

111TH CONGRESS
1ST SESSION

S. 485

To reauthorize the Select Agent Program by amending the Public Health Service Act and the Agricultural Bioterrorism Protection Act of 2002 and to improve oversight of high containment laboratories.

IN THE SENATE OF THE UNITED STATES

FEBRUARY 26, 2009

Mr. BURR (for himself and Mr. KENNEDY) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

A BILL

To reauthorize the Select Agent Program by amending the Public Health Service Act and the Agricultural Bioterrorism Protection Act of 2002 and to improve oversight of high containment laboratories.

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; TABLE OF CONTENTS.**

4 (a) SHORT TITLE.—This Act may be cited as the
5 “Select Agent Program and Biosafety Improvement Act
6 of 2009”.

7 (b) TABLE OF CONTENTS.—The table of contents for
8 this Act is as follows:

- Sec. 1. Short title; table of contents.
 Sec. 2. Findings.

TITLE I—SELECT AGENT PROGRAM REAUTHORIZATION

- Sec. 101. Reauthorization of select agent program.
 Sec. 102. Select agent program review.
 Sec. 103. Revision of the list of biological agents and toxins.
 Sec. 104. Sharing information with trusted State partners.
 Sec. 105. Improvements to inventorying and monitoring of agents.
 Sec. 106. Smallpox definition clarification.
 Sec. 107. Plan for surge in samples of biological agents and toxins.

TITLE II—BIOSAFETY IMPROVEMENTS

- Sec. 201. Improvement of oversight of biocontainment laboratories.
 Sec. 202. Improvement of training for laboratory personnel.
 Sec. 203. Biological laboratory incident reporting system.

1 **SEC. 2. FINDINGS.**

2 Congress finds the following:

3 (1) The Centers for Disease Control and Pre-
 4 vention regulates the possession, use, and transfer of
 5 select agents and toxins that have the potential to
 6 pose a severe threat to public health and safety.

7 (2) The Animal and Plant Health Inspection
 8 Service regulates the possession, use, and transfer of
 9 select agents and toxins that have the potential to
 10 pose a severe threat to animal or plant health, or to
 11 animal or plant products.

12 (3) As of February 2009, there are 82 select
 13 agents and toxins, 13 of which are found naturally
 14 in the United States.

15 (4) As of February 2009, there are 336 entities
 16 registered with the Centers for Disease Control and
 17 Prevention to work with select agents and toxins and

1 64 entities registered with the Animal and Plant
2 Health Inspection Service. There are 10,463 individ-
3 uals approved to work with select agents and toxins
4 through the Centers for Disease Control and Preven-
5 tion and 4,149 through the Animal and Plant
6 Health Inspection Service.

7 (5) Biocontainment laboratories are used by sci-
8 entists to study infectious materials safely and effec-
9 tively. Laboratory biological research is categorized
10 by the safety level at which it is performed. There
11 are 4 safety levels, termed Biosafety Level (BSL) 1
12 through 4.

13 **TITLE I—SELECT AGENT** 14 **PROGRAM REAUTHORIZATION**

15 **SEC. 101. REAUTHORIZATION OF SELECT AGENT PROGRAM.**

16 (a) REAUTHORIZATION OF SELECT AGENT PRO-
17 GRAM.—

18 (1) AMENDMENT TO THE PUBLIC HEALTH
19 SERVICE ACT.—Section 351A(m) of the Public
20 Health Service Act (42 U.S.C. 262a(m)) is amended
21 by striking “2002 through 2007” and inserting
22 “2010 through 2014”.

23 (2) AMENDMENT TO THE AGRICULTURAL BIO-
24 TERRORISM PROTECTION ACT OF 2002.—Section
25 212(m) of the Agricultural Bioterrorism Protection

1 Act of 2002 (7 U.S.C. 8401(m)) is amended by
2 striking “2002 through 2007” and inserting “2010
3 through 2014”.

4 (b) APPROPRIATE TRAINING.—

5 (1) AMENDMENT TO THE PUBLIC HEALTH
6 SERVICE ACT.—Section 351A(e)(2)(A) of the Public
7 Health Service Act (42 U.S.C. 262a(e)(2)(A)) is
8 amended by inserting “, and appropriate training,”
9 after “have a legitimate need”.

10 (2) AMENDMENT TO THE AGRICULTURAL BIO-
11 TERRORISM PROTECTION ACT OF 2002.—Section
12 212(e)(2)(A) of the Agricultural Bioterrorism Pro-
13 tection Act of 2002 (7 U.S.C. 8401(e)(2)(A)) is
14 amended by inserting “, and appropriate training,”
15 after “have a legitimate need”.

16 (c) COVERED AGENCIES.—

17 (1) AMENDMENT TO THE PUBLIC HEALTH
18 SERVICE ACT.—Section 351A(h)(2)(A) (42 U.S.C.
19 262a(h)(2)(A)) of the Public Health Service Act is
20 amended by inserting “the Department of Homeland
21 Security,” after “the Department of Agriculture,”.

22 (2) AMENDMENT TO THE AGRICULTURAL BIO-
23 TERRORISM PROTECTION ACT OF 2002.—Section
24 212(h)(2)(A) of the Agricultural Bioterrorism Pro-
25 tection Act of 2002 (7 U.S.C. 8401(h)(2)(A)) is

1 amended by inserting “the Department of Homeland
2 Security,” after “the Department of Agriculture,”.

3 **SEC. 102. SELECT AGENT PROGRAM REVIEW.**

4 (a) IN GENERAL.—The Secretary of Health and
5 Human Services, in consultation with the Secretary of Ag-
6 riculture, shall enter into a contract with the National
7 Academy of Sciences to conduct a review of the select
8 agent program under section 351A of the Public Health
9 Service Act (42 U.S.C. 262a) and section 212 of the Agri-
10 cultural Bioterrorism Protection Act of 2002 (7 U.S.C.
11 8401). Such review shall focus on—

12 (1) the extent to which the program has en-
13 hanced biosecurity and biosafety in the United
14 States;

15 (2) the effects of the program on—

16 (A) international scientific collaboration;

17 and

18 (B) scientific advances in the United
19 States; and

20 (3) other issues as requested by the Secretary
21 of Health and Human Services and the Secretary of
22 Agriculture.

23 (b) REPORT; RECOMMENDATIONS.—Not later than
24 240 days after the date of enactment of this Act, the Na-
25 tional Academy of Sciences shall submit a report to the

1 Secretary of Health and Human Services, the Secretary
2 of Agriculture, the Committee on Health, Education,
3 Labor, and Pensions of the Senate, the Committee on En-
4 ergy and Commerce of the House of Representatives, and
5 other congressional committees of relevant interest, on the
6 results of the review conducted under subsection (a). Such
7 report shall include recommendations for improving the
8 structure of the select agent program for—

9 (1) enhancing the biosecurity and biosafety of
10 the United States;

11 (2) eliminating or reducing adverse effects of
12 the program, if any, on—

13 (A) international scientific collaboration;
14 and

15 (B) scientific advances in the United
16 States; and

17 (3) other issues as requested by the Secretary
18 of Health and Human Services and the Secretary of
19 Agriculture.

20 **SEC. 103. REVISION OF THE LIST OF BIOLOGICAL AGENTS**
21 **AND TOXINS.**

22 (a) AMENDMENT TO THE PUBLIC HEALTH SERVICE
23 ACT.—Section 351A(a)(1)(B)(i) of the Public Health
24 Service Act (42 U.S.C. 262a(a)(1)(B)(i)) is amended—

1 (1) in subclause (III), by striking “; and” and
2 inserting a semicolon;

3 (2) by redesignating subclause (IV) as sub-
4 clause (VII); and

5 (3) by inserting after subclause (III) the fol-
6 lowing:

7 “(IV) whether the agent or toxin
8 is endemic to the United States, as
9 defined by the Secretary;

10 “(V) information available from
11 biological risk assessments conducted
12 by the Department of Homeland Se-
13 curity;

14 “(VI) newly discovered agents of
15 disease, including genetically modified
16 organisms or agents created syn-
17 thetically; and”.

18 (b) AMENDMENT TO THE AGRICULTURAL BIOTER-
19 RORISM PROTECTION ACT OF 2002.—Section
20 212(a)(1)(B)(i) of the Agricultural Bioterrorism Protec-
21 tion Act of 2002 (7 U.S.C. 8401(a)(1)(B)(i)) is amend-
22 ed—

23 (1) in subclause (III), by striking “; and” and
24 inserting a semicolon;

1 (2) by redesignating subclause (IV) as sub-
2 clause (VII); and

3 (3) by inserting after subclause (III) the fol-
4 lowing:

5 “(IV) whether the agent or toxin
6 is endemic to the United States, as
7 defined by the Secretary;

8 “(V) information available from
9 biological risk assessments conducted
10 by the Department of Homeland Se-
11 curity;

12 “(VI) newly discovered agents of
13 disease, including genetically modified
14 organisms or agents created syn-
15 thetically; and”.

16 (c) **RULE OF CONSTRUCTION.**—The amendments
17 made by subsections (a) and (b) shall not be construed
18 to preclude the listing of a biological agent or toxin that
19 is endemic to the United States.

20 **SEC. 104. SHARING INFORMATION WITH TRUSTED STATE**
21 **PARTNERS.**

22 (a) **AMENDMENT TO THE PUBLIC HEALTH SERVICE**
23 **ACT.**—Section 351A(h)(5) of the Public Health Service
24 Act (42 U.S.C. 262a(h)(5)) is amended—

1 (1) in subparagraph (A), by striking “; or” and
2 inserting a semicolon;

3 (2) in subparagraph (B), by striking the period
4 and inserting “; or”; and

5 (3) by inserting at the end the following:

6 “(C) to withhold information regarding a
7 State that will assist with the State’s emer-
8 gency preparedness planning from the health
9 director (or equivalent State official) of such
10 State, if such State has in place a law to pro-
11 tect against the further release of such informa-
12 tion as determined by the Secretary.”.

13 (b) AMENDMENT TO THE AGRICULTURAL BIOTER-
14 RORISM PROTECTION ACT OF 2002.—Section 212(h)(5)
15 of the Agricultural Bioterrorism Protection Act of 2002
16 (7 U.S.C. 8401(h)(5)) is amended—

17 (1) in subparagraph (A), by striking “; or” and
18 inserting a semicolon;

19 (2) in subparagraph (B), by striking the period
20 and inserting “; or”; and

21 (3) by inserting at the end the following:

22 “(C) to withhold information regarding a
23 State that will assist with the State’s emer-
24 gency preparedness planning from an elected or
25 appointed senior State agricultural official or

1 equivalent State official (such as a State veteri-
2 narian or a State plant health regulatory offi-
3 cial) of such State, if such State has in place
4 a law to protect against the further release of
5 such information as determined by the Sec-
6 retary.”.

7 **SEC. 105. IMPROVEMENTS TO INVENTORYING AND MONI-**
8 **TORING OF AGENTS.**

9 (a) IMPROVED METHOD TO INVENTORY AND MON-
10 ITOR LISTED BIOLOGICAL AGENTS.—Not later than 180
11 days after enactment of this Act, the Secretary of Health
12 and Human Services, in coordination with the Secretary
13 of Agriculture, and in consultation with individuals with
14 appropriate scientific expertise, shall issue guidance on
15 inventorying and monitoring the biological agents listed
16 under section 351A(a)(1) of the Public Health Service Act
17 (42 U.S.C. 262a(a)(1)) and the biological agents listed
18 under section 212(a)(1) of the Agricultural Bioterrorism
19 Protection Act of 2002 (7 U.S.C. 8401(a)(1)).

20 (b) CONSIDERATIONS.—In issuing the guidance
21 under subsection (a), the Secretaries shall consider—

22 (1) the effectiveness of measures to inventory
23 and monitor listed biological agents that can propa-
24 gate relative to the burden of these measures on lab-
25 oratory personnel;

1 (2) qualitative and quantitative control proce-
2 dures for such listed agents, rather than only quan-
3 titative control procedures; and

4 (3) in what situations registered persons are re-
5 quired to keep inventory records.

6 **SEC. 106. SMALLPOX DEFINITION CLARIFICATION.**

7 Not later than 90 days after the date of enactment
8 of this Act, the Attorney General, in coordination with the
9 Secretary of Health and Human Services, shall issue pub-
10 lic guidance regarding how the Attorney General inter-
11 prets the scope of the statutory definition of “variola
12 virus” in section 175c of title 18, United States Code.

13 **SEC. 107. PLAN FOR SURGE IN SAMPLES OF BIOLOGICAL**
14 **AGENTS AND TOXINS.**

15 The Secretary of Health and Human Services, in co-
16 ordination with the Secretary of Agriculture and State of-
17 ficials, shall develop and disseminate guidelines for how
18 laboratories and laboratory personnel that do not regularly
19 test for listed agents and toxins (as such terms are defined
20 in section 351A of the Public Health Service Act (42
21 U.S.C. 262a) and section 212 of the Agricultural Bioter-
22 rorism Protection Act of 2002 (7 U.S.C. 8401)) may be
23 rapidly accessed and utilized during emergencies in which
24 laboratories and laboratory personnel that regularly test

1 for such agents and toxins are overwhelmed by a surge
2 of samples of such listed agents and toxins.

3 **TITLE II—BIOSAFETY**
4 **IMPROVEMENTS**

5 **SEC. 201. IMPROVEMENT OF OVERSIGHT OF BIOCONTAIN-**
6 **MENT LABORATORIES.**

7 (a) DEFINITION.—For purposes of this section, the
8 term “high containment biological laboratory” means a
9 laboratory that has Biosafety Level 3 or Biosafety Level
10 4 facilities, as defined by the Secretary of Health and
11 Human Services and the Secretary of Agriculture.

12 (b) EVALUATION.—The Secretary of Health and
13 Human Services, in coordination with the Secretary of Ag-
14 riculture, and in consultation with the Secretary of De-
15 fense and the Secretary of Homeland Security (referred
16 to in this section as the “Secretaries”) shall, either di-
17 rectly or through a contract, evaluate national needs of,
18 and oversight of, high containment biological laboratories.

19 (c) CONSIDERATIONS.—In conducting the evaluation
20 under subsection (b), the Secretaries shall consider—

21 (1) whether the construction of high contain-
22 ment biological laboratories that are in existence or
23 planned as of the date of enactment of this Act, is
24 likely to provide sufficient capacity for the needs of

1 Government biodefense and infectious disease re-
2 search;

3 (2) how laboratory capacity and lessons learned
4 can be best shared across the biodefense and infec-
5 tious disease research communities, domestically and
6 internationally;

7 (3) whether guidance on laboratory infrastruc-
8 ture, commissioning, operation, and maintenance of
9 such laboratories is adequate, and if such guidance
10 is found to be inadequate, how to improve and
11 streamline such guidance; and

12 (4) ways to improve and streamline the training
13 of the personnel of such laboratories, including rec-
14 ommendations regarding the minimum standards for
15 laboratory biosafety and biosecurity training under
16 section 202.

17 (d) REPORT TO CONGRESS.—Not later than 240 days
18 after the date of enactment of this Act, the Secretary of
19 Health and Human Services shall submit to Congress a
20 report on the findings and recommendations from the
21 evaluation under this section.

22 **SEC. 202. IMPROVEMENT OF TRAINING FOR LABORATORY**
23 **PERSONNEL.**

24 (a) DEFINITION.—For purposes of this section, the
25 term “high containment biological laboratory” means a

1 laboratory that has Biosafety Level 3 or Biosafety Level
2 4 facilities, as defined by the Secretary of Health and
3 Human Services and the Secretary of Agriculture.

4 (b) DEVELOPMENT OF MINIMUM STANDARDS.—The
5 Secretary of Health and Human Services, acting through
6 the Director of the Centers for Disease Control and Pre-
7 vention and the Director of the National Institutes of
8 Health, and in coordination with the Secretary of Agri-
9 culture and scientific experts representing appropriate
10 professional groups and international health organiza-
11 tions, shall develop minimum standards for laboratory bio-
12 safety and biosecurity training for relevant personnel of
13 high containment biological laboratories. In developing
14 such standards, the Secretary of Health and Human Serv-
15 ices shall consider existing laboratory guidelines and train-
16 ing modules.

17 (c) REQUIREMENT FOR APPROVAL.—A person may
18 not register with the Secretary of Health and Human
19 Services or the Secretary of Agriculture for the possession,
20 use, or transfer of listed agents in accordance with section
21 351A of the Public Health Service Act (42 U.S.C. 262a)
22 and section 212 of the Agricultural Bioterrorism Protec-
23 tion Act of 2002 (7 U.S.C. 8401) unless the person pro-
24 vides to its appropriate personnel biosafety and biosecurity
25 training that meets the minimum standards under sub-

1 section (b) in addition to any other requirements deter-
2 mined appropriate by the Secretary of Health and Human
3 Services or the Secretary of Agriculture.

4 (d) DISSEMINATION.—The Secretary of Health and
5 Human Services, in coordination with the Secretary of Ag-
6 riculture, may disseminate the minimum standards under
7 subsection (b) for voluntary use, such as when use is not
8 required under subsection (b), in laboratories and aca-
9 demic programs in the United States and in other coun-
10 tries.

11 **SEC. 203. BIOLOGICAL LABORATORY INCIDENT REPORTING**
12 **SYSTEM.**

13 (a) IN GENERAL.—The Secretary of Health and
14 Human Services, in coordination with the Secretary of Ag-
15 riculture (referred to in this section as the “Secretaries”),
16 shall establish an integrated Biological Laboratory Inci-
17 dent Reporting System through which personnel of biologi-
18 cal laboratories may voluntarily report biosafety or bio-
19 security incidents of concern and the Secretaries may
20 identify trends in such incidents and protocols for bio-
21 safety or biosecurity improvements. In developing such re-
22 porting system, the Secretaries shall consider options for
23 integrating existing voluntary and required reporting
24 mechanisms.

1 (b) FUNCTIONS.—In implementing the reporting sys-
2 tem under subsection (a), the Secretaries shall enter into
3 a contract with a public or private entity that does not
4 regulate biological laboratories to administer the reporting
5 system. Such entity shall—

6 (1) receive and process incident reports;

7 (2) analyze, interpret incident data, and iden-
8 tify incident trends;

9 (3) issue alert messages within an appropriate
10 time period;

11 (4) disseminate reports and other appropriate
12 information, which shall not include facility-specific
13 information;

14 (5) not have authority to direct corrective ac-
15 tion or to initiate enforcement action;

16 (6) ensure anonymity of individuals reporting to
17 the system, to the extent permitted by law; and

18 (7) conduct other activities as requested by the
19 Secretaries.

○