

DRAFT Select Agent Program and Biosecurity Improvement Act

A bill to reauthorize and improve the Select Agent Program, enhance national biosecurity, 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, and plant health and safety. There are 81 select agents and toxins, 13 of which are found naturally in the United States.

Since 2001 there has been a significant increase in the number of high containment laboratories, nationally and internationally. There are currently 15 Biosafety Level 4 laboratories in the United States, up from five in 2001; nine of these are federal government laboratories.

Note: Since 2001 there has been a significant increase in the number of Biosafety Level 3 BSL-3 laboratories, nationally and internationally. According to current data, there are currently 6 operational Biosafety Level 4 laboratories (maximum containment) in the United States (the Centers for Disease Control and Prevention and Georgia State University (GSU) in Atlanta, GA; National Institutes of Health in Bethesda, MD; University of Texas Medical Branch at Galveston in Galveston, TX; Southwest Foundation for Biomedical Research in San Antonio, TX; and the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID) at Fort Detrick, MD. All laboratories are configured for workers to wear positive pressure protective suits with the exception of GSU where workers use Class III Biological Safety Cabinets to achieve maximum containment. The recently completed Biosafety Level 4 National Institute of Allergy and Infectious Diseases Rocky Mountain Laboratory in Hamilton, MT is not currently operational. Three of these are federal government laboratories.

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

- **Requires a Program Evaluation:** Requires GAO to evaluate the extent to which the Select Agent Program has enhanced biosecurity and biosafety in the United States, enhanced or hindered international scientific collaboration, and enhanced or hindered scientific advances.
 - Was a program evaluation required or suggested by the 2002 select agent regulation? If so, has it been carried out and what were the results of the evaluation?
 - It is most prudent that GAO solicit the services of individuals knowledgeable in the disciplines of biosecurity and biosafety to participate in the program evaluation. The American Biological Safety Association (ABSA) is uniquely positioned and qualified to manage, direct and assist with these evaluations as its membership constitutes the country’s recognized experts in human, animal and plant biological safety. ABSA is capable of leading this process and involving all appropriate stakeholders, including representatives from federal agencies and allied professional organizations.
- **Revises Current Regulations:** Requires HHS and USDA to revise the framework for listing agents and toxins, improve the method of inventorying and monitoring listed agents and toxins within a laboratory, streamline the process for transferring clearance of authorized personnel and for transferring agents between labs.

- Streamlining the process for clearance of authorized personnel would enhance and promote biological safety program interaction between registered entities. The opportunity for individuals to visit, work and be trained and mentored at other containment facilities (BSL-3 and -4 laboratories) would be enhanced if the clearance process were streamlined.
- It is hoped that the new method of inventorying listed agents will be streamlined and less burdensome than the current method. A qualitative mechanism for inventories would be as meaningful and useful as the current quantitative mechanism.
- We support all measures to reduce the paperwork burden of the current select agent regulation.

- **Redefines Smallpox:** Require the Secretary of HHS and Attorney General to establish a new definition for smallpox, which better reflects scientific advances and public health threats, and is legally enforceable. This new definition would replace current law.
 - Any definitions or changes in the current law(s) should only be considered after a careful and exhaustive review of existing laws and regulations. Specifically, any changes or revisions should be in compliance with the *Biological Weapons Convention* document.

- **Shares Information with State Partners:** Encourages HHS and USDA to share with state officials information regarding the agents being studied within their jurisdictions, and to ensure state laws are adequate to protect such information from further disclosure.
 - Federal and non-federal agencies should be required to share their lessons learned from every laboratory-acquired infection (LAI). To accomplish this, there should be a designated entity (such as the Centers for Disease Control (CDC) in Atlanta, GA, or a similarly designated entity) having the responsibility for collecting LAI data. The CDC currently serves to collect and distribute data on specific reportable human diseases for educational purposes.
 - Sharing of such valuable information could be mediated through funding of applied biosafety research; in particular research addressing the efficacy of various decontaminating agents and disinfectants.
 - Sharing of training programs and training information should be encouraged. This would promote the improvement, standardization and harmonization of training. Using this approach by closely-located facilities would be enhanced because funding expenditures would be minimized - all parties working together to achieve a common goal.
 - If this is accomplished, it is hoped that the federal government will encourage those states that have parallel select agent regulations to terminate their regulations and use the information provided by the federal government.

- **Plans for Surge Capabilities:** Requires HHS and USDA, in collaboration with State officials, 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 utilize other laboratory personnel and other laboratories not normally utilized for Select Agent testing.
 - This approach should be reviewed carefully to take into consideration the existing infrastructure consisting of the Laboratory Response Network (LRN), the

National Biocontainment Laboratories (NBL), the Regional Biocontainment Laboratories (RBL), the Animal Health Laboratory Network, and the National Plant Diagnostic Network. The LRN was established by the CDC in accordance with Presidential Decision Directive 39, which outlined national anti-terrorism policies and assigned specific missions to federal departments and agencies. The LRN is charged with the task of maintaining an integrated network of state and local public health, federal, military, and international laboratories that can respond to bioterrorism, chemical terrorism and other public health emergencies. In 2003, the NIAID provided funds to support the construction of new NBLs and RBLs to be used for biomedical research and research training. Funds were provided to program, design, construct, and commission comprehensive state-of-the-art laboratories that will support research on the NIAID Category A, B and C priority pathogens and emerging infectious diseases. Both the NBLs and RBLs provide an additional source of personnel, procedures and expertise for surge capacity in the event of an emergency.

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

- **Improves Training for Laboratory Workers:** Requires CDC and NIH to work with professional associations and international health organizations to develop minimum standards for biosafety training for Biosafety Level 3 and 4 laboratory personnel. Such model curricula could be disseminated for use in graduate schools and other countries.
 - Minimum standards for work with microorganisms and their toxins was published in the CDC/NIH publication entitled Biosafety in Microbiological and Biomedical Laboratories (February, 2007; available at http://www.cdc.gov/OD/ohs/biosfty/bmb15/BMBL_5th_Edition.pdf).
 - ABSA currently offers a number of courses geared to build upon the foundation of individuals working in containment laboratories. A partial listing of available courses is available at <http://www.absa.org/conpastprecon.html>. General information about ABSA is available at www.absa.org.
Although minimum standards for biosafety training are not available, there are minimum standards for individuals to be recognized as biosafety professionals. Recognition is granted by ABSA (see <http://www.absa.org/bioreg.html>) and the National Registry of Microbiologists of the American Society for Microbiology (see <http://www.asm.org/Academy/index.asp?bid=2250>) after meeting defined criteria.
Additional training for individuals seeking recognition as a biosafety professional is available through formal fellowship training programs conducted by the National Biosafety and Biocontainment Training Program (NBBTP) at the NIH, Washington University School of Medicine and the University of Chicago. In January 2008, Colorado State University embarked on a training program culminating in awarding of the Master of Science in Microbiology with a concentration in Biological Safety.
 - The above examples serve as model curricula for use in graduate schools and in other countries to complement a variety of safety-related courses offered by few U.S. academic institutes. Accompany the awarding of a degree in Biological Safety, funding must be made available for students to support their independent research. Preferably their research would be in applied biosafety so that newer

technologies and procedures could be explored for possible implementation in laboratories. It is anticipated that this approach would provide for safer working conditions and an increase in the margin of safety for both the laboratory and community environment. This approach would be a marvelous advancement to promote the sharing of training programs and training information and standardization and harmonization of training.

- **Evaluates Ways to Improve Oversight of Biocontainment Laboratories:** Requires HHS to evaluate the national needs and governance for high containment (BSL 3 and BSL 4) biological research laboratories, including:
 - Whether the construction of new and planned labs is likely to create sufficient capacity to meet the need for government biodefense research;
 - How capacity and lessons learned can best be shared across the research community;
 - Whether guidance on construction, 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 above.
 - Oversight could be mediated through an accreditation program for biocontainment laboratories.
 - ABSA believes that it is necessary to immediately develop and establish a biological containment laboratory accreditation program. Such oversight would assure a community that a laboratory is operating safely and that necessary practices, procedures, and equipment are in place to protect people, animals, plants, and the environment.
 - Accreditation is an objective, independent assessment of the technical competence and quality system of an organization or laboratory as it relates to biohazard management, including personnel training and experience. It would serve as an essential tool for ensuring the safe operation of containment laboratories.
 - Accreditation of laboratories, using relevant national and international standards, is an effective way of ensuring competence in a comprehensive and uniform manner in laboratories working with biohazards. A biosafety management standard was recently developed through the CEN (European Standards Organization) Workshop Agreement process and will be published in 2008. This standard, together with U.S. adopted standard(s), including the existing U.S. biosafety guidelines (*Biosafety in Microbiological and Biomedical Laboratories* (BMBL) and *NIH Guidelines for Research Involving Recombinant DNA Molecules [NIH Guidelines]*) would provide the foundation for a biosafety accreditation program.
 - ABSA is uniquely positioned and qualified to develop such a laboratory accreditation process, as its membership constitutes the country's recognized experts in biological safety. ABSA proposes to lead a process involving all appropriate stakeholders, including representatives from federal agencies and allied professional organizations. The product of this effort would be an accreditation program that organizations would seek voluntarily in order to assure that their competence in management of biological hazards is recognized.