

110TH CONGRESS  
2D SESSION

# S. 3127

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.

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## IN THE SENATE OF THE UNITED STATES

JUNE 12, 2008

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

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## 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 2008”.

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 April 2008, there are 72 select agents  
13 and toxins, 13 of which are found naturally in the  
14 United States.

15 (4) As of April 2008, there are 325 entities reg-  
16 istered with the Centers for Disease Control and  
17 Prevention to work with select agents and toxins and

1 75 entities registered with the Animal and Plant  
2 Health Inspection Service. There are 9,918 individ-  
3 uals approved to work with select agents and toxins  
4 through the Centers for Disease Control and Preven-  
5 tion and 4,336 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 “2009 through 2013”.

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 “2009  
3 through 2013”.

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 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.

○