

AGRICULTURAL BIOTERRORISM PROTECTION ACT OF 2002

[Public Law 107–188; June 12, 2002]

[As Amended Through P.L. 115–334, Enacted December 20, 2018]

【Currency: This publication is a compilation of the text of title I of Public Law 107-188. It was last amended by the public law listed in the As Amended Through note above and below at the bottom of each page of the pdf version and reflects current law through the date of the enactment of the public law listed at <https://www.govinfo.gov/app/collection/comps/>】

【Note: While this publication does not represent an official version of any Federal statute, substantial efforts have been made to ensure the accuracy of its contents. The official version of Federal law is found in the United States Statutes at Large and in the United States Code. The legal effect to be given to the Statutes at Large and the United States Code is established by statute (1 U.S.C. 112, 204).】

[Subtitles B and C of Title II and miscellaneous provisions of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002]

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TITLE II—ENHANCING CONTROLS ON DANGEROUS BIOLOGICAL AGENTS AND TOXINS

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¹ This table of contents is not part of the Act but is included for user convenience.

Subtitle B—Department of Agriculture

SEC. 211. [7 U.S.C. 8401 note] SHORT TITLE.

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

SEC. 212. [7 U.S.C. 8401] REGULATION OF CERTAIN BIOLOGICAL AGENTS AND TOXINS.

(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;

(IV)(aa) whether such inclusion would have a substantial negative impact on the research and development of solutions for the animal or plant disease caused by the agent or toxin; and

(bb) whether the negative impact described in item (aa) would substantially outweigh the risk posed by the agent or toxin to animal or plant health if it is not included on the list; and

(V) 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.

(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 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.
- (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 collaboration with the Secretary of Homeland Security and 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 de-

termines 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 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 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 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 judicial proceeding conducted pursuant to such review, neither the Sec-

retary 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, ap-

proved, 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 per-

son 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.

SEC. 213. [7 U.S.C. 8401 note] 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).

(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. [7 U.S.C. 8411] INTERAGENCY COORDINATION.

(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.

(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.

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TITLE III—ENHANCING CONTROLS ON DANGEROUS BIOLOGICAL AGENTS AND TOXINS

Subtitle A—Protection of Food Supply

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SEC. 313. [7 U.S.C. 8319] SURVEILLANCE OF ZONOTIC DISEASES.

The Secretary of Health and Human Services, through the Commissioner of Food and Drugs and the Director of the Centers for Disease Control and Prevention, and the Secretary of Agriculture shall coordinate the surveillance of zoonotic diseases.

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Subtitle C—General Provisions Relating to Upgrade of Agricultural Security

SEC. 331. [7 U.S.C. 8320] EXPANSION OF ANIMAL AND PLANT HEALTH INSPECTION SERVICE ACTIVITIES.

(a) IN GENERAL.—The Secretary of Agriculture (referred to in this section as the “Secretary”) may utilize existing authorities to give high priority to enhancing and expanding the capacity of the Animal and Plant Health Inspection Service to conduct activities to—

- (1) increase the inspection capacity of the Service at international points of origin;
- (2) improve surveillance at ports of entry and customs;
- (3) enhance methods of protecting against the introduction of plant and animal disease organisms by terrorists;
- (4) develop new and improve existing strategies and technologies for dealing with intentional outbreaks of plant and animal disease arising from acts of terrorism or from unintentional introduction, including—

(A) establishing cooperative agreements among Veterinary Services of the Animal and Plant Health Inspection Service, State animal health commissions and regulatory agencies for livestock and poultry health, and private veterinary practitioners to enhance the preparedness and ability of Veterinary Services and the commissions and agencies to respond to outbreaks of such animal diseases; and

(B) strengthening planning and coordination with State and local agencies, including—

- (i) State animal health commissions and regulatory agencies for livestock and poultry health; and
- (ii) State agriculture departments; and

(5) otherwise improve the capacity of the Service to protect against the threat of bioterrorism.

(b) AUTOMATED RECORDKEEPING SYSTEM.—The Administrator of the Animal and Plant Health Inspection Service may implement a central automated recordkeeping system to provide for the reli-

able tracking of the status of animal and plant shipments, including those shipments on hold at ports of entry and customs. The Secretary shall ensure that such a system shall be fully accessible to or fully integrated with the Food Safety Inspection Service.

(c) **AUTHORIZATION OF APPROPRIATIONS.**—There is authorized to be appropriated to carry out this section, \$30,000,000 for fiscal year 2002, and such sums as may be necessary for each subsequent fiscal year.

SEC. 332. [21 U.S.C. 679c] EXPANSION OF FOOD SAFETY INSPECTION SERVICE ACTIVITIES.

(a) **IN GENERAL.**—The Secretary of Agriculture may utilize existing authorities to give high priority to enhancing and expanding the capacity of the Food Safety Inspection Service to conduct activities to—

(1) enhance the ability of the Service to inspect and ensure the safety and wholesomeness of meat and poultry products;

(2) improve the capacity of the Service to inspect international meat and meat products, poultry and poultry products, and egg products at points of origin and at ports of entry;

(3) strengthen the ability of the Service to collaborate with relevant agencies within the Department of Agriculture and with other entities in the Federal Government, the States, and Indian tribes (as defined in section 4(e) of the Indian Self-Determination and Education Assistance Act (25 U.S.C. 450b(e))) through the sharing of information and technology; and

(4) otherwise expand the capacity of the Service to protect against the threat of bioterrorism.

(b) **AUTHORIZATION OF APPROPRIATIONS.**—There is authorized to be appropriated to carry out this section, \$15,000,000 for fiscal year 2002, and such sums as may be necessary for each subsequent fiscal year.

SEC. 333. BIOSECURITY UPGRADES AT THE DEPARTMENT OF AGRICULTURE.

There is authorized to be appropriated for fiscal year 2002, \$180,000,000 for the purpose of enabling the Agricultural Research Service to conduct building upgrades to modernize existing facilities, of which (1) \$100,000,000 shall be allocated for renovation, updating, and expansion of the Biosafety Level 3 laboratory and animal research facilities at the Plum Island Animal Disease Center (Greenport, New York), and of which (2) \$80,000,000 shall be allocated for the Agricultural Research Service/Animal and Plant Health Inspection Service facility in Ames, Iowa. There are authorized to be appropriated such sums as may be necessary for fiscal years 2003 through 2006 for the purpose described in the preceding sentence, for the planning and design of an Agricultural Research Service biocontainment laboratory for poultry research in Athens, Georgia, and for the planning, updating, and renovation of the Arthropod-Borne Animal Disease Laboratory in Laramie, Wyoming.

SEC. 334. [7 U.S.C. 3353] AGRICULTURAL BIOSECURITY.

(a) **SECURITY AT COLLEGES AND UNIVERSITIES.**—

(1) **GRANTS.**—The Secretary of Agriculture (referred to in this section as the “Secretary”) may award grants to covered

entities to review security standards and practices at their facilities in order to protect against bioterrorist attacks.

(2) COVERED ENTITIES.—Covered entities under this subsection are colleges or universities that—

(A) are colleges or universities as defined in section 1404 of the National Agricultural Research, Extension, and Teaching Policy Act of 1977 (7 U.S.C. 3103); and

(B) have programs in food and agricultural sciences, as defined in such section.

(3) LIMITATION.—Each individual covered entity may be awarded one grant under paragraph (1), the amount of which shall not exceed \$50,000.

(4) CONTRACT AUTHORITY.—Colleges and universities receiving grants under paragraph (1) may use such grants to enter into contracts with independent private organizations with established and demonstrated security expertise to conduct the security reviews specified in such paragraph.

(b) GUIDELINES FOR AGRICULTURAL BIOSECURITY.—

(1) IN GENERAL.—The Secretary may award grants to associations of food producers or consortia of such associations for the development and implementation of educational programs to improve biosecurity on farms in order to ensure the security of farm facilities against potential bioterrorist attacks.

(2) LIMITATION.—Each individual association eligible under paragraph (1) may be awarded one grant under such paragraph, the amount of which shall not exceed \$100,000. Each consortium eligible under paragraph (1) may be awarded one grant under such paragraph, the amount of which shall not exceed \$100,000 per association participating in the consortium.

(3) CONTRACT AUTHORITY.—Associations of food producers receiving grants under paragraph (1) may use such grants to enter into contracts with independent private organizations with established and demonstrated expertise in biosecurity to assist in the development and implementation of educational programs to improve biosecurity specified in such paragraph.

(c) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section such sums as may be necessary for each fiscal year.

SEC. 335. [7 U.S.C. 3354] AGRICULTURAL BIOTERRORISM RESEARCH AND DEVELOPMENT.

(a) IN GENERAL.—The Secretary of Agriculture (referred to in this section as the “Secretary”) may utilize existing research authorities and research programs to protect the food supply of the United States by conducting and supporting research activities to—

(1) enhance the capability of the Secretary to respond in a timely manner to emerging or existing bioterrorist threats to the food and agricultural system of the United States;

(2) develop new and continue partnerships with institutions of higher education and other institutions to help form stable, long-term programs to enhance the biosecurity and food safety of the United States, including the coordination of the development, implementation, and enhancement of diverse capabilities for addressing threats to the nation’s agricultural economy and food supply, with special emphasis on planning,

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training, outreach, and research activities related to vulnerability analyses, incident response, detection, and prevention technologies;

(3) strengthen coordination with the intelligence community to better identify research needs and evaluate materials or information acquired by the intelligence community relating to potential threats to United States agriculture;

(4) expand the involvement of the Secretary with international organizations dealing with plant and animal disease control;

(5) continue research to develop rapid detection field test kits to detect biological threats to plants and animals and to provide such test kits to State and local agencies preparing for or responding to bioterrorism;

(6) develop an agricultural bioterrorism early warning surveillance system through enhancing the capacity of and coordination between State veterinary diagnostic laboratories, Federal and State agricultural research facilities, and public health agencies; and

(7) otherwise improve the capacity of the Secretary to protect against the threat of bioterrorism.

(b) **AUTHORIZATION OF APPROPRIATIONS.**—There is authorized to be appropriated to carry out this section, \$190,000,000 for fiscal year 2002, and such sums as may be necessary for each subsequent fiscal year.

SEC. 336. ANIMAL ENTERPRISE TERRORISM PENALTIES.

【Omitted-Amendments】