“(A) such biological product is in a product class for which a biological product in such product class is the subject of an application approved under such section 356 not later than the date of enactment of this Act [Mar. 23, 2010]; and

“(B) such application—

“(i) has been submitted to the Secretary of Health and Human Services (referred to in this subtitle [subtitle A (§§7001–7003) of title VII of Pub. L. 111–148, see Short Title of 2010 Amendment note under section 201 of this title] as the ‘Secretary’) before the date of enactment of this Act; or

“(ii) is submitted to the Secretary not later than the date that is 10 years after the date of enactment of this Act.

“(3) LIMITATION.—Notwithstanding paragraph (2), an application for a biological product may not be submitted under section 505 of the Federal, Drug, and Cosmetic Act (21 U.S.C. 355) if there is another biological product approved under subsection (a) of section 351 of the Public Health Service Act (42 U.S.C. 262) that could be a reference product with respect to such application (within the meaning of such section 351) if such application were submitted under subsection (k) of such section 351.

“(4) DEEMED APPROVED UNDER SECTION 351.—An approved biological product for a section 505 of the Federal, Drug, and Cosmetic Act (21 U.S.C. 355) shall be deemed to be a license for the biological product under such section 351 on the date that is 10 years after the date of enactment of this Act.

“(5) DEFINITIONS.—For purposes of this subsection, the term ‘biological product’ has the meaning given such term under section 351 of the Public Health Service Act (42 U.S.C. 262) (as amended by this Act).”

COSTS OF REVIEWING BIOSIMILAR BIOLOGICAL PRODUCT APPLICATIONS


“(A) such biological product is in a product class for which a biological product in such product class is the subject of an application approved under such section 356 not later than the date of enactment of this Act [Mar. 23, 2010]; and

“(B) such application—

“(i) has been submitted to the Secretary of Health and Human Services [referred to in this subtitle (subtitle A (§§7001–7003) of title VII of Pub. L. 111–148, see Short Title of 2010 Amendment note under section 201 of this title] as the ‘Secretary’) before the date of enactment of this Act; or

“(ii) is submitted to the Secretary not later than the date that is 10 years after the date of enactment of this Act.

“(3) LIMITATION.—Notwithstanding paragraph (2), an application for a biological product may not be submitted under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) if there is another biological product approved under subsection (a) of section 351 of the Public Health Service Act (42 U.S.C. 262) that could be a reference product with respect to such application (within the meaning of such section 351) if such application were submitted under subsection (k) of such section 351.

“(4) DEEMED APPROVED UNDER SECTION 351.—An approved biological product for a section 505 of the Federal, Drug, and Cosmetic Act (21 U.S.C. 355) shall be deemed to be a license for the biological product under such section 351 on the date that is 10 years after the date of enactment of this Act.

“(5) DEFINITIONS.—For purposes of this subsection, the term ‘biological product’ has the meaning given such term under section 351 of the Public Health Service Act (42 U.S.C. 262) (as amended by this Act).”

ENHANCED PENALTIES AND CONTROL OF BIOLOGICAL AGENTS


“(a) FINDINGS.—The Congress finds that—

“(1) certain biological agents have the potential to pose a severe threat to public health and safety;

“(2) such biological agents can be used as weapons by individuals or organizations for the purpose of domestic or international terrorism or for other criminal purposes;

“(3) the transfer and possession of potentially hazardous biological agents should be regulated to protect public health and safety; and

“(4) efforts to protect the public from exposure to such agents should ensure that individuals and groups with legitimate objectives continue to have access to such agents for clinical and research purposes.

“(b) CRIMINAL ENFORCEMENT.—[Amended sections 175, 177, and 178 of Title 18, Crimes and Criminal Procedure.]

“(c) TERRORISM.—[Amended section 2332a of Title 18.]”
(B) Criteria

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

(i) consider—

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

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

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

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

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

(2) Biennial review

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

(b) Regulation of transfers of listed agents and toxins

The Secretary shall by regulation provide for—

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

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

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

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

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

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

(c) Possession and use of listed agents and toxins

The Secretary shall by regulation provide for the establishment and enforcement of standards and procedures governing the possession and use of listed agents and toxins, including the provisions described in paragraphs (1) through (4) of subsection (b) of this section, in order to protect the public health and safety.

(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 public health and safety (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;

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

(D) limit or deny access to such agents and toxins by individuals whom the Attorney General has identified as within any category under paragraph (3)(B)(ii), if limiting or denying such access by the individuals involved is determined appropriate by the Secretary, in consultation with the Attorney General.
§ 262a

(3) Submitted names; use of databases by attorney general

(A) In general

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

(B) Certain individuals

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

(i) the individual is a restricted person; or

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

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

(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 a restricted person or is reasonably suspected by any Federal law enforcement or intelligence agency of being within any category specified in paragraph (3)(B)(ii) (as applied to persons, including individuals). Such regulations shall provide that a person who seeks to register under either of such subsections is subject to the same processes described in paragraphs (2) and (4) as apply to names and other identifying information submitted to the Attorney General under paragraph (2)(B). Paragraph (5) does not apply for purposes of this subparagraph. The Secretary may exempt Federal, State, or local governmental agencies from the requirements of this subparagraph.

(7) Review

(A) Administrative review

(i) In general

Regulations under subsections (b) and (c) 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 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 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 3339B(c)(5) of title 18 (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 Secretary nor the Attorney General may be required to disclose to the public any information that under subsection (b) 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) 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 listed agents or toxins that are contained in specimens presented for diagnosis, verification, or proficiency testing, provided that—

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

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

(2) Products

(A) In general

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

(B) Relevant laws

For purposes of subparagraph (A), the Acts specified in this subparagraph are the following:


(ii) Section 262a of this title.


(C) Investigational use

(i) In general

The Secretary may exempt an investigational product that is, bears, or contains a listed agent or toxin from the applicability of provisions of regulations under subsection (b) or (c) 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 public health and safety.

(ii) Certain processes

Regulations under subsections (b) and (c) of this section 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.

(3) Public health emergencies

The Secretary may temporarily exempt a person from the applicability of the require-
ments of this section, in whole or in part, if the Secretary determines that such exemption is necessary to provide for the timely participation of the person in a response to a domestic or foreign public health emergency (whether determined under section 247d(a) of this title or otherwise) that involves a listed agent or toxin. With respect to the emergency involved, such exemption for a person may not exceed 30 days, except that the Secretary, after review of whether such exemption remains necessary, may provide one extension of an additional 30 days.

(4) Agricultural emergencies

Upon request of the Secretary of Agriculture, after the granting by such Secretary of an exemption under section 8401(g)(1)(D) of title 7 pursuant to a finding that there is an agricultural emergency, the Secretary of Health and Human Services may temporarily exempt a person from the applicability of the requirements of this section, in whole or in part, to provide for the timely participation of the person in a response to the agricultural emergency. With respect to the emergency involved, the exemption under this paragraph for a person may not exceed 30 days, except that upon request of the Secretary of Agriculture, the Secretary of Health and Human Services may, after review of whether such exemption remains necessary, provide one extension of an additional 30 days.

(h) Disclosure of information

(1) Nondisclosure of certain information

No Federal agency specified in paragraph (2) shall disclose under section 552 of title 5 any of the following:

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

(B) The national database developed pursuant to subsection (d) 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 public health or safety.

(2) Covered agencies

For purposes of paragraph (1) only, the Federal agencies specified in this paragraph are the following:

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

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

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

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

(3) Other exemptions

This subsection may not be construed as altering the application of any exemptions to public disclosure under section 552 of title 5, except as to subsection 152(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;

(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 2
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 section 1320a-7a of this title (other than subsections (a), (b), (h), and (i), the first sentence of subsection (c), and paragraphs (1) and (2) of subsection (f)) shall apply to a civil money penalty under paragraph (1) in the same manner as such provisions apply to a penalty or proceeding under section (b) or (c) of this section; and

(3) The term "listed agents or toxins" means biological agents and toxins—
(A) are listed pursuant to subsection (a)(1) of this section; and
(B) is listed pursuant to section 8401(a)(1) of title 7.

(4) The term "toxin" have the meanings given such terms in section 175b of title 18.

(5) The term "registered person" means a person registered under regulations under subsection (b) or (c) of this section.

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

(7) The term "restricted person" has the meaning given such term in section 175b of title 18.

(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.

REFERENCES IN TEXT


AMENDMENTS

tion 262a of this title] are deemed to have been promulgated under section 351A of the Public Health Service Act [this section], as added by section 201 of this Act. Section 262a regulations, including the list under (former) sub-
section (d)(1) of such section 511, that were in effect on 
the day before the date of the enactment of this Act [June 12, 2002] remain in effect until modified by the 
Secretary in accordance with such section 351A and 
with section 202 of this Act [set out as a note below]."

**NATIONAL SCIENCE ADVISORY BOARD FOR BIOSECURITY**

Pub. L. 109–417, title II, §229, Dec. 19, 2006, 120 Stat. 2851, provided that: "The National Science Advisory Board for Biosecurity shall, when requested by the Secretary of Health and Human Services, provide to re-
levant Federal agencies and departments advice, guidance, 
or recommendations concerning—

"(1) a core curriculum and training requirements for 
workers in maximum containment biological labor-
atories; and

"(2) periodic evaluations of maximum containment 
biological laboratory capacity nationwide and 
assessments of the future need for increased laboratory 
capacity."

**REPORT TO CONGRESS**


"(a) **DATE CERTAIN FOR NOTICE OF POSSESSION.**—Not 
later than 90 days after the date of the enactment of 
this Act [June 12, 2002], all persons (unless exempt 
under subsection (g) of section 351A of the Public Health 
Service Act [subsec. (g) of this section], as 
added by section 201 of this Act) in possession of bio-
logical agents or toxins listed under such section 351A of 
the Public Health Service Act [this section] shall no-

ify 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 guid-
ance on how such notice is to be provided to the Sec-
retary.

"(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 [June 12, 2002], the Secretary of Health and 
Human Services shall promulgate an interim final rule 
for carrying out section 351A of the Public Health Ser-
vice Act [this section], subject to subsection (c). Such 
interim final rule shall take effect 30 days after the 
date on which such rule is promulgated, including for 
purposes of—

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

"(2) section 351A(i) of the Public Health Service Act 
[subsec. (i) of this section] (related to civil pen-
alties).

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

**EX. ORD. NO. 13546, OPTIMIZING THE SECURITY OF BIO-
LOGICAL SELECT AGENTS AND TOXINS IN THE UNITED 
STATES**

Ex. Ord. No. 13546, July 2, 2010, 75 F.R. 39439, provided:

By the authority vested in me as President by the Constitution and the laws of the United States of America, it is hereby ordered as follows:

**SECTION 1. Policy.** It is the policy of the United States that:

(a) A robust and productive scientific enterprise that 
utilizes biological select agents and toxins (BSAT) is 

essential to national security;
(b) BSAT shall be secured in a manner appropriate to 
their risk of misuse, theft, loss, and accidental release; 
and
(c) Security measures shall be taken in a coordinated 
manner that balances their efficacy with the need to 

minimize the adverse impact on the legitimate use of 
BSAT.

**SIC. 2. Definitions.** (a) "Select Agent Program" (SAP) 

means the regulatory oversight and administrative ac-

tivities conducted by the Secretaries of Health and 
Human Services and Agriculture and the Attorney Gen-
eral to implement the Public Health Security and Bio-
terrorism Preparedness and Response Act of 2002 and 
the Agricultural Bioterrorism Protection Act of 2002.

(b) "Select Agent Regulations" (SAR) means the Fed-
eral regulations found in Part 73 of Title 42 of the Code 
of Federal Regulations, Part 331 of Title 7 of the Code 
of Federal Regulations, and Part 121 of Title 9 of the 
Code of Federal Regulations.

(c) "Biological Select Agents and Toxins" means bio-

logical agents and toxins with the potential to pose a 

severe threat to public health and safety, animal and 
plant health, or animal and plant products and whose 

possession, use, and transfer are regulated by the De-
partment of Health and Human Services and the De-
partment of Agriculture under the SAR.

**SIC. 3. Findings.** (a) The use of BSAT presents the 

risk that BSAT might be lost, stolen, or diverted for 

malicious purpose. The SAP exists to provide effective 

regulatory oversight of the possession, use, and trans-
fer of BSAT that reduces the risk of their misuse or 
mishandling. The absence of clearly defined, risk-based 

security measures in the SAR/SAP has raised concern 

about the need for optimized security and for risk man-
gement.

(b) In addition, variations in, and limited coordina-
tion of, individual executive departments' and agen-
cies' oversight, security practices, and inspections have 

raised concerns that the cost and complexity of compli-
ance for those who are registered to work with BSAT 

could discourage research or other legitimate activi-

ties.

(c) Understanding that research and laboratory work 

on BSAT is essential to both public health and national 
security, it is in the interest of the United States to ad-
dress these issues.

**SIC. 4. Risk-based Tiering of the Select Agent List. To 
help ensure that BSAT are secured according to level 
of risk, the Secretaries of Health and Human Services and 
Agriculture shall, through their ongoing review of the 
biological Select Agents and Toxins List ("Select Agent 
List") contained in regulations, and no later than 
18 months from the date of this order—

(a) designate a subset of the Select Agent List (Tier 1) that 

presents the greatest risk of deliberate misuse with 
most significant potential for mass casualties or 
devastating effects to the economy, critical infrastruc-
ture, or public confidence; and
(b) explore options for graded protection of Tier 1 agents and toxins as described in subsection (a) of this 

section to permit tailored risk management practices 
based upon relevant contextual factors; and
(c) consider reducing the overall number of agents 
and toxins on the Select Agent List.

**SIC. 5. Revision of Regulations, Rules, and Guidance to 
Accommodate a Tiered Select Agent List.** Consistent with 
section 4 of this order, I request that:

(a) The Secretaries of Health and Human Services 

and Agriculture, no later than 15 months from the date 
of this order, propose amendments to their respective 
parts of the SAR that would establish security standards 
specific to Tier 1 agents and toxins.
(b) The Secretaries of Health and Human Services and Agriculture each, no later than 27 months from the date of this order, promulgate final rules and guidance that clearly articulate security actions for registrants who possess, use, or transfer Tier 1 agents and toxins.

SAC. 6. Coordination of Federal Oversight for BSAT Security. To ensure that the policies and practices used to secure BSAT are harmonized and that the related oversight activities of the Federal Government are coordinated, the heads of executive departments and agencies identified in section 7(a)(ii) of this order shall:

(i) articulate a mechanism for coordinated and reciprocal inspection of and harmonized administrative practices for facilities registered with the SAP;
(ii) ensure consistent and timely identification and resolution of BSAT security and compliance issues;
(iii) facilitate information sharing among departments and agencies regarding ongoing oversight and inspection activities; and
(iv) the criteria for comprehensive and effective Federal oversight of BSAT security; and
(b) no later than 6 months from the issuance of final rules and guidance as described in section 5 of this order, and annually thereafter, review for inconsistent requirements and revise or rescind, as appropriate, any regulations, directives, guidance, or policies regarding BSAT security within their department or agency that exceed those in the updated SAR and guidance as described in section 5 of this order.


(i) There is hereby established, within the Department of Health and Human Services for administrative purposes only, the Federal Experts Security Advisory Panel (Panel), which shall make technical and substantive recommendations on BSAT security concerning the SAP.
(ii) The Panel shall consist of representatives from the following, who may consult with additional experts from their department or agency as required:
1. the Department of State;
2. the Department of Defense;
3. the Department of Justice;
4. the Department of Agriculture (Co-Chair); 6. the Department of Health and Human Services (Co-Chair);
7. the Department of Transportation;
8. the Department of Labor;
9. the Department of Energy;
10. the Department of Veterans Affairs;
11. the Department of Homeland Security;
12. the Environmental Protection Agency;
13. the Office of the Director of National Intelligence;
14. the Office of Science and Technology Policy;
15. the Joint Chiefs of Staff; and
16. any other department or agency designated by the Co-Chairs.

(iii) To assist the Secretaries of Health and Human Services and Agriculture and the Attorney General in implementing the policies set forth in sections 1, 4, 5, and 6 of this order, the Panel shall, no later than 4 years subject to renewal through the interagency policy committee process any issues that require further deliberation or adjudication.
(b) Nothing in this order shall be construed to impair, otherwise affect the authority granted by law to a department or agency, or the head thereof, or functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.
(c) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.
(d) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

BARACK OBAMA.

§ 263. Preparation of biological products by Service

(a) The Service may prepare for its own use any product described in section 262 of this title and any product necessary to carrying out any of the purposes of section 241 of this title.
(b) The Service may prepare any product described in section 262 of this title for the use of other Federal departments or agencies, and public or private agencies and individuals engaged in work in the field of medicine when such product is not available from establishments licensed under such section.

(1941, ch. 373, title III, §352, 58 Stat. 703.)

TRANSFER OF FUNCTIONS

Functions of Public Health Service, Surgeon General of Public Health Service, and all other officers and em-