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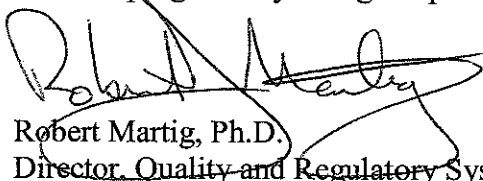
Centers for Disease Control and Prevention  
Division of Select Agents and Toxins  
1600 Clifton Road, MS A-46  
Atlanta, GA 30333

### **Comments on the changes to the list of select agents and toxins**

Midwest Research Institute (MRI) writes to provide comments on the Federal Register notice dated July 21, 2010, reference the current HHS list of select agents and toxins, on the “tiering” of the HHS select agent list, and on the stratification of security requirements. MRI is an independent, not-for-profit organization that performs contract research for government and industry. MRI is vitally interested in assuring that a robust and productive scientific enterprise with select agents and toxins is carried out in a safe and secure manner and meets national security requirements.

MRI supports the risk-based tiering of the select agent list and believes that HHS and USDA, in consultation with the ISATTAC and the Federal Experts Security Advisory Panel, has the requisite expertise to first recommend a comprehensive rationale and second, designation of Tier 1 agents and toxins and appropriate practices to ensure reliability of personnel and facility security. MRI recommends that HHS consider the recommendations of the 5<sup>th</sup> edition of the BMBL on risk assessment to include organisms that are not currently listed in risk groups, namely known microorganisms of unknown pathogenic potential or the unknown, non-cultivable pathogens, genetically altered (i.e. engineered or natural reassortments), or rapidly evolving pathogens. Work with these agents would be allowed with security and safety requirements consistent with the risk. Facilities should be required to prepare written risk assessments and risk management documents under standards developed and recommended in WHO/NIH publications.

MRI supports the application of stratified security requirements for entities that possess the highest tier agents, and that those security requirements be risk-based (based on a security risk assessment), rather than being prescriptive. A risk-based perspective permits the laboratory management to fully implement safeguards and countermeasures that are appropriately based upon the risks associated with the agent and the mission/scope of the facility. More prescriptive regulations will discourage science research and inhibit collaborations. The stratified security requirements should take into consideration the needs of researchers to import and export select agents. A personnel reliability program should take into consideration the expertise that can be provided to research programs by foreign experts and graduate students.



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