November 30, 2011

Centers for Disease Control and Prevention
Select Agent Program
1600 Clifton Road, NE
Mailstop A-46
Atlanta, GA 30333
ATTN: RIN 0920-AA34

Dear Select Agent Program:

The Association of Public Health Laboratories (APHL) appreciates the opportunity to provide feedback on the recently released proposal to revise the Select Agent Rule, *Possession, Use and Transfer of Select Agents and Toxins; Biennial Review; Proposed Rule*, per the Federal Register volume 76, No. 191, October 3, 2011.

APHL member state and local public health laboratories (PHLs) comprise the majority of the Laboratory Response Network (LRN) Reference Level and these laboratories would be greatly impacted by the additional requirements imposed on Tier 1 Biological Select Agents or Toxins (BSAT).

APHL does not agree with the selection of agents such as *Bacillus anthracis* Pasteur Strain, botulinum neurotoxin, and toxin-producing strains of *Clostridium botulinum* for the proposed Tier 1 or the increased physical, personnel and cybersecurity requirements that accompany Tier 1 agents. APHL agrees with some changes to the current select agents and toxins list, including the removal of agents such as *Coccidioides posadasii* and *C. immitis*, that reduce the burden in the clinical and public health community.

Therefore, APHL and its members strongly recommend the following:

- Exemption of all LRN reference laboratories from the proposed Tier 1 requirements. APHL encourages the National Select Agents Registry Program to consider the recommendation from the Federal Experts Security Advisory Panel (FESAP), where they noted: *The FESAP recognizes that there are unique facilities such as diagnostic, public health, animal health, and environmental laboratories, such as the laboratories of the Laboratory Response Network, which perform a vital national security function and may require different methods of implementation of the recommended standards. In these instances, the FESAP encourages the Select Agent Program, through their authority in Section 4 of E.O. 13546, to “explore options for graded protection of Tier 1 agents and toxins... to permit tailored risk management practices based upon relevant contextual*
factors.” (FESAP, Recommendations Concerning the Select Agent Program, Released June 12, 2011).

- Representation of local and state public health laboratories during the development of codifying changes and guidance documents, in a manner comparable to that used in the development of the Guidelines for Biosafety Laboratory Competency (MMWR Vol. 60, April 15, 2011).
- Removal of *Bacillus anthracis* Pasteur Strain, botulinum neurotoxin, and toxin-producing strains of *Clostridium botulinum* from Tier 1 designation.

APHL believes:

- Additional costs to comply with the proposed changes to the rule would adversely impact other critical public health programs that are supported by state and local public health laboratories, many of which have had to take significant budget reductions during the past three years.
- Public health laboratories already foster an environment of biosafety and biosecurity to protect against physical and cyber attacks and insider threats.
- Promoting continued exemplary practices of engaging leadership, encouraging teamwork, building relationships with employees and providing ethics training has greater value than the use of a “spot in time” personnel reliability program.
- Additional requirements for select agents may result in some laboratories abandoning the LRN, resulting in a weakened capability for national response.
- Modifying occupational health programs or adding personnel reliability program requirements will put further strain, including legal ramifications for request for health information, on laboratories already facing worker shortages.
- Increased biosecurity requirements will be damaging to public health laboratories storing limited quantities of BSAT used during response to public health emergencies and would compromise lab preparedness and the ability of the US to detect and respond to threats.
- Public health laboratories are already highly regulated under the National Select Agent Registry (NSAR), Occupational Safety and Hazard Administration (OSHA), National Environmental Laboratory Accreditation Commission (NELAC), Clinical Laboratory Improvement Amendments (CLIA), and the College of American Pathologists (CAP).
In September 2010 and again in July 2011, APHL participated in meetings of the FESAP to provide input on the final recommendations issued in their report, *Recommendations Concerning the Select Agent Program* released on June 12, 2011. APHL informed the panel of existing biosecurity practices within state and local public health laboratories that comprise the LRN and the impact of changes to the select agent regulations on these laboratories.

The LRN, formed in 1999 through a partnership between Centers for Disease Control and Prevention (CDC), the Federal Bureau of Investigation (FBI) and APHL, is the nation’s premier laboratory network and a key national security asset. The network remains a model for all other networks, responding to actual events on a daily basis and continually proves its utility during events such as Amerithrax, the H1N1 pandemic, disease outbreaks and natural disasters. The true value of the LRN is demonstrated through the communications and relationships built with clinicians, hospitals, law enforcement, first responder and epidemiology communities. These well established partnerships are the cornerstone that allows the LRN to effectively respond to all threats.

State and local public health laboratories in the LRN are primarily funded by the CDC Public Health Emergency Preparedness Cooperative Agreement. As has been the case with many industries, these funds have seen considerable budget reductions with no end in sight. Imposing additional costs even with supplementary funding could cause the final erosion of the LRN and compromise the robust preparedness infrastructure that has been established and proven in its utility over the past decade. Rebuilding such a system would require exponentially more resources than preserving the established network.

We thank you for your efforts to integrate federal, state and local partners in the ongoing improvement of the National Select Agents Registry Program and we look forward to our continued engagement in this critical initiative.

Sincerely,

Scott J. Becker, MS
Executive Director

*APHL represents governmental laboratories that detect and monitor public health threats. APHL’s members include state, territorial, and local public health laboratories; state environmental testing laboratories, state agricultural and food safety laboratories; and individual scientists, public health officials, and academicians.*