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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

August 30, 2010

Ladies and Gentlemen,

The American Biological Safety Association (ABSA) is an international group of biological safety professionals and is known as one of the world's foremost resources on biological safety practices. ABSA has reviewed the July 21, 2010 Federal Register announcement regarding the biennial review and republication of the Department of Health and Human Services (HHS) list of select agents and toxins published in the CDC Select Agents Regulations (SAR) (42 CFR Part 73). Please consider these comments.

Regarding tiering the current SAT list:

ABSA notes that the biosafety community is very familiar and comfortable with the concept of stratifying experiments using microorganisms according to varying levels of likelihood and consequences of exposure to and infection by these agents. This concept is most familiarly encompassed in the assignment of biosafety levels (a grouping of control measures such as facilities, equipment, and practices) based on the risks presented by the agents and the experiments to be conducted.

Likewise, ABSA is supportive of a similar stratification for control measures against intentional release, theft, or misuse of the same microorganisms. ABSA emphasizes that such stratification MUST be based on an assessment of the likelihood and consequences of the release, theft or misuse. In addition to the evaluation of the inherent properties of the agent to cause harm, a biosecurity risk assessment also includes the likelihood the agent can be used as a weapon, the likelihood of theft from the facility and include an assessment of the range of possible adversaries, among other factors.

ABSA advocates the use of a common biosecurity risk assessment to evaluate each of the current listed Select Agents and Toxins and to tier these agents accordingly. It is likely that such a consistent model will show that some agents require greater security measures than those currently required by the Select Agent and Toxin regulations and that some agents will not require enough security measures to warrant regulation.

Without use of appropriate biosecurity risk assessment measures, it is our consensus that there is likely to be little advantage to the tiering of the list of select agents and toxins. As the SAR are currently written, a security plan would still need to be prepared and implemented regardless of whether an agent is listed as a higher or lower tiered agent. At this time, redundant layers of security are still be typically expected by agency inspectors to be in place at regulated facilities regardless of the biosafety or biosecurity risk posed by the agent.

If a SAT tiering and stratification process for security of these agents is used, consideration must be given to how to rationally implement these provisions in facilities with multiple SAT. The tiering would also not necessarily beneficially affect such facilities. Conversely, it could create confusion if different criteria were to be applied to different laboratories within the same facility, especially as projects and staff change over time.

Regarding specific select agents on the list:

We provide the below examples which could be considered for removal, although, as stated above, ABSA advocates a common and reproducible biosecurity risk assessment of the entire list of SAT:

- *Yersinia pestis* – Even though this agent is an undoubted potential human pathogen if a case is undiagnosed and/or untreated, it has also been known to have killed entire prairie dog colonies. Despite this potential pathogenicity to U.S. wildlife, the U.S. Department of Agriculture and Animal and Plant Health Inspection Service (USDA/APHIS) have chosen not to regulate it. This agent, like a number of other agents on the list, is naturally occurring. This particular agent is endemic to some parts of the southwestern United States. This is not a hearty organism - it does not survive for long outside of its rodent host due to its susceptibility to heat and sunlight. Because of these characteristics, decontamination of surfaces is highly effective in limiting its spread, and there are treatments readily available for those who may become exposed to it either in the work environment or in the community. The properties of this organism would not make it a good choice for terrorists to use as a malicious weapon. We recommend that this agent be considered for removal from the list based on the similar rationale used by USDA/APHIS.
- *Coxiella burnetii*- This agent can produce illness, but it is typically not serious and often self-limiting. Sheep workers and researchers working with this agent may be often asymptomatic following exposure to the agent, and many resulting infections are this type. Person to person transmission of the disease is rare, and it is fatal less than 1% of the time. A vaccine is available for this agent internationally, but not domestically. We recommend that this agent be considered for removal from the list based on the stated rationale.

- *Burkholderia mallei* and *pseudomallei* – These two are endemic in a number of areas of the world and disease resulting from these agents is treatable with low morbidity. It is questionable how these agents would be used as bioweapons and we recommend that this agent be considered for removal from the list based on the stated rationale.
- Japanese encephalitis virus - There is an effective vaccine available and very limited opportunity or potential for airborne transmission. It is not listed on the HHS or the overlap select agents and toxins list. We recommend that this agent be considered for removal from the list based on the stated rationale.
- Newcastle disease virus (NDV) - According to the national Select Agent Program, select agents are biological agents and toxins that have the potential to pose a severe threat to public health and safety, to animal health, or to animal products. In 2008, the Select Agent Program changed the listed strains of Newcastle Disease Virus (NDV) from velogenic strains to virulent strains, thereby adding several mesogenic (moderate disease) strains to the list. The mesogenic strains do not appear to fit the definition of select agents because they do not cause severe disease in unvaccinated poultry. If present at all, the disease will exhibit mild to moderate respiratory signs with no death. Furthermore, in the US almost all commercial poultry are vaccinated, and in those vaccinated birds the mesogenic strains do not produce any disease. In its study, the National Research Council (*Responsible Research with Biological Select Agents and Toxins*, 2009; available at www.nap.edu) argued that if the purpose of the Select Agent Program is to protect the public against terrorist use of agents where the consequences cannot be easily managed, then the select agent list should not include microorganisms with little or no potential use as a biothreat agent or those whose impact can be effectively managed in other ways, such as by preventive or therapeutic interventions. Therefore we request that the designation "virulent Newcastle disease virus" be removed from the Select Agent list and replaced with "velogenic Newcastle disease virus."

This brief list of examples is representative of some commonly raised questions regarding the nature of the select agent list from within the biosafety and scientific communities. It is not meant to be all-inclusive nor exhaustive. We instead strongly recommend that additional consideration should be dedicated to timely and necessary review of the current select agent list via a common and reproducible biosecurity risk assessment. Such a process should have a clearly defined strategy for inclusion and/or tiering so that proper justification is in place following the publication of the revised list.

We appreciate this opportunity to provide comments.
Sincerely,

Benjamin Fontes, MPH, CBSP
President
American Biological Safety Association