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.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) Short Title.—This Act may be cited as the “Select Agent Program and Biosafety Improvement Act of 2009”.

(b) Table of Contents.—The table of contents for this Act is as follows:
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 Prevention regulates the possession, use, and transfer of select agents and toxins that have the potential to pose a severe threat to public health and safety.

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

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

6 (4) As of February 2009, there are 336 entities registered with the Centers for Disease Control and Prevention to work with select agents and toxins and
64 entities registered with the Animal and Plant Health Inspection Service. There are 10,463 individuals approved to work with select agents and toxins through the Centers for Disease Control and Prevention and 4,149 through the Animal and Plant Health Inspection Service.

(5) Biocontainment laboratories are used by scientists to study infectious materials safely and effectively. Laboratory biological research is categorized by the safety level at which it is performed. There are 4 safety levels, termed Biosafety Level (BSL) 1 through 4.

**TITLE I—SELECT AGENT PROGRAM REAUTHORIZATION**

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

(a) Reauthorization of Select Agent Program.—

(1) Amendment to the Public Health Service Act.—Section 351A(m) of the Public Health Service Act (42 U.S.C. 262a(m)) is amended by striking “2002 through 2007” and inserting “2010 through 2014”.

(2) Amendment to the Agricultural Bioterrorism Protection Act of 2002.—Section 212(m) of the Agricultural Bioterrorism Protection
Act of 2002 (7 U.S.C. 8401(m)) is amended by
striking “2002 through 2007” and inserting “2010
through 2014”.

(b) **Appropriate Training.—**

(1) **Amendment to the Public Health Service Act.**—Section 351A(e)(2)(A) of the Public Health Service Act (42 U.S.C. 262a(e)(2)(A)) is amended by inserting “, and appropriate training,” after “have a legitimate need”.

(2) **Amendment to the Agricultural Bioterrorism Protection Act of 2002.**—Section 212(e)(2)(A) of the Agricultural Bioterrorism Protection Act of 2002 (7 U.S.C. 8401(e)(2)(A)) is amended by inserting “, and appropriate training,” after “have a legitimate need”.

(e) **Covered Agencies.—**

(1) **Amendment to the Public Health Service Act.**—Section 351A(h)(2)(A) (42 U.S.C. 262a(h)(2)(A)) of the Public Health Service Act is amended by inserting “the Department of Homeland Security,” after “the Department of Agriculture,”.

(2) **Amendment to the Agricultural Bioterrorism Protection Act of 2002.**—Section 212(h)(2)(A) of the Agricultural Bioterrorism Protection Act of 2002 (7 U.S.C. 8401(h)(2)(A)) is
amended by inserting “the Department of Homeland Security,” after “the Department of Agriculture.”

SEC. 102. SELECT AGENT PROGRAM REVIEW.

(a) IN GENERAL.—The Secretary of Health and Human Services, in consultation with the Secretary of Agriculture, shall enter into a contract with the National Academy of Sciences to conduct a review of the select agent program under section 351A of the Public Health Service Act (42 U.S.C. 262a) and section 212 of the Agricultural Bioterrorism Protection Act of 2002 (7 U.S.C. 8401). Such review shall focus on—

(1) the extent to which the program has enhanced biosecurity and biosafety in the United States;

(2) the effects of the program on—

(A) international scientific collaboration;

and

(B) scientific advances in the United States; and

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

(b) REPORT; RECOMMENDATIONS.—Not later than 240 days after the date of enactment of this Act, the National Academy of Sciences shall submit a report to the
Secretary of Health and Human Services, the Secretary of Agriculture, the Committee on Health, Education, Labor, and Pensions of the Senate, the Committee on Energy and Commerce of the House of Representatives, and other congressional committees of relevant interest, on the results of the review conducted under subsection (a). Such report shall include recommendations for improving the structure of the select agent program for—

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

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

(A) international scientific collaboration;

and

(B) scientific advances in the United States; and

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

SEC. 103. REVISION OF THE LIST OF BIOLOGICAL AGENTS AND TOXINS.

(a) Amendment to the Public Health Service Act.—Section 351A(a)(1)(B)(i) of the Public Health Service Act (42 U.S.C. 262a(a)(1)(B)(i)) is amended—
(1) in subclause (III), by striking “; and” and inserting a semicolon;

(2) by redesignating subclause (IV) as subclause (VII); and

(3) by inserting after subclause (III) the following:

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

“(V) information available from biological risk assessments conducted by the Department of Homeland Security;

“(VI) newly discovered agents of disease, including genetically modified organisms or agents created synthetically; and”.

(b) Amendment to the Agricultural Bioterrorism Protection Act of 2002.—Section 212(a)(1)(B)(i) of the Agricultural Bioterrorism Protection Act of 2002 (7 U.S.C. 8401(a)(1)(B)(i)) is amended—

(1) in subclause (III), by striking “; and” and inserting a semicolon;
(2) by redesignating subclause (IV) as sub-
clause (VII); and

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

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

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

“(VI) newly discovered agents of
disease, including genetically modified
organisms or agents created syn-
theticly; and”.

(e) Rule of Construction.—The amendments
made by subsections (a) and (b) shall not be construed
to preclude the listing of a biological agent or toxin that
is endemic to the United States.

SEC. 104. SHARING INFORMATION WITH TRUSTED STATE
PARTNERS.

(a) Amendment to the Public Health Service
Act.—Section 351A(h)(5) of the Public Health Service
Act (42 U.S.C. 262a(h)(5)) is amended—
(1) in subparagraph (A), by striking “; or” and inserting a semicolon;

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

(3) by inserting at the end the following:

“(C) to withhold information regarding a State that will assist with the State’s emergency preparedness planning from the health director (or equivalent State official) of such State, if such State has in place a law to protect against the further release of such information as determined by the Secretary.”.

(b) Amendment to the Agricultural Bioterrorism Protection Act of 2002.—Section 212(h)(5) of the Agricultural Bioterrorism Protection Act of 2002 (7 U.S.C. 8401(h)(5)) is amended—

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

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

(3) by inserting at the end the following:

“(C) to withhold information regarding a State that will assist with the State’s emergency preparedness planning from an elected or appointed senior State agricultural official or
equivalent State official (such as a State veterinarian or a State plant health regulatory official) of such State, if such State has in place a law to protect against the further release of such information as determined by the Secretary.”.

SEC. 105. IMPROVEMENTS TO INVENTORYING AND MONITORING OF AGENTS.

(a) Improved Method to Inventory and Monitor Listed Biological Agents.—Not later than 180 days after enactment of this Act, the Secretary of Health and Human Services, in coordination with the Secretary of Agriculture, and in consultation with individuals with appropriate scientific expertise, shall issue guidance on inventorying and monitoring the biological agents listed under section 351A(a)(1) of the Public Health Service Act (42 U.S.C. 262a(a)(1)) and the biological agents listed under section 212(a)(1) of the Agricultural Bioterrorism Protection Act of 2002 (7 U.S.C. 8401(a)(1)).

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

(1) the effectiveness of measures to inventory and monitor listed biological agents that can propagate relative to the burden of these measures on laboratory personnel;
(2) qualitative and quantitative control procedures for such listed agents, rather than only quantitative control procedures; and

(3) in what situations registered persons are required to keep inventory records.

SEC. 106. SMALLPOX DEFINITION CLARIFICATION.

Not later than 90 days after the date of enactment of this Act, the Attorney General, in coordination with the Secretary of Health and Human Services, shall issue public guidance regarding how the Attorney General interprets the scope of the statutory definition of “variola virus” in section 175c of title 18, United States Code.

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

The Secretary of Health and Human Services, in coordination with the Secretary of Agriculture and State officials, shall develop and disseminate guidelines for how laboratories and laboratory personnel that do not regularly test for listed agents and toxins (as such terms are defined in section 351A of the Public Health Service Act (42 U.S.C. 262a) and section 212 of the Agricultural Bioterrorism Protection Act of 2002 (7 U.S.C. 8401)) may be rapidly accessed and utilized during emergencies in which laboratories and laboratory personnel that regularly test
for such agents and toxins are overwhelmed by a surge
of samples of such listed agents and toxins.

**TITLE II—BIOSAFETY IMPROVEMENTS**

**SEC. 201. IMPROVEMENT OF OVERSIGHT OF BIOCONTAINMENT LABORATORIES.**

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

(b) **EVALUATION.**—The Secretary of Health and Human Services, in coordination with the Secretary of Agriculture, and in consultation with the Secretary of Defense and the Secretary of Homeland Security (referred to in this section as the “Secretaries”) shall, either directly or through a contract, evaluate national needs of, and oversight of, high containment biological laboratories.

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

(1) whether the construction of high containment biological laboratories that are in existence or planned as of the date of enactment of this Act, is likely to provide sufficient capacity for the needs of
Government biodefense and infectious disease research;

(2) how laboratory capacity and lessons learned can be best shared across the biodefense and infectious disease research communities, domestically and internationally;

(3) whether guidance on laboratory infrastructure, commissioning, operation, and maintenance of such laboratories is adequate, and if such guidance is found to be inadequate, how to improve and streamline such guidance; and

(4) ways to improve and streamline the training of the personnel of such laboratories, including recommendations regarding the minimum standards for laboratory biosafety and biosecurity training under section 202.

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

SEC. 202. IMPROVEMENT OF TRAINING FOR LABORATORY PERSONNEL.

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

(b) DEVELOPMENT OF MINIMUM STANDARDS.—The Secretary of Health and Human Services, acting through the Director of the Centers for Disease Control and Prevention and the Director of the National Institutes of Health, and in coordination with the Secretary of Agriculture and scientific experts representing appropriate professional groups and international health organizations, shall develop minimum standards for laboratory biosafety and biosecurity training for relevant personnel of high containment biological laboratories. In developing such standards, the Secretary of Health and Human Services shall consider existing laboratory guidelines and training modules.

(c) REQUIREMENT FOR APPROVAL.—A person may not register with the Secretary of Health and Human Services or the Secretary of Agriculture for the possession, use, or transfer of listed agents in accordance with section 351A of the Public Health Service Act (42 U.S.C. 262a) and section 212 of the Agricultural Bioterrorism Protection Act of 2002 (7 U.S.C. 8401) unless the person provides to its appropriate personnel biosafety and biosecurity training that meets the minimum standards under sub-
section (b) in addition to any other requirements deter-
mined appropriate by the Secretary of Health and Human
Services or the Secretary of Agriculture.

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

SEC. 203. BIOLOGICAL LABORATORY INCIDENT REPORTING
SYSTEM.

(a) IN GENERAL.—The Secretary of Health and
Human Services, in coordination with the Secretary of Ag-
riculture (referred to in this section as the “Secretaries”),
shall establish an integrated Biological Laboratory Inci-
dent Reporting System through which personnel of biologi-
cal laboratories may voluntarily report biosafety or bio-
security incidents of concern and the Secretaries may
identify trends in such incidents and protocols for bio-
safety or biosecurity improvements. In developing such re-
porting system, the Secretaries shall consider options for
integrating existing voluntary and required reporting
mechanisms.
(b) FUNCTIONS.—In implementing the reporting system under subsection (a), the Secretaries shall enter into a contract with a public or private entity that does not regulate biological laboratories to administer the reporting system. Such entity shall—

1. receive and process incident reports;
2. analyze, interpret incident data, and identify incident trends;
3. issue alert messages within an appropriate time period;
4. disseminate reports and other appropriate information, which shall not include facility-specific information;
5. not have authority to direct corrective action or to initiate enforcement action;
6. ensure anonymity of individuals reporting to the system, to the extent permitted by law; and
7. conduct other activities as requested by the Secretaries.