NOTIFICATIONS REGARDING THEFT OR LOSS OF AGENTS**	
(g) **EXEMPTIONS**.— (1) OVERLAP AGENTS AND TOXINS.— (A) (i) … 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. (i) …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.	

(D) AGRICULTURAL EMERGENCIES. (E) PUBLIC HEALTH EMERGENCIES…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 there from 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. (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.	
(i) **CIVIL MONEY PENALTY** (1) …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.	
(j) **NOTIFICATION IN EVENT OF RELEASE**	
SEC. 213. IMPLEMENTATION BY DEPARTMENT OF AGRICULTURE.	
(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. (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— (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).	
(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	
(c) **MEMORANDUM OF UNDERSTANDING**. (1) …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).	
(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 (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.	
Subtitle D—Criminal Penalties Regarding Certain Biological Agents and Toxins **SEC. 231. CRIMINAL PENALTIES.** (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.''.	