

Comments on Biennial Review and Reorganization of the Select Agent and Toxin List
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August 20, 2010

1. Sandia has long been supportive of tiering the Select Agent, and Toxin List and stratifying the biosecurity requirements based on the agent tiering (see Gaudio and Salerno, "Biosecurity and Research: Minimizing Adverse Impacts," Science, Vol 304, 2004, p. 687). However, it is important that an intellectually defensible and transparent biosecurity methodology for the protection of high-risk agents and toxins be developed and applied. Such a transparent methodology can be understood by the regulated community; this knowledge may eliminate frustration with the current process for determining what is on the Select Agent list, and may help persuade the scientific community to comply with future regulations.
2. The Department of Homeland Security Biennial Biothreat Agent Risk Assessment (BTRA), mandated by Homeland Security Presidential Directive 10, should be used to inform the tiering of the Select Agent list. However, since those results are classified, a separate, transparent methodology for tiering the Select Agent list should be developed. This methodology can extract unclassified, but useful, information regarding biological agents from the detailed classified information contained in the BTRAs by combining the detailed criterion into more general risk categories. The methodology should be rigorously reviewed by subject matter experts in the fields of biosecurity, the biosciences, and risk assessment. The agent criteria of the methodology should be scored and weighted by subject matter experts using academically rigorous risk assessment methods.
3. We think that tiering of the select agent list should be based on the risk that an agent could be stolen from a facility and subsequently used to execute a bioterrorism attack. Determination of this relative bioterrorism risk should include an assessment of both the relative consequences and the relative likelihood of misuse of each agent; in other words, the agent criteria should clearly contribute to either the likelihood or consequences side of the risk assessment equation; if a criterion should influence both likelihood and consequences, the methodology should make that clearly understood. The assessment of the relative likelihood of misuse should include consideration of factors such as acquisition pathways, transmissibility, stability, ease or difficulty to produce a suitable quantity of the agent in a suitable form, ease or difficulty in dispersing the agent, and the adversary's awareness of the agent. The assessment of relative consequences needs to consider the disease impacts, socioeconomic impacts, and impact of secondary transmission. Disease impacts would be based on a specific host in a normalized population, including morbidity, mortality, and disease mitigation measures, such as effective and available anti-microbials.
4. Although EO 13456 directs the agencies to develop only a Tier 1, we believe that the Select Agent list should be divided into at least four tiers. We are concerned that agents such as smallpox and 1918 influenza will be the only agents in Tier 1, and that the overwhelming majority of Select Agents will not be affected by the tiering exercise if

there are effectively only two tiers. Since so very few labs have smallpox and 1918 influenza, the impact of tiering the Select Agent list will be minimal. The scientific community, therefore, would not think highly of the tiering process. It's equally important to distinguish between those high risk agents that are not as "unique" as smallpox and 1918 influenza, but are at considerably higher risk of misuse than the majority of the Select Agents. Many, many labs work with these high risk Select Agents, and the protection of those agents should be more substantive than for the low risk Select Agents.

5. We think that the list of Select Agents is too long. If the "tiering" risk assessment methodology is robust and reliable, the government should consider eliminating the lowest (fourth) tier of agents from the Select Agent list, possibly requiring only incident reporting for agents in this fourth tier. Although we have not completed a comprehensive analysis of the Select Agents from this perspective, we suspect that perhaps as many as 15-20 agents could be placed in Tier 4 and eliminated from the Select Agent list.
6. On the current list of select agents and toxins, we think consideration should be given to adding severe acute respiratory syndrome (SARS) virus as a select agent.
7. The stratification of the biosecurity requirements for the Tiers of Select Agents and Toxins should be explicitly linked to the agent tiering methodology. In other words, the tiering of Select Agents and the stratification of the security requirements should not be separate activities. The security requirements of each tier should be explicitly linked to the security risks identified in the agent risk assessment methodology. For instance, if an agent is high risk but is also ubiquitous in nature, the high security elements should focus on internal security measures, such as access controls and personnel reliability.
8. The stratification of the biosecurity requirements for the tiers of Select Agents and Toxins should address all elements of biosecurity, not just a stratification of physical security requirements. Personnel reliability, material control & accountability (including inventory), training requirements are all examples of biosecurity elements that should be stratified and implemented to achieve graded protection commensurate with the risks.
9. The stratification of biosecurity requirements should not be overly prescriptive; it should allow individual laboratories to implement different security measures based on site-specific risk assessments. Two labs may have the same agent, but may have different risks to mitigate based on their different operations.
10. The stratification of biosecurity requirements should be rigorously reviewed by subject matter experts in the fields of biosecurity, the biosciences, and risk assessment.
11. We think that the security requirements for facilities with Tier 1 and 2 agents should be more rigorous than the current Select Agent requirements.
12. We think that the security requirements for facilities with Tier 3 agents should be less rigorous than the current Select Agent requirements.

13. We think that Tier 4 agents should no longer be Select Agents.