

Sap Comments (CDC)

From: Mike Durham [mdurham@lsu.edu]
Sent: Monday, August 30, 2010 5:36 PM
To: Sap Comments (CDC)
Cc: Gregory V Hayes
Subject: Comments on Select Agent Rules



Louisiana State University and LSU Ag Center



TO: Division of Select Agents and Toxins
Centers for Disease Control and Prevention
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Subject: Comments On The Changes To The List Of Select Agents And Toxins

Louisiana State University and Agricultural and Mechanical College (LSU) and the LSU Agricultural Center (AgCenter) submits the following comments regarding improving our response to threats of biological terror, and improving procedures and processes in providing appropriate containment of dangerous pathogens and toxins:

"the appropriateness of the current HHS list of select agents and toxins,"

The list includes agents which are common endemic diseases of the US and which are readily available and regularly studied using basic biosafety level 2 containment and for which treatments are available.

We suggest that Brucella abortus and Brucella suis, which cause endemic zoonotic bacterial diseases of livestock be preferably removed as select agents or at least moved to a much lower tier. This is due to their biological characteristics; both are extremely poor potential bioterrorist agents. Brucella spp. are adversely affected by environmental conditions and can be diagnosed and controlled in animals and readily treated in humans. LSU has worked extensively with these organisms for over 30 years, and for many of these years infected animals were maintained in an outdoor facility.

Brucellosis researchers are of the opinion that neither B. abortus nor B. suis would be the agent of choice for bioterrorism. Although essentially eradicated from domestic livestock, both organisms are currently found in wildlife reservoirs throughout the US. The classification of these bacteria as select agents has hampered, and in some cases caused a suspension of, research that could result in vaccines that would protect susceptible animal populations. Brucellosis is a worldwide disease of human and animal importance; and the US's restrictions on brucella research has hindered the progress of diagnostic, therapeutic, and preventative measures.

While brucellosis will remain a disease of agricultural significance and reportable for both man and animals, B. abortus and B. suis are not ideal biological weapons. We suggest B. melitensis remain on the select agent list as it is a foreign animal disease and the most infectious of all the species. The removal of B. abortus and B. suis from the select agent list will facilitate the use of modern genetic techniques to select novel vaccine candidates that can then be tested in animal models for efficacy. Overall, the animal and human populations of the entire world will benefit from such action.

Additionally, Eastern Equine Encephalitis (EEE) is a very common US disease which is diagnosed and isolated regularly. It is also easily handled at biosafety level 2. Its designation as a select agent has increased the cost of this diagnosis considerably due to the additional regulatory requirements including security requirements.

"whether the security requirements for agents in the highest tier should be further stratified based on type of use or other factors."

Answer: yes

Large animal high containment research facilities for select agent research currently are required to be designed to USDA's standards developed by Agricultural Research Services (ARS). We base this observation on the inspection/certification checklist provided by APHIS for ABSL3 - Ag facilities. The ABSL3-Ag facilities are ABSL3 facilities with certain ABSL4 enhancements. The facilities designed to the standards and specifications of the ARS are prohibitively expensive and totally non-necessary for many agents such as *Brucella abortus* and *Brucella suis*. Unfortunately, this has had the effect of unfairly and unreasonably restricting research in developing vaccines which can help eradicate animal diseases of significant global impact. We encourage APHIS and the Select Agent program oversight personnel to use logic and input from the affected university research community in accommodating alternate designs for these facilities. A potential conflict of interest exists in this area, as APHIS not only regulates, it also does research in direct competition with university research facilities and private research entities.

In regards to inspections we believe the heavy fines and high profile "federal cases" made over inspection results are unnecessary and detrimental to US research activities. This antagonistic oversight will ultimately drive many to abandon their research efforts. University researchers are scientists who are striving to make the world a better, safer place to live. Having the threat of assumed guilty until proven innocent hanging over their heads is draconian in nature at best.

Finally, We believe that the federal select agent program can foster a culture of security and responsibility without losing sight of public, animal and plant safety by providing and/or encouraging a means to effectively communicate among entities which are involved in select agent research, transportation, and disposal. Currently the secrecy surrounding information about select agent research' and the identities of locations where it is performed, is hampering this communication. Sharing experiences with one another without bringing down the weight of public scrutiny and media attention is a way to improve our overall efforts at providing security and safety while making the gains we want to make in science. Bringing together universities, federal government lab entities, state and local government labs, and private entities, both profit and nonprofit through a medium would be advantageous in this need.

Thank you for allowing us input to this important topic.

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