§ 262a. Enhanced control of dangerous 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 shall by regulation establish and maintain a list of each biological agent and each toxin that has the potential to pose a severe threat to public health and safety.

(B) Criteria

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

(i) consider—

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

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

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

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

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

(2) Biennial review

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

(b) Regulation of transfers of listed agents and toxins

The Secretary shall by regulation provide for—

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

(A) proper training, including with respect to notification requirements under this section, of—

(i) individuals who are involved in the handling and use of such agents and toxins, including appropriate skills to handle such agents and toxins;

(ii) individuals whose responsibilities routinely place them in close proximity to laboratory facilities in which such agents and toxins are being transferred, possessed, or used; and

(iii) individuals who perform administrative or oversight functions of the facility related to the transfer, possession, or use of such agents and toxins on behalf of registered persons;

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

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

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

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

(c) Possession and use of listed agents and toxins

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

(d) Registration; identification; database

(1) Registration

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

(2) Identification; database

Regulations under subsections (b) and (c) shall require that registration include (if available to the person registering) information regarding the characterization of listed agents and toxins to facilitate their identification, including their source. The Secretary shall maintain a national database that includes the names and locations of registered persons, the listed agents and toxins such persons are possessing, using, or transferring, and information regarding the characterization of such agents and toxins.

(e) Safeguard and security requirements for registered persons

(1) In general

Regulations under subsections (b) and (c) shall include appropriate safeguard and secu-
rity 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 risks posed by the release, theft, or loss of such agent or toxin, or 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.

(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 (3)(B)(ii), if limiting or denying such access by the individuals involved is determined appropriate by the Attorney General, submit the names and other identifying information under paragraph (2)(B), promptly after first determining that the individuals involved are within any of the categories specified in paragraph (3)(B)(ii) (as defined in section 1801 of title 50).

(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, for the sole purpose of identifying 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 determining 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 sub-
sections is subject to the same processes de-
scribed in paragraphs (2) and (4) as apply to
names and other identifying information
submitted to the Attorney General under
paragraph (3)(B). Paragraph (5) does not
apply for purposes of this subparagraph.
The Secretary may exempt Federal, State, or
local governmental agencies from the re-
quirements of this subparagraph.

(7) Review

(A) Administrative review

(i) In general

Regulations under subsections (b) and (c)
shall provide for an opportunity for a re-
view by the Secretary—

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

(II) when requested by the person in-
volved, of a determination under para-
graph (6) to deny or revoke registration
for such person.

(ii) Ex parte review

During a review under clause (i), the
Secretary may consider information rel-
vant to the review ex parte to the extent
that disclosure of the information could
compromise national security or an inves-
tigation 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 judi-
cial proceedings

When reviewing a decision of the Sec-
retary under subparagraph (A), and upon
request made ex parte and in writing by
the United States, a court, upon a suffi-
cient 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 enforce-
ment agency, or to substitute a summary
of the information to which the person
may respond. Any order by the court au-
thorizing the disclosure of information
that the United States believes could com-
promise national security or an investiga-
tion by any law enforcement agency shall
be subject to the processes set forth in sub-
paragraphs (A) and (B)(i) of section 2339B(f)(5) of title 18 (relating to interlocu-
tory appeal and expedited consideration).

(ii) Disclosure of information

In a review under subparagraph (A), and
in any judicial proceeding conducted pur-
suant to such review, neither the Sec-
retary nor the Attorney General may be
required to disclose to the public any in-
formation that under subsection (h) shall
not be disclosed under section 552 of title 5.

(8) Notifications regarding theft or loss of
agents

Requirements under paragraph (1) shall in-
clude the prompt notification of the Sec-
retary, 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 At-
torney General, may provide technical assist-
ance to registered persons to improve security
of the facilities of such persons.

(f) Inspections

The Secretary shall have the authority to in-
spect persons subject to regulations under sub-
section (b) or (c) to ensure their compliance
with such regulations, including prohibitions on
restricted persons and other provisions of sub-
section (e).

(g) Exemptions

(1) Clinical or diagnostic laboratories

Regulations under subsections (b) and (c)
shall exempt clinical or diagnostic labora-
tories and other persons who possess, use, or
transfer listed agents or toxins that are con-
tained 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 Sec-
retary by regulation.

(2) Products

(A) In general

Regulations under subsections (b) and (c)
shall exempt products that are, bear, or con-
tain 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 sub-
section (b) or (c) to a specific product is
necessary to protect public health and safe-
ty.

(B) Relevant laws

For purposes of subparagraph (A), the Acts
specified in this subparagraph are the fol-

1So in original. Probably should be “judicial”.
§ 262a

(3) Public health emergencies

The Secretary may temporarily exempt a person from the applicability of the requirements of this section, in whole or in part, if the Secretary determines that such exemption is necessary to provide for the timely participation of the person in a response to a domestic or foreign public health emergency (whether determined under section 247d(a) of this title or otherwise) that involves a listed agent or toxin. The Secretary determines that applying additional regulations under subsections (b) and (c) to such product is not necessary to protect public health and safety.

(ii) Certain processes

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

(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.

(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) for the possession, use, or transfer of a listed agent or toxin; or information derived therefrom to the extent that such information identifies the listed agent or toxin possessed, used, or transferred by a specific registered person or discloses the identity or location of a specific registered person.

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

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

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

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

(2) Covered agencies

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

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

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

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

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

(3) Other exceptions

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 2552(b)(3) of such title.

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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); or

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

(5) Disclosures to Congress; other disclosures

This subsection may not be construed as providing any authority—

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

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

(i) Civil money penalty

(1) In general

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

(2) Applicability of certain provisions

The provisions of section 1320a–7a of this title (other than subsections (a), (b), (h), and (l), the first sentence of subsection (c), and paragraphs (1) and (2) of subsection (i)) 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 1320a–7a(a) of this title. The Secretary may delegate authority under this subsection in the same manner as provided in section 1320a–7a(j)(2) of this title, and such authority shall include all powers as contained in section 406 of title 5.

(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 biocounteraction area of a facility of the registered person. Upon receipt of such notification and a finding by the Secretary that the release poses a threat to public health or safety, the Secretary shall take appropriate action to notify relevant State and local public health authorities, other relevant Federal authorities, and, if necessary, other appropriate persons (including the public). If the released listed agent or toxin is an overlap agent or toxin (as defined in subsection (l)), the Secretary shall promptly notify the Secretary of Agriculture upon notification by the registered person.

(k) Reports

(1) Notification with respect to Federal facilities

In the event of the release, loss, or theft of an agent or toxin listed by the Secretary pursuant to subsection (a)(1), or by the Secretary of Agriculture pursuant to section 8401(a)(1) of title 7, from or within a laboratory facility owned or operated by the Department of Health and Human Services, or other Federal laboratory facility subject to the requirements of this section, the Secretary, in a manner that does not compromise national security, shall—

(A) not later than 72 hours after such event is reported to the Secretary, notify the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives of such event, including—

(i) the Federal laboratory facility in which such release, loss, or theft occurred; and

(ii) the circumstances of such release, loss, or theft; and

(B) not later than 14 days after such notification, update such Committees on—

(i) any actions taken or planned by the Secretary to mitigate any potential threat such release, loss, or theft may pose to public health and safety; and

(ii) any actions taken or planned by the Secretary to review the circumstances of such release, loss, or theft, and prevent similar events.

(2) Annual report

The Secretary shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives on an annual basis a report—

(A) summarizing the number and nature of notifications received under subsection (e)(8) (relating to theft or loss) and subsection (j) (relating to releases), during the preceding fiscal year;

(B) describing actions taken by the Secretary to address such incidents, such as any corrective action plans required and steps taken to promote adherence to, and compliance with, safety and security best practices, standards, and regulations; and

(C) describing any gaps, challenges, or limitations with respect to ensuring that such safety and security practices are consistently applied and adhered to, and actions taken to address such gaps, challenges, or limitations.
(3) Implementation of recommendations of the Federal Experts Security Advisory Panel and the fast track action committee on select agent regulations

(A) In general
Not later than 1 year after June 24, 2019, the Secretary shall report to the congressional committees of jurisdiction on the implementation of recommendations of the Federal Experts Security Advisory Panel concerning the select agent program.

(B) Continued updates
The Secretary shall report to the congressional committees of jurisdiction annually following the submission of the report under subparagraph (A) until the recommendations described in such subparagraph are fully implemented, or a justification is provided for the delay in, or lack of, implementation.

(i) Definitions
For purposes of this section:

(1) The terms “biological agent” and “toxin” have the meanings given such terms in section 176 of title 18.

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

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

(4) The term “overlap agents and toxins” means biological agents or toxins that—

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

(B) are listed pursuant to section 8401(a)(1) of title 7.

(5) The term “overlap agent or toxin” means a biological agent or toxin that—

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

(B) is listed pursuant to section 8401(a)(1) of title 7.

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

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

(8) The term “restricted person” has the meaning given such term in section 175b of title 18.

(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 2023 through 2027.


Editorial Notes

REFERENCES IN TEXT

The Federal Food, Drug, and Cosmetic Act, referred to in subsec.(g)(2)(B)(i), is act June 25, 1938, ch. 765, 52 Stat. 1040, which is classified generally to chapter 9 (§901 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)(2)(B)(iii), is the eighth paragraph under the heading “Bureau of Animal Industry” of act Mar. 4, 1913, ch. 145, 37 Stat. 582, 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.


Statutory Notes and Related Subsidiaries

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.

EFFECTIVE DATE


REGULATIONS

the Public Health Service Act (42 U.S.C. 262a), as added by section 201 of this Act. Such regulations, including the list under [former] subsection (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]."

IMPROVING RESEARCH AND DEVELOPMENT OF MEDICAL-countermeasures for novel pathogens

Pub. L. 117–328, div. FF, title II, § 2303(a), Dec. 29, 2022, 136 Stat. 5758, provided that:

“(1) SAMPLE ACCESS.—Not later than 1 year after the date of enactment of this Act [Dec. 29, 2022], the Secretary of Health and Human Services (referred to in this subsection as the ‘Secretary’) shall make publicly available policies and procedures related to public and private entities accessing specimens of, or specimens containing, pathogens, as appropriate, including applicable safeguard and security measures; and

“(2) GUIDANCE.—The Secretary shall issue guidance regarding the procedures for carrying out paragraph (1), including—

“(A) the method for requesting such samples;

“(B) considerations for sample availability and use of suitable surrogates or alternatives to such pathogens as appropriate, including applicable safeguard and security measures; and

“(C) information required to be provided in order to receive such samples or suitable surrogates or alternatives.”

STRATEGY FOR FEDERAL HIGH-CONTAINMENT LABORATORIES

Pub. L. 117–328, div. FF, title II, § 2312, Dec. 29, 2022, 136 Stat. 5751, provided that:

“(a) STRATEGY FOR FEDERAL HIGH-CONTAINMENT LABORATORIES.—Not later than 1 year after the date of enactment of this Act [Dec. 29, 2022], the Director of the Office of Science and Technology Policy, in consultation with relevant Federal departments and agencies, shall establish a strategy for the management, maintenance, and oversight of federally-owned laboratory facilities operating at Biosafety Level 3 or 4, including equivalent classification levels and facilities with Biosafety Level 4 capabilities. Such strategy shall include—

“(1) a description of the roles and responsibilities of relevant Federal departments and agencies with respect to the management, maintenance, and oversight of Biosafety Level 3 or 4 laboratory facilities;

“(2) an assessment of the needs of the Federal Government with respect to Biosafety Level 3 or 4 laboratory facilities;

“(3) a summary of existing federally-owned Biosafety Level 3 or 4 laboratory facility capacity;

“(4) a summary of other Biosafety Level 3 or 4 laboratory facility capacity established through Federal funds;

“(5) a description of how the capacity described in paragraphs (3) and (4) addresses the needs of the Federal Government, including—

“(A) how relevant Federal departments and agencies coordinate to provide access to appropriate laboratory facilities to reduce unnecessary duplication; and

“(B) any gaps in such capacity related to such needs after such date;

“(6) a summary of plans that are in place for the maintenance of such capacity within each relevant Federal department or agency, as applicable and appropriate, including processes for determining whether to maintain or expand such capacity, and a description of how the Federal Government will address rapid changes in the need for such capacity within each relevant Federal department or agency during a public health emergency; and

“(7) a description of how the heads of relevant Federal departments and agencies will coordinate to ensure appropriate oversight of federally-owned laboratory facility capacity and leverage such capacity within each relevant Federal department, as appropriate, to fulfill the needs of each Federal department and agency in order to reduce unnecessary duplication and improve collaboration within the Federal Government.

“(b) CLARIFICATION.—The strategy under subsection (a) shall not be construed to supersede the authorities of each relevant Federal department or agency with respect to the management, maintenance, and oversight of the Federally-owned laboratory facilities operated by any such Federal department or agency.”

RESEARCH TO IMPROVE BIOSAFETY


“(a) IN GENERAL.—The Secretary of Health and Human Services (referred to in this section as the ‘Secretary’) shall, as appropriate, conduct or support research to improve the safe conduct of biomedical research activities involving pathogens of pandemic potential or biological agents or toxins listed pursuant to section 351A(a)(1) of the Public Health Service Act (42 U.S.C. 262a(a)(1)).

“(b) REPORT.—Not later than 5 years after the date of enactment of this Act [Dec. 29, 2022], the Secretary shall prepare and submit a report to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives regarding an overview of any research conducted or supported under this section, any relevant findings, and steps the Secretary is taking to disseminate any such findings to support the reduction of risks associated with biomedical research involving pathogens of pandemic potential or biological agents or toxins listed pursuant to section 351A(a)(1) of the Public Health Service Act (42 U.S.C. 262a(a)(1))."

NATIONAL SCIENCE ADVISORY BOARD FOR BIOSECURITY

Pub. L. 117–328, div. FF, title II, § 2315, Dec. 29, 2022, 136 Stat. 5765, formerly set out as a note under this section, was transferred and is set out as a National Science Advisory Board for Biosecurity: Provision of Advice, Guidance, or Recommendations note under section 2323 of this title.

REPORT TO CONGRESS

Pub. L. 117–328, div. FF, title II, § 2316, Dec. 29, 2022, 136 Stat. 5766, required the Secretary of Health and Human Services to report to Congress not later than one year after June 12, 2002, on the implementation, compliance, and future plans under this section.

IMPLEMENTATION BY DEPARTMENT OF HEALTH AND HUMAN SERVICES

Pub. L. 117–328, div. FF, title II, § 2317, Dec. 29, 2022, 136 Stat. 5766, provided that:

“(a) DATE CERTAIN FOR NOTICE OF POSSESSION.—Not later than 90 days after the date of enactment of this Act [June 12, 2002], all persons (unless exempt under subsection (g) of section 351A of the Public Health Service Act (42 U.S.C. 262a(g)), as added by section 201 of this Act) in possession of biological agents or toxins listed under such section 351A of the Public Health Service Act (42 U.S.C. 262a) shall notify the Secretary of Health and Human Services of such possession. Not later than 30 days after such date of enactment, the Secretary shall provide written guidance on how such notice is to be provided to the Secretary.
“(b) Date Certain for Promulgation; Effective Date Regarding Criminal and Civil Penalties.—Not later than 180 days after the date of the enactment of this Act [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 Service Act [42 U.S.C. 262a], subject to subsection (c). Such interim final rule shall take effect 40 days after the date on which such rule is promulgated, including for purposes of—

(1) section 176(i) of title 18, United States Code (relating to criminal penalties), as added by section 231(a)(5) of this Act; and

(2) section 351A(i) of the Public Health Service Act (42 U.S.C. 262a(i)) (relating to civil penalties).

(c) Transitional Provision Regarding Current Research and Education.—The interim final rule under subsection (b) shall include time frames for the applicability of the rule that minimize disruption of research or educational projects that involve biological agents and toxins listed pursuant to section 351A(a)(1) of the Public Health Service Act (42 U.S.C. 262a(a)(1)) and that were underway as of the effective date of such rule.

Executive Documents

Ex. Ord. No. 13546, Optimizing the Security of Biological 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.

SISC. 2. Definitions. (a) “Select Agent Program” (SAP) means the regulatory oversight and administrative activities conducted by the Secretaries of Health and Human Services and Agriculture and the Attorney General to implement the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 and the Agricultural Bioterrorism Protection Act of 2002.


(c) “Biological Select Agents and Toxins” means biological 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 Department of Health and Human Services and the Department of Agriculture under the SAR.

SISC. 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 transfer 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 management.

(b) In addition, variations in, and limited coordination of, individual executive departments’ and agencies’ oversight, security practices, and inspections have raised concerns that the cost and complexity of compliance for those who are registered to work with BSAT could discourage research or other legitimate activities.

(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 address these issues.

SISC. 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 infrastructure, or public confidence;

(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.

SISC. 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.

SISC. 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:

(a) no later than 6 months from the date of this order, develop and implement a plan for the coordination of BSAT security oversight that:

(i) articulates a mechanism for coordinated and reciprocal inspection of and harmonized administrative practices for facilities registered with the SAP;

(ii) ensures consistent and timely identification and resolution of BSAT security and compliance issues;

(iii) facilitates information sharing among departments and agencies regarding ongoing oversight and inspection activities; and

(iv) provides 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);
§ 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.

(1944, ch. 373, title III, §352, 58 Stat. 703.)

Statutory Notes and Related Subsidiaries

CHANGE OF NAME

“Secretary of Health and Human Services” substituted for “Secretary of Health, Education, and Welfare” pursuant to section 509(b) of Pub. L. 96–88, which is classified to section 3508(b) of Title 20, Education.

Executive Documents

TRANSFER OF FUNCTIONS


§ 263–1. Education on biological products

(a) Internet website

(1) In general

The Secretary may maintain and operate an internet website to provide educational materials for health care providers, patients, and caregivers, regarding the meaning of the terms, and the standards for review and licensing of, biological products, including biosimilar biological products and interchangeable biosimilar biological products.

(2) Content

Educational materials provided under paragraph (1) may include—

(A) explanations of key statutory and regulatory terms, including “biosimilar” and “interchangeable”, and clarification regarding the use of interchangeable biosimilar biological products;