

**ABSA**

American Biological Safety Association

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Dear ABSA Members,

One of the major objectives of the Legislative Committee is to monitor biosafety legislation. While the Legislative Committee reports developments to ABSA Council, we feel it is important to share our information with all ABSA members. Through this Open Letter to the ABSA membership, we hope to provide members with knowledge on key current biosafety legislative issues. Once conversant with the issues, we hope that members will contact their legislators and voice their opinion on behalf of their institutions.

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The Biosafety/Biosecurity Legislation Landscape

We are at a critical juncture in biosafety/biosecurity legislative history. In the last year numerous government agencies, commissions, and non-government organizations have published reports, opinions, and studies on biosafety and biosecurity. Below is a list of some of the most noteworthy:

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- ▶ The United States Government Accountability Office, Report on High Containment Biosafety Laboratories (10/4/2007),
- ▶ The Commission of the Prevention of WMD Proliferation and Terrorism's World at Risk report (12/2/08),
- ▶ The Congressional Research Service Report on Oversight of High-Containment Laboratories (3/5/09),
- ▶ The National Science Advisory Board for Biosecurity (NSABB) report on Enhancing Personnel Reliability Among Individuals with Access to Select Agents,
- ▶ The American Association for the Advancement of the Science's (AAAS) workshop report on Biological Safety Training Programs as a Component of Personnel Reliability,
- ▶ The Center for Biosecurity of the University of Pittsburgh Medical Center, Letter to Representatives Jane Harman and Mike Rogers.

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Perhaps more importantly, by early Fall of 2009, reports are expected from the Trans-Federal Task Force on Optimizing Biosafety and Biocontainment Oversight, the Executive Order Working Group (EOWG) on Strengthening the Biosecurity of the United States, the National Science Advisory Board for Biosecurity (NSABB), and the National Academy of Sciences (NAS).

Executive Director

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The Issues

Why are the above reports and publications important? Because all of them, both published and not yet published, will undoubtedly influence congressional decision making on pending and future biosafety and biosecurity legislation.^a

What legislation should ABSA members be aware of? 1) Senate Bill 485, known as the Select Agent Program and Biosafety Improvement Act of 2009; 2) House Bill 1225 known as the Select Agent Program and Biosafety Improvement Act of 2009; 3) future legislation from Senators Lieberman and Collins which we anticipate may be announced during the summer of 2009, and, 4) Executive Order 13486 (1/9/2009), entitled "Strengthening Laboratory Biosecurity in the United States."^b

We have identified the above reports and legislation so that interested ABSA members can obtain and review the reports and legislation and stay informed. We understand ABSA members would like a synopsis of the proposed legislation, but such a lengthy analysis is impossible in this Open Letter. Instead, below we have provided a summary of the key issues surrounding biosafety and biosecurity legislation to date. We have also outlined several ways in which ABSA members can contact Congress and the Executive Order Working Group in order to air their viewpoints.

I. Department of Homeland Security (DHS) Oversight of the Select Agent Program

The World at Risk report recommended that Congress: "identify a lead federal agency to oversee and enforce the registration process (of select agents), and create a government-wide database of all high-containment labs in the United States." (*World at Risk*, page 30). It appears that Senators Lieberman and Collins may harness the lead federal agency approach advocated in the World at Risk report to transfer select agent oversight from the United States Department of Health and Human Services (HHS) Centers for Disease Control and Prevention (CDC) and United States Department of Agriculture (USDA) Animal and Plant Health Inspection Service (APHIS), where it currently resides, to the Department of Homeland Security (DHS). Senators Lieberman and Collins *may* introduce legislation proposing DHS oversight as early as summer 2009. The ABSA Legislative Committee will continue to monitor developments from these key politicians. In the event that legislation is forthcoming, ABSA members are encouraged to share their viewpoints on DHS oversight by contacting Congress directly.^c

II. Personnel Reliability Programs (PRPs)

PRPs are found in the nuclear regulatory environment, and some groups want similar standards implemented in biosafety and biosecurity. PRP programs can include: background investigations, security clearances, medical examinations, psychological evaluations, polygraph testing, drug and alcohol screening, credit checks, and ongoing monitoring. The NSABB was specifically tasked with analyzing whether PRPs should be implemented for all people with access to select agents. In its report: Enhancing Personnel Reliability Among Individuals with Access to Select Agents, the NSABB concluded that:

^a ABSA members can visit <http://absa.org/abolegislativecomm.html> for links to reports and legislation identified in this letter.

^b Executive Order 13486 established the Executive Order Working Group (EOWG) to analyze biosafety and biosecurity issues. This group held a public meeting on May 13-14, 2009 to listen to opinions of various "stakeholders" in the biosafety and biosecurity field. ABSA was invited to participate, and Past ABSA President Bob Hawley delivered a twelve minute presentation.

^c ABSA members can find links to Congress and EOWG in the "What can ABSA members do?" section of this letter below.

There is currently insufficient evidence of the effectiveness of PRP measures towards mitigating the risk of an insider threat to warrant the additional, significant burden on research institutions...and PRP is likely to have unintended and detrimental consequences for the scientific enterprise that in the future could result in more harm to public health and safety and to national security than an insider threat poses.

(Enhancing Personnel Reliability among Individuals with Access to Select Agents, page IV).

Despite the NSABB's report and recommendations, the debate on PRP is ongoing. For instance, EOWG will be debating this issue during the next month. ABSA members are encouraged to voice their opinions on the effectiveness of PRP to members of Congress and EOWG.

III. Harmonization of Oversight

At the EOWG meeting of May 13 and 14, numerous attendees (including many ABSA members) highlighted compliance challenges associated with the select agent regulations--namely, HHS, USDA, NIH, and state and local entities share oversight responsibilities but often have inconsistent and conflicting requirements. Attendees asked EOWG to recommend harmonizing select agent oversight amongst the various government agencies. ABSA members are encouraged to: 1) share the experiences of their institution (positive or negative) under the current oversight system; 2) voice the necessity for harmonization; and 3) make recommendations on how to harmonize oversight.

IV. Unfunded Mandates

Additional select agent regulations and heightened security standards (if enacted) will force institutions to spend more time and money on compliance. In the past, increased regulations were not accompanied by increased grants or funding--hence the increased compliance requirements were "unfunded mandates."

The concern is that, larger, better funded universities (for example) will be able to comply with additional regulations, while smaller research entities and public health laboratories will be severely impacted due to budgetary constraints. Though this may be an unintended consequence of increasing regulation, it is nonetheless one that could have an impact on some institutions.

ABSA members are encouraged to contact both Congress and EOWG to stipulate that *if* regulations are increased, a new funding mechanism should be developed to fund institutions and entities so that they can meet the increased cost of compliance.

V. Stratification of Select Agents/Tiered Approach

One of the recommendations of the NSABB is that some select agents should be removed from the select agent list, *or* the list should be stratified. (*Enhancing Personnel Reliability Among Individuals with Access to Select Agents, page V*). Both removing select agents from the select agent list, and stratification, were topics of discussion at the EOWG meeting of May 13 and 14. ABSA members can learn more about stratification by reading the NSABB's [Enhancing Personnel Reliability Among Individuals with Access to Select Agents](#) report. ABSA members can also share their viewpoints on either removing agents from the select agent list, or stratification, by contacting Congress and EOWG.^d

^dABSA members can find links to Congress and EOWG in the "What can ABSA members do?" section of this letter below.

VI. Inventory

Current select agent inventory requirements were discussed at the EOWG meeting of May 13 and 14. Costs of compliance associated with current inventory methods were discussed, as were alternative inventory methods (such as vial counts). ABSA members can share their viewpoints on these topics with both Congress and EOWG.

VII. Licensure

The World at Risk report recommended that, "all biosafety officers should be tested and certified by a competent government authority." (*World at Risk*, page 31). A small minority of attendees at the EOWG meeting argued for licensure of all people who have access to select agents and toxins. The minority approach suggests that there should be a federal licensing standard for work with select agents. ABSA members should be aware that some groups are advocating licensing. ABSA members can read more on licensing at <http://www.thebulletin.org/web-edition/columnists/laura-h-kahn/licensing-life-science-researchers>.

ABSA's Role

ABSA Council, in conjunction with the Legislative Committee, is working to provide Congress and EOWG with official stances for many of the above issues. In fact, ABSA President Bob Ellis has already talked with members of Senator Lieberman's staff to discuss some of these issues. ABSA Past-President Bob Hawley delivered a 12-minute presentation at the EOWG meeting in May. Moreover, ABSA will be submitting a formal written statement to EOWG. Also, efforts will be made throughout 2009 to provide legislators with facts and opinions on these important issues. ABSA members should share their views on the above topics with the ABSA Legislative Committee so that ABSA can make informed decisions on how to approach the issues. Please feel free to contact Debra Sharpe of the Legislative Committee (who has agreed to act as liaison with the ABSA membership) with comments via e-mail at sharpe@bslsolutions.com.

What Can ABSA Members Do?

Additional legislation and heightened security standards will affect ABSA members very differently. Some institutions will be able to allocate more money and resources toward compliance, others may have to cease research altogether. The Legislative Committee anticipates that ABSA members may like to assess current events on their own, and possibly reach out to EOWG and Congress to discuss the individual or unique impact which will be felt at their institution. Getting your institution's voice heard can be done in a number of ways:

- 1) Go to <https://writerep.house.gov/writerep/welcome.shtml> (for the House) or http://www.senate.gov/general/contact_information/senators_cfm.cfm (for the Senate) and find out who represents you in Congress. From there, the Legislative Committee recommends that you write your Congressman or Senator. Please note, personalized letters or typed and signed letters are more effective than e-mail.
- 2) If you work in academia, find out if your institution has a public affairs or communications department which reaches out to Congress. If so, meet with the department to see if they can promote your positions.
- 3) Contact EOWG via e-mail at: biosecurity.workgroup@hhs.gov
- 4) Contact the National Academy of Sciences (which may author reports this summer and/or fall) via e-mail at: www.national-academies.org
- 5) If you work in academia, reach out to the school of public policy, or similar entity, at your college or university and inform yourself as to the level of support they have for this legislation and to identify any possible opportunities to educate these very influential groups.

Conclusion

It has been a very busy year for the Legislative Committee. Much of our time has been spent inventorying the sheer number of reports and publications produced each month. May 2009 seems to have been a demarcation point--the key issues which will be debated in Congress for the next year seem to have emerged. The goal of this Open Letter has been to keep ABSA members informed of key developments, and provide some outlets for personal opinion. Our country's current Presidential administration promised change as part of its campaign message; in this case, ABSA members have the knowledge and expertise to guide our decision-makers and should stand ready to influence the imminent changes in biosafety and biosecurity legislation in order to improve and enhance the current infrastructure rather than allow public representatives to make unapprised modifications that will incur lasting and significant damage to the research enterprise and to public health.

Sincerely,

ABSA Legislative Committee^e

Josh Goldberg, Chair
Emmett Barkley
Penny Holeman
Jeff Owens
Francine Rogers
Debra Sharpe
Alexis K. L. Them
Jim Welch

^eThe Legislative Committee would like to acknowledge the efforts of committee member Susan Weekly who was not able to participate in the drafting of this letter.