

Select Agent Program and Biosafety Improvement Act of 2008

A bill to reauthorize and improve the Select Agent Program, enhance national biosecurity and biosafety, and evaluate oversight of high containment laboratories

In 2002, the Select Agent Program was expanded to regulate the possession, use, and transfer of “select agents” that pose a severe threat to public, animal, or plant health and safety. There are 72 select agents and toxins, 13 of which are found naturally in the United States.

Biocontainment laboratories are used by scientists to study contagious 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. Over the last few years, there has been an increase in the number of biosafety laboratories, both domestically and internationally.

This legislation reauthorizes and improves the Select Agent Program and provides for an overall evaluation of the program.

- **Extends the Program:** Reauthorizes the Select Agent Program through 2013. The program funding authorization expired on September 30, 2007.
- **Requires a Program Evaluation:** Requires a comprehensive evaluation of the extent to which the program has enhanced biosecurity and biosafety in the United States, and a review of the effects of the program on international scientific collaboration and scientific advances.
- **Ensures Comprehensive List of Agents:** Requires HHS and USDA to consider newly discovered agents, such as genetically modified organisms and agents created synthetically, as well as information available from DHS biological risk assessments.
- **Shares Information with State Partners:** To facilitate state emergency planning, encourages HHS and USDA to share with state officials information regarding the agents being studied within their jurisdictions.
- **Plans for Surge Capabilities:** Requires HHS and USDA to develop guidelines for use in an emergency when laboratories may be overwhelmed by a surge in Select Agent samples. Such guidelines would identify how to rapidly access and utilize other laboratory personnel and other laboratories not normally involved with Select Agent testing.

- **Clarifies Smallpox Definition:** Requires the Attorney General and Secretary of HHS to issue guidance clarifying the scope of the statutory definition for smallpox. Currently, researchers are concerned legitimate medical countermeasure research could be considered a violation of criminal law.

This legislation improves oversight of high containment laboratories and provides for enhanced biosafety standards.

- **Evaluates Ways to Improve Oversight of Biocontainment Laboratories:** Requires HHS and USDA to evaluate the national needs and oversight of high containment (BSL 3 and BSL 4) biological laboratories, including:
 - Whether the construction of existing and currently planned labs is likely to provide sufficient capacity for the needs of government biodefense research;
 - How laboratory capacity and lessons learned can best be shared across the biodefense and infectious disease research communities;
 - Whether guidance on infrastructure, commissioning, operation, and maintenance of such labs is adequate;
 - Ways to improve and streamline the training of personnel working in these labs and provide recommendations for the minimum standards described below.
- **Improves Training for Laboratory Workers:** Requires HHS and USDA to work with professional associations and international health organizations to develop minimum standards for biosafety and biosecurity training for Biosafety Level 3 and 4 laboratory personnel. Such model curricula could be disseminated for use in graduate schools and other countries.
- **Biological Laboratory Incident Reporting System:** Requires HHS and USDA to establish an integrated Biological Laboratory Incident Reporting System through which laboratory personnel may voluntarily report biosafety and biosecurity incidents of concern. HHS and USDA could also identify trends in such incidents and protocols for biosafety and biosecurity improvements.