

119TH CONGRESS
2^D SESSION

S. _____

To require the Secretary of Health and Human Services, acting through the Assistant Secretary for Preparedness and Response, to carry out a program under which the Secretary requires each covered distributor of a highly pathogenic agent to comply with certain logbook requirements, and for other purposes.

IN THE SENATE OF THE UNITED STATES

Ms. CORTEZ MASTO (for herself and Mr. BANKS) introduced the following bill; which was read twice and referred to the Committee on

A BILL

To require the Secretary of Health and Human Services, acting through the Assistant Secretary for Preparedness and Response, to carry out a program under which the Secretary requires each covered distributor of a highly pathogenic agent to comply with certain logbook requirements, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Preventing Illegal Lab-
5 oratories and Protecting Public Health Act of 2026”.

1 **SEC. 2. REQUIRING CERTAIN DISTRIBUTORS OF HIGHLY**
2 **PATHOGENIC AGENTS TO KEEP A LOGBOOK**
3 **OF SALES, LEASES, LOANS, AND OTHER**
4 **TRANSFERS.**

5 (a) PROGRAM.—The Secretary shall carry out a pro-
6 gram under which the Secretary requires each covered dis-
7 tributor of a highly pathogenic agent to comply with the
8 logbook requirements of subsection (c).

9 (b) LIST OF HIGHLY PATHOGENIC AGENTS.—

10 (1) DEVELOPMENT.—The Secretary shall de-
11 velop and maintain a list of all agents that meet the
12 definition of a highly pathogenic agent in subsection
13 (e).

14 (2) INITIAL LIST.—The Secretary shall develop
15 the initial list required by paragraph (1) not later
16 than 6 months after the date of enactment of this
17 Act.

18 (3) PERIODIC REVIEW.—The Secretary shall
19 annually review and update the list required by
20 paragraph (1).

21 (4) CONSULTATION; CONSIDERATION.—In de-
22 veloping and updating the list required by paragraph
23 (1), the Secretary shall—

24 (A) consult with relevant agencies, includ-
25 ing the Centers for Disease Control and Pre-
26 vention, the National Institutes of Health, the

1 Department of Homeland Security, the Depart-
2 ment of Agriculture, the Department of the In-
3 terior, and the Department of Defense;

4 (B) take into consideration the latest edi-
5 tion of “Biosafety in Microbiological and Bio-
6 medical Laboratories” published by the Centers
7 for Disease Control and Prevention and the Na-
8 tional Institutes of Health (or any successor to
9 such publication); and

10 (C) take into consideration the latest edi-
11 tion of “NIH Guidelines for Research Involving
12 Recombinant or Synthetic Nucleic Acid Mol-
13 ecules” published by the National Institutes of
14 Health (or any successor to such publication).

15 (c) LOGBOOK REQUIREMENTS.—

16 (1) IN GENERAL.—Each covered distributor
17 shall maintain, in accordance with such criteria and
18 format as the Secretary may require, an electronic
19 list (in this section referred to as a “logbook”) of
20 the sales, leases, loans, or other transfers by such
21 distributor of each highly pathogenic agent on the
22 list under subsection (b).

23 (2) CONTENTS.—The covered distributor shall,
24 for each sale, lease, loan, or other transfer referred
25 to in paragraph (1), include in the logbook—

1 (A) the agent by name;

2 (B) the name, address, telephone number,
3 and email address of the purchaser;

4 (C) other relevant identifying business in-
5 formation of the purchaser, as the Secretary de-
6 termines appropriate;

7 (D) a short description of—

8 (i) the purchaser's intended use of the
9 highly pathogenic agent; and

10 (ii) where the purchaser will house the
11 agent;

12 (E) the date and time of the sale, lease,
13 loan, or other transfer;

14 (F) the method, date, and time of transfer
15 of the highly pathogenic agent;

16 (G) a physical or electronic signature of
17 the purchaser; and

18 (H) such other data elements as the Sec-
19 retary may require.

20 (3) SALE REQUIREMENTS.—In the case of a
21 sale, lease, loan, or other transfer to which para-
22 graph (1) applies, the covered distributor shall not
23 sell the highly pathogenic agent unless—

24 (A) the prospective purchaser, in physical
25 form or electronically in compliance with the

1 Electronic Signatures in Global and National
2 Commerce Act (42 U.S.C. 7001 et seq.)—

3 (i) presents an identification card that
4 provides a photograph and is issued by a
5 State or the Federal Government, or a
6 document that, with respect to identifica-
7 tion, is considered acceptable for purposes
8 of sections 274a.2(b)(1)(v)(A) and
9 274a.2(b)(1)(v)(B) of title 8, Code of Fed-
10 eral Regulations (or successor regulations);
11 and

12 (ii) verifies by signature in the log-
13 book—

14 (I) the purchaser's name and ad-
15 dress;

16 (II) a short description of—

17 (aa) the purchaser's in-
18 tended use of the agent; and

19 (bb) where the purchaser
20 will house the agent;

21 (III) the date and time of the
22 sale, lease, loan, or other transfer;
23 and

24 (IV) the method, date, and time
25 of transfer of the agent; and

1 (B) the covered distributor—

2 (i) determines that the name entered
3 in the logbook corresponds to the name
4 provided on the identification card de-
5 scribed in subparagraph (A)(i), and that
6 the information entered pursuant to sub-
7 paragraph (A)(ii) is correct; and

8 (ii) enters in the logbook the name of
9 the highly pathogenic agent.

10 (4) NOTICE.—The covered distributor shall in-
11 clude in the logbook, in accordance with criteria of
12 the Secretary, a notice to purchasers that entering
13 false statements or misrepresentations in the log-
14 book may subject the purchasers to criminal pen-
15 alties under section 1001 of title 18, United States
16 Code, which notice specifies the maximum fine and
17 term of imprisonment under such section.

18 (5) DURATION OF MAINTENANCE OF EN-
19 TRIES.—

20 (A) RETENTION PERIOD.—The covered
21 distributor shall maintain each entry in the log-
22 book for not fewer than 3 years after the date
23 on which the entry is made.

24 (B) SUCCESSOR ENTITY.—If ownership of
25 a covered distributor changes, the successor en-

1 tity shall assume custody of and responsibility
2 for all logbooks for the remainder of the 3-year
3 retention period required by subparagraph (A).

4 (6) DISCLOSURE OF LOGBOOKS.—The Sec-
5 retary shall establish restrictions on disclosure of in-
6 formation in logbooks. Such regulations shall—

7 (A) provide for the disclosure of the infor-
8 mation, as appropriate, to the Secretary, Fed-
9 eral, State, local, Tribal, and territorial law en-
10 forcement agencies, and State health officials;
11 and

12 (B) prohibit accessing, using, or sharing
13 information in the logbooks for any purpose
14 other than—

15 (i) to ensure compliance with this sec-
16 tion;

17 (ii) to protect public health and safe-
18 ty; or

19 (iii) to protect national security.

20 (7) FOIA EXEMPTION.—Logbooks and any de-
21 rivative data are exempt from disclosure under sec-
22 tion 552(b)(3) of title 5, United States Code.

23 (8) APPLICABILITY.—A transfer of a highly
24 pathogenic agent between laboratories within a sin-
25 gle institution of higher education (as defined in sec-

1 tion 101 of the Higher Education Act of 1965 (20
2 U.S.C. 1001)) does not constitute a sale, lease, loan,
3 or other transfer of the agent for purposes of para-
4 graph (1).

5 (9) AUDITS.—The Secretary shall establish a
6 risk-based compliance review process by which the
7 Secretary may conduct audits of logbooks when the
8 Secretary has cause to believe a violation of this sec-
9 tion has occurred. The Secretary shall focus audits
10 conducted under this paragraph on higher-risk dis-
11 tributors and suspicious patterns.

12 (d) FALSE STATEMENTS OR MISREPRESENTATIONS
13 BY PURCHASERS.—For purposes of section 1001 of title
14 18, United States Code, providing information to a cov-
15 ered distributor for purposes of entering such information
16 in a logbook shall be considered a matter within the juris-
17 diction of the executive, legislative, or judicial branch of
18 the Government of the United States.

19 (e) DEFINITIONS.—In this section:

20 (1) The term “covered distributor”—

21 (A) means an entity that sells, leases,
22 loans, or otherwise transfers for value or not for
23 value a highly pathogenic agent, except that
24 such term does not include an employee or
25 agent of such a distributor; and

1 (B) includes a publicly funded repository
2 or biobank that sells, leases, loans, or otherwise
3 transfers a highly pathogenic agent, as de-
4 scribed in subparagraph (A).

5 (2) The term “highly pathogenic agent”—

6 (A) subject to subparagraph (B), means a
7 pathogenic agent that meets the criteria of
8 “risk group 3” or any higher level risk groups
9 as such risk groups are defined in the latest
10 edition of “NIH Guidelines for Research Involv-
11 ing Recombinant or Synthetic Nucleic Acid
12 Molecules” published by the National Institutes
13 of Health (or any successor to such publica-
14 tion); and

15 (B) excludes any biological agent or toxin
16 that is regulated under section 351A of the
17 Public Health Service Act (42 U.S.C. 262a) or
18 section 212 of the Agricultural Bioterrorism
19 Protection Act of 2002 (7 U.S.C. 8401).

20 (3) The term “Secretary” means the Secretary
21 of Health and Human Services, acting through the
22 Assistant Secretary for Strategic Preparedness and
23 Response.

24 (f) RULE OF CONSTRUCTION.—Nothing in this sec-
25 tion shall be construed to supersede or otherwise affect

1 the Federal Select Agent Program under section 351A of
2 the Public Health Service Act (42 U.S.C. 262a) and sec-
3 tion 212 of the Agricultural Bioterrorism Protection Act
4 of 2002 (7 U.S.C. 8401).

5 **SEC. 3. EVALUATION OF HIGH-CONTAINMENT LABORA-**
6 **TORIES.**

7 (a) IN GENERAL.—The National Security Advisor, in
8 consultation with the Secretary of Health and Human
9 Services, the Secretary of Agriculture, the Secretary of
10 Defense, the Secretary of Homeland Security, the Sec-
11 retary of the Interior, the Director of National Intel-
12 ligence, and such other Federal officials as the National
13 Security Advisor determines appropriate, shall identify a
14 single Federal entity to oversee a periodic strategic evalua-
15 tion of high-containment laboratories in the United States.

16 (b) TOPICS.—Each strategic evaluation under sub-
17 section (a) shall include—

18 (1) an assessment of—

19 (A) the number, location, and mission of
20 high-containment laboratories;

21 (B) the capacity of such existing labora-
22 tories to effectively meet national goals to
23 counter threats to biosafety and biosecurity;

24 (C) the physical security measures at high-
25 containment laboratories;

1 (D) the aggregate risks associated with—

2 (i) such existing laboratories; and

3 (ii) expanding the numbers and facili-

4 ties of such laboratories; and

5 (E) the type of oversight needed for high-

6 containment laboratories; and

7 (2) up-to-date national standards, developed by

8 the Federal entity identified under subsection (a),

9 that—

10 (A) are developed by the Federal entity

11 identified under subsection (a) in consultation

12 with members of the scientific community, for

13 the design, construction, commissioning, oper-

14 ation, and long-term maintenance of high-con-

15 tainment laboratories; and

16 (B) take into consideration applicable reg-

17 ulations and guidance for high-containment lab-

18 oratories.

19 (c) REPORTING.—Upon completion of each strategic

20 evaluation under subsection (a), the Federal entity identi-

21 fied under subsection (a) shall submit to the President and

22 to Congress a report on the results of such evaluation and

23 include in each such report recommendations on—

24 (1) addressing gaps in Federal oversight of

25 high-containment laboratories; and

1 (2) utilizing high-containment laboratories for
2 protecting public health and ensuring biosafety and
3 biosecurity in the United States.

4 (d) PUBLIC HEALTH BIOSAFETY AND BIOSECURITY
5 TEAM.—

6 (1) IN GENERAL.—The Federal entity identified
7 under subsection (a) shall maintain a team, to be
8 known as the Public Health Biosafety and Biosecu-
9 rity Team, to serve as a single point of contact for
10 State, local, Tribal, and territorial agencies regard-
11 ing questions relating to laboratory biosafety and
12 biosecurity.

13 (2) ESTABLISHMENT.—The Federal entity
14 identified under subsection (a) shall establish the
15 Public Health and Biosecurity Team, as required by
16 paragraph (1), not later than one year after such of-
17 ficial is first designated.

18 (3) DUTIES.—The Public Health Biosafety and
19 Biosecurity Team shall be the single point of contact
20 in the Federal Government for State, local, Tribal,
21 and territorial agencies on—

22 (A) issues related to—

23 (i) oversight of high-containment lab-
24 oratories;

1 (ii) the impact of high-containment
2 laboratories on public health; or

3 (iii) connecting State, local, Tribal,
4 and territorial officials with the relevant
5 Federal agency or agencies on matters re-
6 lated to high-containment laboratories; and

7 (B) other issues as the Federal entity iden-
8 tified under subsection (a) determines appro-
9 priate.

10 (e) FEASIBILITY STUDY.—

11 (1) IN GENERAL.—The Federal entity identified
12 under subsection (a) shall conduct a feasibility study
13 on establishing and maintaining a database on exist-
14 ing high-containment laboratories in the United
15 States for the purpose of making such database ac-
16 cessible to Federal, State, local, Tribal, and terri-
17 torial officials.

18 (2) DATABASE DESCRIBED.—The database con-
19 sidered under paragraph (1) shall be a database de-
20 signed to include, with respect to each high-contain-
21 ment laboratory, the following information:

22 (A) The identity of the owners of the lab-
23 oratory.

24 (B) The address of the laboratory.

1 (C) The status of any licensing or certifi-
2 cation of the laboratory required under Federal,
3 State, local, Tribal, or territorial law.

4 (D) Any legal violations by, and discipli-
5 nary action taken against, the laboratory.

6 (E) Such additional information as the
7 Federal entity identified under subsection (a)
8 determines appropriate to protect biosafety and
9 biosecurity.

10 (3) REPORT TO CONGRESS.—Upon completion
11 of the feasibility study under this subsection, the
12 Federal entity identified under subsection (a) shall
13 submit to Congress a report on the results of such
14 study.

15 (f) DEFINITION.—In this section, the term “high-
16 containment laboratory” means a laboratory that is suit-
17 able for “biosafety level 3” or any higher biosafety level
18 procedures, as defined in the latest edition of “Biosafety
19 in Microbiological and Biomedical Laboratories” published
20 by the Centers for Disease Control and Prevention and
21 the National Institutes of Health (or any successor to such
22 publication).