
From: Hanna, Michael [mailto:mhanna@umich.edu]
Sent: Friday, August 06, 2010 9:55 AM
To: Sap Comments (CDC)
Subject: Comments on the changes to the list of select agents and toxins

Brucella abortus: Serious consideration should be given to downgrading the risk assessment for vaccine strains of Brucella. Only Strain 19 and RB51 have been excluded as licensed vaccine products, but other research strains having equal levels of biological attenuation have not been excluded. The University of Michigan has attempted to have such exclusion considered on more than one occasion and it seems to us that the only criteria that the ISATTAC will accept for exclusion is licensed drug status. We submit that this extremely high benchmark is not logical nor necessary to protect the public interest, and is disadvantageous to research on this important pathogen in the United States. I include copies of past correspondence with DSAT on this matter.

Burkholdaria pseudomallei: We believe, as many others do, that this agent does not rise to the same level of public health threat or feasibility for weaponization that the others do. It is a true curiosity as to why it was identified listing as a Select Agent in the first place. The presence of lower-risk agents of this sort on the targeted Select Agents listing dilutes and diminishes both the intent positive impacts of the regulation and our ability as biosafety/biosecurity professionals to convincingly validate the programs to those we serve. We recommend its removal from the Select Agents list.

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NOTICE:

CDC's Division of Select Agents and Toxins has begun the biennial review process, which will include consultation with the Intragovernmental Select Agents and Toxins Technical Advisory Committee, which includes employees from USDA, DHS, DoD, FDA, and the National Institutes of Health.

The current list includes Ebola virus, anthrax, ricin, smallpox virus, Shiga toxin, Lassa fever virus, and Marburg virus. It can be found at
<http://www.selectagents.gov/Select%20Agents%20and%20Toxins%20List.html>.

Beyond asking whether any biological agent or toxin should be added to or removed from the list, HHS wants comments on 1) whether it should tier the list based on the relative bioterrorism risk of each agent or toxin, or 2) "possibly further stratify the security requirements for agents in the highest tier based on type of use or other factors."

Comments may be e-mailed to SAPcomments@cdc.gov and should be marked "Comments on the changes to the list of select agents and toxins." They may be mailed to: Centers for Disease Control and Prevention, Division of Select Agents and Toxins, 1600 Clifton Road, MS A-46, Atlanta, GA 30333.