



May 29, 2009

Dr. Laura Kwinn
U.S. Working Group on Strengthening the Biosecurity of the United States
Office of Medicine, Science and Public Health
Office of the Assistant Secretary for Preparedness and Response
U.S. Department of Health and Human Services
330 C Street, SW., Room 5123
Washington, DC 20201

Dear Dr. Kwinn:

The Federation of American Societies for Experimental Biology (FASEB) is pleased to have the opportunity to provide feedback to the Working Group on Strengthening the Biosecurity of the United States. FASEB comprises 22 scientific societies representing approximately 90,000 biomedical researchers, including those actively engaged in biodefense research or fundamental and applied studies using select agents. FASEB is joined in these comments by the Association of American Medical Colleges (AAMC), a not-for-profit association representing all 130 accredited U.S. medical schools; nearly 400 major teaching hospitals and health systems; and nearly 90 academic and scientific societies.

The research community is committed to strengthening our nation's biosecurity and protecting our country against potential biological threats. We support the Select Agent Program's goal of overseeing the possession and use of potentially harmful pathogens and toxins as part of the government's effort to prevent and respond to bioterrorism, and FASEB and the AAMC welcome the Working Group's review of the select agent and related biosecurity regulations.

In general, the select agent regulations have become part of the fabric of the research enterprise, and the scientific community has adapted to the current system. Initial implementation was not easy and concerns remain about delays in the registration process and the costs of compliance, but overall, FASEB and AAMC support the select agent regulations. However, we do believe the current system could be improved in ways that

would strengthen our national biosecurity and facilitate the research that is so critical to our country's biodefense. We hope the Working Group will consider the following more specific comments:

Personnel reliability measures: Following the identification of a scientist in a Federal facility as the lead suspect in the 2001 anthrax attacks, questions have been raised about what could be done to mitigate the risk of an “insider threat.” We endorse the views of the National Science Advisory Board on Biosecurity (NSABB), outlined in their report “Enhancing Personnel Reliability Among Individuals With Access to Select Agents.” In particular, we agree that the current Select Agent Program already contains sufficient personnel reliability measures through the Security Risk Assessment process. This seems to be underscored by the fact that neither the CDC nor the USDA has reported a single incident of theft or attempted theft of a select agent since the regulations were enacted. Moreover, many university research laboratories, particularly high-containment facilities, already have in place additional personnel reliability protocols, beginning with the hiring process, which may include background checks, drug testing, and medical examinations. Allowing research institutions to develop their own personnel reliability programs related to use of select agents enables the institution to work within the framework of hiring practices, applicable state laws, and risk assessment. It is our view that personnel reliability is best assured through active management of laboratory personnel, encompassing regular performance evaluations, ongoing training, and clear mechanisms for reporting concerns.

We agree with the NSABB that greatly increasing requirements for personnel reliability, such as by instituting programs similar to those used by the Department of Defense, would deter talented scientists from working with select agents and would be a significant financial drain on scarce resources to the detriment of our nation's biodefense. In addition, FASEB and AAMC are concerned that there is little evidence that methods used to assess performance reliability, such as psychological testing, are predictive of future criminal behavior. Given the lack of data showing that additional, stringent personnel reliability requirements would actually reduce the “insider threat” and the near surety that implementing these measures would harm ongoing and future biodefense research, moving forward with a personnel reliability program for select agents is unjustified.

Stratification of select agent list: In their report on personnel reliability, the NSABB also recommended that the select agent list be stratified, to allow for a spectrum of security controls relative to the risk posed by the agent. We agree that the Working Group should give careful consideration to this idea. We recognize that the National Academies are currently working on a project to identify scientific criteria for gene-based classification of select agents, which may help create a more nuanced list of pathogens to be controlled. However, the current system treats all agents on the select agent list as equal risk, despite differences in pathogenicity and ability to be used as an agent of bioterrorism. It may make sense to have stricter security measures (i.e, greater personnel reliability measures, increased physical security, etc.) for extremely high risk agents not

found in nature, such as smallpox, while allowing greater access to less pathogenic and ubiquitous agents. Practically speaking, it may be difficult for research institutions to implement a spectrum of security measures, and laboratories may choose to implement the highest common denominator of security or safety measures. For example, some research institutions handle anthrax, which is a biosafety level (BSL) 3 organism, in their BSL-4 laboratories. Yet a stratification of the select agents by risk category would allow a stratification of regulations, giving institutions greater flexibility in ensuring maximum security for the pathogens and toxins posing the highest risk, while enabling less costly, more reasonable, and risk-appropriate controls for less risky select agents.

Performance-based versus prescriptive standards: Regulatory systems operate best when there is clear federal guidance that allows the flexibility of developing site-specific performance-based standards, and this principle should apply to the select agent regulations, as well. As an example, it makes sense to set minimum standards for physical security of select agents, such as mandating a locked barrier to prevent unauthorized access. But institutions should have the flexibility to decide whether the barrier exists at the gate entrance, the door to the building, or the door to the laboratory, based on their own site-specific physical structures, resources, and the risk posed by the agents they possess. More prescriptive standards could result in costly retrofitting of laboratory facilities or research administration infrastructure, without appreciable increases in security. While we believe it is important that any performance-based standards put in place are able to be assessed, FASEB and AAMC urge the Working Group to generally avoid recommending prescriptive regulations.

Inventory of select agents: It is important for all laboratories and research facilities working with select agents to have an accurate list of exactly which select agents are present in the facility at any given time as well as some detail on the characteristics of the strain or experimental manipulations. The select agent regulations were a positive step forward for our nation from a time when we were unable to answer the question of how many U.S. labs possessed *Yersinia pestis* or *Bacillus anthracis*, and it is important that research facilities remain accountable for the agents in their possession. However, for the infectious agents on the select agent list, the inventory requirement is at odds with the biology of microorganisms, and the regulation needs to be modified. Keeping count of the number of vials or quantity removed has little meaning when dealing with agents that can not only rapidly replicate but can be transferred with no discernible loss in volume or mass (for example, through dipping of a wire loop or pin). While keeping a detailed inventory may make sense for chemicals, radioactive materials, or even the toxins on the select agent list, the inventory requirement is inappropriate for living organisms and is a waste of valuable laboratory personnel time and resources. Furthermore, there is always the risk that valuable samples or cultures will be destroyed as research institutions or labs decide that the inventory requirements are too onerous a burden under which to operate. FASEB and AAMC request that the Working Group consider recommending the regulations be revised with regard to select agent inventories.

Inspection of select agent labs: Many laboratories working with select agents report being subject to multiple inspections by a number of entities, including federal agencies such as the CDC, USDA, and DOD, and local authorities, such as the health department or university health and safety office. These inspections typically take multiple days and involve large teams of inspectors. While we appreciate the need to have thorough inspections of select agent facilities, to ensure security plans are being properly implemented, we urge the Working Group to explore ways to harmonize these inspections, at least on a federal level. Particularly problematic are reports that registered entities frequently receive conflicting recommendations from inspectors from different agencies and are left with little to no guidance on how to reconcile the conflict. Such ambiguity results in increased cost of compliance and takes time away from important research with no commensurate increase in biosecurity. The federal government should also consider providing guidance to research facilities on how to minimize disruption to ongoing research activities due to inspections. For example, an inspector entering a room where non-human primates are housed could cause significant stress which will vastly alter physiological data being collected from the animals. This could easily be solved through the use of live, movable cameras or similar remote technology, but registered entities need to be aware of these alternatives prior to being inspected.

Need for more data: Recent public fora on biosecurity topics have made it clear that there is much to learn about the current status of biosecurity of research laboratories, and we hope that the Working Group's report will provide insight into critical questions. For example, how many registered entities in the select agent program currently have voluntary security measures, such as physical security elements, personnel reliability programs, or intensive training requirements, above and beyond that required by the Select Agent Program? Are data available from personnel reliability programs used in nuclear and chemical security programs that can demonstrate risk factors that might be relevant to misuse of biological agents? Are there research facilities using select agents that do not provide at least minimal biosafety training for laboratory personnel?

Differentiating biosafety and biosecurity: FASEB and AAMC request that the Working Group, in its final report, make very clear the distinction between biosafety and biosecurity, while at the same time recognize the opportunities to harmonize these interrelated concepts. We strongly support the national biosafety guidelines delineated in the U.S. Public Health Service's *Biosafety in Microbiological and Biomedical Laboratories* and NIH *Guidelines for Research Involving Recombinant DNA Molecules*, and we recommend all research personnel working with infectious agents or other biohazardous material should have appropriate training in biosafety. In fact, we believe that the current system adequately provides this training, although there may be value in ongoing or continuing education. FASEB and AAMC suggest that the Working Group recognize and build upon the foundation of this existent system of biosafety regulations, practices, and training protocols when considering new policy recommendations related to biosecurity, which may have overlapping aims.

While the news media and policymakers may use the terms biosafety and biosecurity interchangeably, there may be distinct differences from a policy and regulatory point of view. Best practices in biosafety, which aim to protect personnel working in the lab from the materials with which they are working, greatly contribute to biosecurity, the goal of which is to protect dangerous biological materials from inadvertent or deliberate release. However, FASEB and AAMC are concerned that issues related to biosafety, such as cases where lab workers are exposed to infectious agents or questions about the number of BSL laboratories, are being inappropriately used to justify more stringent biosecurity measures. For example, the exposure of a laboratory worker to a non-contagious pathogen such as anthrax during the course of handling it in the lab is of serious biosafety and occupational safety concern, and we believe it should be reported and steps taken to prevent future occurrences. But this does not constitute a biosecurity problem; there was no increased risk to anyone other than the lab worker. We hope that the Working Group's report will carefully consider this subtle distinction in formulating its recommendations.

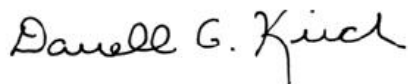
Finally, FASEB and AAMC recommend that as the Working Group considers these ideas in developing its report and recommendations, it recognizes that new regulations and policies are not without cost. The regulatory requirements faced by the research community, often in the form of unfunded mandates, are burdensome, and we have reached the point in which additional requirements are likely to harm research progress, something we can not afford in the biodefense arena.

Again, FASEB and AAMC greatly appreciate the opportunity to provide feedback to the Working Group on the select agent regulations and related biosecurity issues. If there is additional information we may provide, please do not hesitate to contact us.

Sincerely,



Richard B. Marchase, Ph.D.
FASEB President



Darrell G. Kirch, M.D.
AAMC President and CEO