



August 30, 2010

Centers for Disease Control and Prevention
Division of Select Agents and Toxins
MS-A46
Atlanta, GA 30333
Email: SAPcomments@cdc.gov

RE: Comments on the changes to the list of select agents and toxins

The Association of Public Health Laboratories (APHL) represents governmental laboratories that detect and monitor public health threats, many of which are also members of the Laboratory Response Network (LRN). 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. We thank the Department of Health and Human Services (HHS), Centers for Disease Control and Prevention (CDC), Division of Select Agents and Toxins for the opportunity to comment on the recent Federal Register Notice (Vol. 75, No. 139), Public Health Security and Bioterrorism Preparedness and Response Act of 2002; Biennial Review and Republication of the Select Agent and Toxin List. This review provides an excellent opportunity for the public health laboratory and other communities to comment on the list of select agents and toxins, including whether any biological agent or toxin should be added or removed from the list, as well as whether the HHS select agent list should be "tiered" and security requirements "stratified."

Proposed Changes to the List of Select Agents

Upon careful review of the current list of select agents, APHL does not recommend that any additional agents or toxins be added to the HHS list. However, we recommend eliminating the following agents from the list due to their wide distribution in nature, lack of ease of production and limited pathogenicity: *Coccidioides posadasii/Coccidioides immitis*; *Rickettsia rickettsii*; Monkeypox virus; Cercopithecine herpesvirus 1 (Herpes B virus); Saxitoxin; Shiga-like ribosome inactivating proteins; Shigatoxin; T-2 toxin; Tetrodotoxin; Conotoxins; Diacetoxyscirpenol; *Clostridium perfringens* epsilon toxin.

Proposed Tiering of Select Agents

APHL supports a tiered HHS select agent list commensurate with the risk that a particular agent could be misused to cause significant harm to public health. However, we do not support any tiering categorization that would result in an increase in biosecurity for any select agents. A proposed strategy for creating a tiered, risk-based HHS select agent list would be to align biosecurity requirements with the public health risk categories already established by the CDC, where Tier 1 agents would include those major threat agents that

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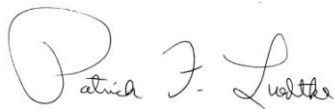
have been extinguished from nature and/or which require special consideration (i.e., Smallpox virus) and require stringent security measures as currently required in the select agent regulations. Subsequent tiers would encompass lower biosecurity requirements which are also aligned with the public health risk categories as currently defined by CDC. Of note, the existing select agent regulations already include sufficient biosecurity requirements, such as personnel clearances.

Another strategy for creating a tiered list would be to stratify agents based on the laboratory designation or mission of the facility using the agent. This includes production laboratories (vaccine production or other high volume agent use), research laboratories (academic and contract laboratories performing aerosolization studies and animal studies) and public health (detection, surveillance and diagnosis) laboratories. Parameters to further consider include type of work being performed, how the agent is used, how the agent is stored, volume of agent being handled and the biosafety level associated with use.

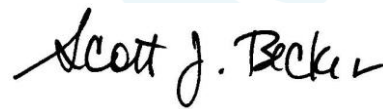
Increased biosecurity requirements would be damaging to public health laboratories storing limited quantities of select agents used during response to public health emergencies and would compromise laboratory preparedness and the ability of the United States to detect and respond to bioterrorism or naturally occurring diseases caused by select agents.

If there is more information that you believe we can provide, please feel free to contact Sikha Singh, Laboratory Response Network Specialist, at 240-485-2726 or via email at Sikha.Singh@aphl.org.

Sincerely,



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