

110TH CONGRESS
2D SESSION

H. R. 6671

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 HOUSE OF REPRESENTATIVES

JULY 30, 2008

Ms. HARMAN (for herself and Mr. ROGERS of Michigan) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committees on Agriculture and the Judiciary, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

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”.

1 (b) TABLE OF CONTENTS.—The table of contents for
 2 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.

3 **SEC. 2. FINDINGS.**

4 Congress finds the following:

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

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

14 (3) As of April 2008, there are 72 select agents
 15 and toxins, 13 of which are found naturally in the
 16 United States.

1 (4) As of April 2008, there are 325 entities reg-
2 istered with the Centers for Disease Control and
3 Prevention to work with select agents and toxins and
4 75 entities registered with the Animal and Plant
5 Health Inspection Service. There are 9,918 individ-
6 uals approved to work with select agents and toxins
7 through the Centers for Disease Control and Preven-
8 tion and 4,336 through the Animal and Plant
9 Health Inspection Service.

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

16 **TITLE I—SELECT AGENT**
17 **PROGRAM REAUTHORIZATION**

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

19 (a) REAUTHORIZATION OF SELECT AGENT PRO-
20 GRAM.—

21 (1) AMENDMENT TO THE PUBLIC HEALTH
22 SERVICE ACT.—Section 351A(m) of the Public
23 Health Service Act (42 U.S.C. 262a(m)) is amended
24 by striking “2002 through 2007” and inserting
25 “2009 through 2013”.

1 (2) AMENDMENT TO THE AGRICULTURAL BIO-
2 TERRORISM PROTECTION ACT OF 2002.—Section
3 212(m) of the Agricultural Bioterrorism Protection
4 Act of 2002 (7 U.S.C. 8401(m)) is amended by
5 striking “2002 through 2007” and inserting “2009
6 through 2013”.

7 (b) APPROPRIATE TRAINING.—

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

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

19 (c) COVERED AGENCIES.—

20 (1) AMENDMENT TO THE PUBLIC HEALTH
21 SERVICE ACT.—Section 351A(h)(2)(A) (42 U.S.C.
22 262a(h)(2)(A)) of the Public Health Service Act is
23 amended by inserting “the Department of Homeland
24 Security,” after “the Department of Agriculture,”.

1 (2) AMENDMENT TO THE AGRICULTURAL BIO-
2 TERRORISM PROTECTION ACT OF 2002.—Section
3 212(h)(2)(A) of the Agricultural Bioterrorism Pro-
4 tection Act of 2002 (7 U.S.C. 8401(h)(2)(A)) is
5 amended by inserting “the Department of Homeland
6 Security,” after “the Department of Agriculture,”.

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

8 (a) IN GENERAL.—The Secretary of Health and
9 Human Services, in consultation with the Secretary of Ag-
10 riculture, shall enter into a contract with the National
11 Academy of Sciences to conduct a review of the select
12 agent program under section 351A of the Public Health
13 Service Act (42 U.S.C. 262a) and section 212 of the Agri-
14 cultural Bioterrorism Protection Act of 2002 (7 U.S.C.
15 8401). Such review shall focus on—

16 (1) the extent to which the program has en-
17 hanced biosecurity and biosafety in the United
18 States;

19 (2) the effects of the program on—

20 (A) international scientific collaboration;

21 and

22 (B) scientific advances in the United
23 States; and

1 (3) other issues as requested by the Secretary
2 of Health and Human Services and the Secretary of
3 Agriculture.

4 (b) REPORT; RECOMMENDATIONS.—Not later than
5 240 days after the date of enactment of this Act, the Na-
6 tional Academy of Sciences shall submit a report to the
7 Secretary of Health and Human Services, the Secretary
8 of Agriculture, the Committee on Health, Education,
9 Labor, and Pensions of the Senate, the Committee on En-
10 ergy and Commerce of the House of Representatives, and
11 other congressional committees of relevant interest, on the
12 results of the review conducted under subsection (a). Such
13 report shall include recommendations for improving the
14 structure of the select agent program for—

15 (1) enhancing the biosecurity and biosafety of
16 the United States;

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

19 (A) international scientific collaboration;
20 and

21 (B) scientific advances in the United
22 States; and

23 (3) other issues as requested by the Secretary
24 of Health and Human Services and the Secretary of
25 Agriculture.

1 **SEC. 103. REVISION OF THE LIST OF BIOLOGICAL AGENTS**
2 **AND TOXINS.**

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

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

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

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

12 “(IV) whether the agent or toxin
13 is endemic to the United States, as
14 defined by the Secretary;

15 “(V) information available from
16 biological risk assessments conducted
17 by the Department of Homeland Se-
18 curity;

19 “(VI) newly discovered agents of
20 disease, including genetically modified
21 organisms or agents created syn-
22 thetically; and”.

23 (b) AMENDMENT TO THE AGRICULTURAL BIOTER-
24 RORISM PROTECTION ACT OF 2002.—Section
25 212(a)(1)(B)(i) of the Agricultural Bioterrorism Protec-

1 tion Act of 2002 (7 U.S.C. 8401(a)(1)(B)(i)) is amend-
2 ed—

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

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

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

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

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

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

20 (c) RULE OF CONSTRUCTION.—The amendments
21 made by subsections (a) and (b) shall not be construed
22 to preclude the listing of a biological agent or toxin that
23 is endemic to the United States.

1 **SEC. 104. SHARING INFORMATION WITH TRUSTED STATE**
2 **PARTNERS.**

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

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

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

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

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

18 (b) AMENDMENT TO THE AGRICULTURAL BIOTER-
19 RORISM PROTECTION ACT OF 2002.—Section 212(h)(5)
20 of the Agricultural Bioterrorism Protection Act of 2002
21 (7 U.S.C. 8401(h)(5)) is amended—

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

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

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

1 “(C) to withhold information regarding a
2 State that will assist with the State’s emer-
3 gency preparedness planning from an elected or
4 appointed senior State agricultural official or
5 equivalent State official (such as a State veteri-
6 narian or a State plant health regulatory offi-
7 cial) of such State, if such State has in place
8 a law to protect against the further release of
9 such information as determined by the Sec-
10 retary.”.

11 **SEC. 105. IMPROVEMENTS TO INVENTORYING AND MONI-**
12 **TORING OF AGENTS.**

13 (a) IMPROVED METHOD TO INVENTORY AND MON-
14 ITOR LISTED BIOLOGICAL AGENTS.—Not later than 180
15 days after enactment of this Act, the Secretary of Health
16 and Human Services, in coordination with the Secretary
17 of Agriculture, and in consultation with individuals with
18 appropriate scientific expertise, shall issue guidance on
19 inventorying and monitoring the biological agents listed
20 under section 351A(a)(1) of the Public Health Service Act
21 (42 U.S.C. 262a(a)(1)) and the biological agents listed
22 under section 212(a)(1) of the Agricultural Bioterrorism
23 Protection Act of 2002 (7 U.S.C. 8401(a)(1)).

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

1 (1) the effectiveness of measures to inventory
2 and monitor listed biological agents that can propa-
3 gate relative to the burden of these measures on lab-
4 oratory personnel;

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

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

10 **SEC. 106. SMALLPOX DEFINITION CLARIFICATION.**

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

17 **SEC. 107. PLAN FOR SURGE IN SAMPLES OF BIOLOGICAL**
18 **AGENTS AND TOXINS.**

19 The Secretary of Health and Human Services, in co-
20 ordination with the Secretary of Agriculture and State of-
21 ficials, shall develop and disseminate guidelines for how
22 laboratories and laboratory personnel that do not regularly
23 test for listed agents and toxins (as such terms are defined
24 in section 351A of the Public Health Service Act (42
25 U.S.C. 262a) and section 212 of the Agricultural Bioter-

1 rorism Protection Act of 2002 (7 U.S.C. 8401)) may be
2 rapidly accessed and utilized during emergencies in which
3 laboratories and laboratory personnel that regularly test
4 for such agents and toxins are overwhelmed by a surge
5 of samples of such listed agents and toxins.

6 **TITLE II—BIOSAFETY** 7 **IMPROVEMENTS**

8 **SEC. 201. IMPROVEMENT OF OVERSIGHT OF BIOCONTAIN-** 9 **MENT LABORATORIES.**

10 (a) DEFINITION.—For purposes of this section, the
11 term “high containment biological laboratory” means a
12 laboratory that has Biosafety Level 3 or Biosafety Level
13 4 facilities, as defined by the Secretary of Health and
14 Human Services and the Secretary of Agriculture.

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

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

24 (1) whether the construction of high contain-
25 ment biological laboratories that are in existence or

1 planned as of the date of enactment of this Act, is
2 likely to provide sufficient capacity for the needs of
3 Government biodefense and infectious disease re-
4 search;

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

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

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

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

1 **SEC. 202. IMPROVEMENT OF TRAINING FOR LABORATORY**
2 **PERSONNEL.**

3 (a) DEFINITION.—For purposes of this section, the
4 term “high containment biological laboratory” means a
5 laboratory that has Biosafety Level 3 or Biosafety Level
6 4 facilities, as defined by the Secretary of Health and
7 Human Services and the Secretary of Agriculture.

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

21 (c) REQUIREMENT FOR APPROVAL.—A person may
22 not register with the Secretary of Health and Human
23 Services or the Secretary of Agriculture for the possession,
24 use, or transfer of listed agents in accordance with section
25 351A of the Public Health Service Act (42 U.S.C. 262a)
26 and section 212 of the Agricultural Bioterrorism Protec-

1 tion Act of 2002 (7 U.S.C. 8401) unless the person pro-
2 vides to its appropriate personnel biosafety and biosecurity
3 training that meets the minimum standards under sub-
4 section (b) in addition to any other requirements deter-
5 mined appropriate by the Secretary of Health and Human
6 Services or the Secretary of Agriculture.

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

14 **SEC. 203. BIOLOGICAL LABORATORY INCIDENT REPORTING**
15 **SYSTEM.**

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

1 integrating existing voluntary and required reporting
2 mechanisms.

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

8 (1) receive and process incident reports;

9 (2) analyze, interpret incident data, and iden-
10 tify incident trends;

11 (3) issue alert messages within an appropriate
12 time period;

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

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

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

20 (7) conduct other activities as requested by the
21 Secretaries.

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