Sap Comments (CDC)

From: Jeff Perkins [jtperkins@colorado-serum.com]

Sent: Tuesday, August 24, 2010 11:53 AM

To: Sap Comments (CDC)
Cc: 'DR. Phil Sprino'

Subject: Comments on the changes to the list of select agents and toxins **Attachments:** Select Agent Comments from Dr Songer and Dr Haffer.pdf

To Whom It May Concern,

I am writing on behalf of the Colorado Serum Company in response to the biennial review of the Select Agent list. We have worked with some of the agents listed on the Select Agent list and feel through our years of experience that the following agents [Clostridium perfringens type D epsilon toxin, Brucella abortus strain 1119-3, and Eastern Equine Encephalomyelitis virus] should be removed from the list or at the very least be moved to the lowest tier in a proposed Select Agent tiered system.

Colorado Serum Company's contention is that Clostridium perfringens type D and its toxin are naturally found in the environment, the use of this toxin as a bioterrorism weapon is highly unlikely due to several factors including the method and effectiveness of administration, and the lack of potential secondary transmission to uninfected individuals.

Laboratory exposures to C. botulinum toxin and to ricin have both been well documented while exposure to epsilon toxin has not been documented. If epsilon toxin were such a danger to humans then most surely some documented exposure incidents should have taken place through all the years of work with this toxin. In our decades of work with Clostridium perfringens type D epsilon toxin, we have not had an exposure causing a health threat to any of our laboratory personnel. The short duration in production also minimizes the biosafety and biosecurity risks. Attached are comments from two consultants who both have doctorate degrees.

We feel that Brucella abortus strain 1119-3 should be removed from the Select Agent list since Brucella abortus strain 1119-3 is identical using conventional typing tests to strain 19 (APPLIED MICROBIOLOGY, Sept. 1969, p. 511-512, Vol. 18, No. 3) and is used for as an antigen strain in diagnostic tests. The fact that this strain exists in wildlife also should be considered in its removal. The primary mode of transmission for Brucella abortus is through contact with contaminated fluids/tissues. The pathogenicity of Brucella abortus is described as moderate (the same designation as Brucella canis which is not on anyone's Select Agent list). Brucella abortus infections are routinely treated with antibiotics and these treatments tend to do an effective job with less than 10% relapsing. (emedicine.medscape.com/article/830118-overview).

We feel that Eastern Equine Encephalomyelitis virus should at least be moved to the lowest tier of a proposed tiered Select Agent list as this virus occurs naturally in the environment, direct person to person transmission does not occur, and the CDC has designated it as a Category B agent. We have worked with this virus for 40 years and have never had an individual contract an infection, we believe the infection rate to be extremely low or non-existent based on our experience.

Finally, we would like to point out that Clostridium perfringens type D epsilon toxin and Eastern Equine Encephalomyelitis virus have been removed from the USDA select agent list. The use of these three agents as an effective bioterrorist weapon is highly unlikely based upon the aforementioned reasons.

We respectfully submit these requests for removal and appreciate the opportunity to voice our opinions.

Sincerely,

Jeff Perkins

Asst. Vice President- Regulatory Affairs Colorado Serum Company