detecting, controlling, or eradicating diseases of aquaculture species and promoting species-specific best management practices.

(b) Cooperative agreements between eligible entities and the Secretary

(1) Duties

As a condition of entering into a cooperative agreement with the Secretary under this section, an eligible entity shall agree to—

(A) assume responsibility for the non-Federal share of the cost of carrying out the project under the national aquatic health plan, as determined by the Secretary in accordance with paragraph (2); and

(B) act in accordance with applicable disease and species specific best management practices relating to activities to be carried out under such project.

(2) Non-Federal share

The Secretary shall determine the non-Federal share of the cost of carrying out a project under the national aquatic health plan on a case-by-case basis for each such project. Such non-Federal share may be provided in cash or in-kind.

(c) Applicability of other laws

In carrying out this section, the Secretary may make use of the authorities under the Animal Health Protection Act (7 U.S.C. 8301 et seq.), including the authority to carry out operations and measures to detect, control, and eradicate pests and diseases and the authority to pay claims arising out of the destruction of any animal, article, or means of conveyance.

(d) Authorization of appropriations

There is authorized to be appropriated such sums as may be necessary to carry out this section for each of fiscal years 2008 through 2012.

(e) Eligible entity defined

In this section, the term ''eligible entity'' means a State, a political subdivision of a State, Indian tribe, or other appropriate entity, as determined by the Secretary of Agriculture.

(Pub. L. 110–234, title XI, § 11013, May 22, 2008, 122 Stat. 1361; Pub. L. 110–246, § 4(a), title XI, § 11013, June 18, 2008, 122 Stat. 1664, 2122.)

REFERENCES IN TEXT

The Animal Health Protection Act, referred to in subsec. (c), is subtitle E (§§ 10401–10418) of title X of Pub. L. 107–171, May 13, 2002, 116 Stat. 494, which is classified principally to this chapter. For complete classification of this Act to the Code, see Short Title note set out under section 8301 of this title and Tables.

CODIFICATION

Pub. L. 110–234 and Pub. L. 110–246 enacted identical sections. Pub. L. 110–234 was repealed by section 4(a) of Pub. L. 110–246.

Section was enacted as part of the Food, Conservation, and Energy Act of 2008, and not as part of the Animal Health Protection Act, which in part comprises this chapter.

EFFECTIVE DATE

Enactment of this section and repeal of Pub. L. 110–234 by Pub. L. 110–246 effective May 22, 2008, the date of enactment of Pub. L. 110–234, see section 4 of Pub. L. 110–246, set out as a note under section 8701 of this title.

CHAPTER 110—ENHANCING CONTROLS ON DANGEROUS BIOLOGICAL AGENTS AND TOXINS

SUBCHAPTER I—DEPARTMENT OF AGRICULTURE

Sec.
8401. Regulation of certain biological agents and toxins.

SUBCHAPTER II—INTERAGENCY COORDINATION REGARDING OVERLAP AGENTS AND TOXINS

8411. Interagency coordination.

SUBCHAPTER I—DEPARTMENT OF AGRICULTURE

§ 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; 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.

(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) of this section, 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) of this section 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) of this section.

(2) Identification; database

Regulations under subsections (b) and (c) of this section 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) of this section 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 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) of this section), 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 (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;

(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).

(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) of this section 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) of this section 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) of this section 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 (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) of this section 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[1] 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.

(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 com-

[1] So in original.

promise 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 (relating to interlocutory appeal and expedited consideration).

(ii) Disclosure of information

In a review under subparagraph (A), and in any judical[2] 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) of this section shall not be disclosed under section 552 of title 5.

(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) of this section to ensure their compliance with such regulations, including prohibitions on restricted persons and other provisions of subsection (e) of this section.

(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) of this section 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) of this section; and

(bb) are listed pursuant to section 262a(a)(1) of title 42.[3]

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

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

(bb) is listed pursuant to section 262a(a)(1) of title 42.[3]

(B) Clinical or diagnostic laboratories

Regulations under subsections (b) and (c) of this section 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) of this section 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) of this section 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 [21 U.S.C. 301 et seq.].

(II) Section 351 of the Public Health Service Act [42 U.S.C. 262].

(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 [7 U.S.C. 136 et seq.].

(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) of this section 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) of this section 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) of this section 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:

[2] So in original. Probably should be ''judicial''.

[3] See References in Text note below.

(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 262a(g)(3)[4] of title 42 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) of this section 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 any of the following:

(A) Any registration or transfer documentation submitted under subsections (b) and (c) of this section, or permits issued prior to June 12, 2002, 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) of this section, or any other compilation of the registration or transfer information submitted under subsections (b) and (c) of this section 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) of this section, 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) of this section 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, except as to subsection[5] 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, or the obligation of any Federal agency to disclose under section 552 of title 5, any information, including information relating to—

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

[4] So in original. Probably should be preceded by ''section''.

[5] So in original. Probably should be ''section''.

(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) of this section; 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) of this section 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 [7 U.S.C. 7701 et seq.].

(j) Notification in event of release

Regulations under subsections (b) and (c) of this section 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) of this section (relating to theft or loss) and subsection (j) of this section (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.

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

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

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

(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) of this section.

(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.

(Pub. L. 107–188, title II, §212, June 12, 2002, 116 Stat. 647; Pub. L. 107–296, title XVII, §1709(b), Nov. 25, 2002, 116 Stat. 2319.)

REFERENCES IN TEXT

Section 262a(a)(1) of title 42, referred to in subsec. (g)(1)(A)(ii), was in the original ''section 315A(a)(1) of the Public Health Service Act'', and was translated as meaning section 351A(a)(1) of that Act to reflect the probable intent of Congress, because the Public Health Service Act does not contain a section 315A and section 351A refers to a list of biological agents and toxins.

The Federal Food, Drug, and Cosmetic Act, referred to in subsec. (g)(1)(C)(ii)(I), is act June 25, 1938, ch. 675, 52 Stat. 1040, as amended, which is classified generally to chapter 9 (§301 et seq.) of Title 21, Food and Drugs. For complete classification of this Act to the Code, see section 301 of Title 21 and Tables.

The Act commonly known as the Virus-Serum-Toxin Act, referred to in subsec. (g)(1)(C)(ii)(III), is the eighth paragraph under the heading ''Bureau of Animal Industry'' of act Mar. 4, 1913, ch. 145, 37 Stat. 832, as amended, which is classified generally to chapter 5 (§151 et seq.) of Title 21, Food and Drugs. For complete classification of this Act to the Code, see Short Title note set out under section 151 of Title 21 and Tables.

The Federal Insecticide, Fungicide, and Rodenticide Act, referred to in subsec. (g)(1)(C)(ii)(IV), is act June 25, 1947, ch. 125, as amended generally by Pub. L. 92–516, Oct. 21, 1972, 86 Stat. 973, which is classified generally to subchapter II (§136 et seq.) of chapter 6 of this title. For complete classification of this Act to the Code, see Short Title note set out under section 136 of this title and Tables.

The Plant Protection Act, referred to in subsec. (i)(2), is title IV of Pub. L. 106–224, June 20, 2000, 114 Stat. 438, as amended, which is classified principally to chapter 104 (§7701 et seq.) of this title. For complete classification of this Act to the Code, see Short Title note set out under section 7701 of this title and Tables.

AMENDMENTS

2002—Subsec. (e)(1). Pub. L. 107–296 substituted ''collaboration with the Secretary of Homeland Security and'' for ''consultation with''.

EFFECTIVE DATE OF 2002 AMENDMENT

Amendment by Pub. L. 107–296 effective 60 days after Nov. 25, 2002, see section 4 of Pub. L. 107–296, set out as an Effective Date note under section 101 of Title 6, Domestic Security.

SHORT TITLE

Pub. L. 107–188, title II, § 211, June 12, 2002, 116 Stat. 647, provided that: ''This subtitle [subtitle B (§§ 211–213) of title II of Pub. L. 107–188, enacting this subchapter] may be cited as the 'Agricultural Bioterrorism Protection Act of 2002'.''

IMPLEMENTATION BY DEPARTMENT OF AGRICULTURE

Pub. L. 107–188, title II, § 213, June 12, 2002, 116 Stat. 656, provided that:

''(a) DATE CERTAIN FOR PROMULGATION OF LIST.—Not later than 60 days after the date of the enactment of this Act [June 12, 2002], 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) [7 U.S.C. 8401(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) [7 U.S.C. 8401(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 [June 12, 2002], the Secretary shall promulgate an interim final rule for carrying out section 212 [7 U.S.C. 8401], 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 [7 U.S.C. 8401(i)] (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) [7 U.S.C. 8401(a)(1)] and that were underway as of the effective date of such rule.''

SUBCHAPTER II—INTERAGENCY COORDINATION REGARDING OVERLAP AGENTS AND TOXINS

§ 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)[1] of the Public Health Service Act [42 U.S.C. 262a(a)(1)], as added by section 201 of this Act; and

(ii) is listed pursuant to section 212(a)(1) of this Act [7 U.S.C. 8401(a)(1)].

(B) The term ''section 351A program'' means the program under section 351A of the Public Health Service Act [42 U.S.C. 262a].

(C) The term ''section 212 program'' means the program under section 212 of this Act [7 U.S.C. 8401].

(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 June 12, 2002, 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

[1] So in original. Probably should be ''351A(a)(1)''.