



COMMONWEALTH of VIRGINIA

Department of General Services

Division of Consolidated Laboratory Services

600 North 5th Street
Richmond, Virginia 23219-3691
(804) 648-4480
FAX (804) 371-7973

Denise Pettit
Division of Consolidated Laboratory Services
600 North 5th Street
Richmond, VA 23298

August 30, 2010

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

To Whom It May Concern:

I would like to thank the Centers for Disease Control and Prevention, Division of Select Agent and Toxins and the Department of Health and Human Services for the opportunity to provide comments on the review and republication of the Biological Select Agent and Toxin (BSAT) list as requested in the Federal Register 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. I am currently the Laboratory Bioterrorism Response Coordinator for Virginia and a Select Agent Principle Investigator at the Division of Consolidated Laboratory Services (DCLS) in Virginia. DCLS is the only Reference Laboratory Response Network facility in Virginia and we currently store and utilize a variety of select agents as controls for assays to detect and characterize these biological threats. The comments are solely directed to those agents under the category of HHS Select Agents and Toxins and Overlap Select Agents and Toxins.

The appropriateness of the current HHS list:

The existing list of Select Agents and Toxins should be reduced and/or stratified. I agree with the recommendation put forth in the *Report of the Working Group on Strengthening the Biosecurity of the United States* that states "a risk assessment should be conducted for each select agent and toxin on the BSAT list and a stratification scheme should be developed." I support the establishment of a Biological Select Agents and Toxins Advisory Committee to accomplish this task and strongly encourage the committee to include representation of Public Health Laboratories, since they represent the largest portion of laboratories currently registered in the BSAT program and they play a critical role in biodefense strategies that address naturally occurring disease outbreaks and the (un)intentional release of biothreat agents. The initial goal of the Advisory Committee should be to establish a rational biosecurity risk assessment that can be used to evaluate the appropriateness of each agent and toxin on the list. Once an agent is deemed to be appropriate, it can be placed on a tiered and/or stratified list.

The addition of new agents or toxins:

I do not recommend adding new agents or toxins to the BSAT list at this time.

The deletion of agents or toxins:

I recommend deleting the following agents:

- *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*
- Nucleic acid derived from BSAT positive polarity RNA viruses
- Eastern Equine Encephalomyelitis virus (EEE)

EEE should be removed from the list since local and state health departments and mosquito control agencies routinely release information regarding the location of arboviral activity in the community. This is done to inform the public and promote preventative measures in areas at risk. A terrorist could simply trap mosquitoes from the environment and initiate culture to obtain EEE. Therefore, upholding strict biosecurity measures in a laboratory has little to no impact on reducing a terrorist's ability to acquire this agent. Furthermore vector-borne disease agents would likely require sophisticated dispersion strategies.

Tiering of the BSAT list based on relative bioterrorism risk:

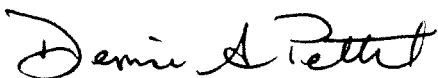
I support a tiered BSAT list takes into account the existing biosafety level of the agent and the relative public health risk associated with of the agent. The top tier should only possess agents that have the potential to be used as a biological weapon and are classified as BSL 4 agents. Biosecurity enhancements should be evaluated for this tier and include parameters such as intrusion detection systems, electronic access- control, 24/7 security monitoring, CCTV surveillance. The mid-tier should contain those agents on the CDC Category A list (which is based on relative public health risk) that are classified as BSL 2 or 3. The existing biosecurity measures for select agents should be maintained in this tier. The lowest tier should contain those agents on the CDC Category B list that are classified as BSL 2 or 3. Reduction of the existing biosecurity measures could be evaluated for the agents in this category that are currently on the select agent list.

Stratification of the BSAT list based on type of use or other factors:

I support the stratification of biosecurity standards for agents on a tiered BSAT list. Parameters that should be consider in stratification include the mission of the laboratory (clinical, public health, research, or production), 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. Laboratories that routinely produce large quantities of a BSAT agent (research or production facilities i.e. vaccine or proteomic research), should be distinguished and held to higher biosecurity standards than clinical or public health laboratories that maintain and use small quantities of agent for control purposes. Clinical and public health laboratories do not possess the equipment needed to produce a weapon of mass destruction, the instrumentation needed to transfect nucleic acids that require select agent registration, and the equipment and facilities needed to disseminate biothreat agents. For example, a public health laboratory may possess EEE nucleic acid for use as a control in detection assays, but the laboratory does not possess the instrumentation needed to transfect cells to make replication competent virus. In addition, public health laboratories would not have the equipment necessary to disperse the agent (Insectaries).

I appreciate the opportunity to voice my opinions regarding the review and republication of the Select Agent and Toxin list. I strongly encourage the establishment of a Biological Select Agents and Toxins Advisory Committee that includes public health laboratory representation. Public Health Laboratories are a critical component of biological emergency response. Implementing more stringent biosecurity measures for agents routinely detected in public health laboratories (*Brucella* spp., *B. anthracis*, *F. tularensis*, *Burkholderia* spp., EEE) would compromise our ability to respond to naturally occurring biological emergencies. In addition, more stringent regulation may negatively impact our ability to sustain our existing role in responding to acts of terrorism.

Sincerely,



Denise A. Pettit, PhD
Laboratory Bioterrorism Response Coordinator