
RESOLUTION NUMBER: 17 APPROVED

SOURCE: COMMITTEE ON CATTLE AND BISON

SUBJECT MATTER: Permitted Research on *Brucella Abortus* as a Select Agent

BACKGROUND INFORMATION:

Select Agent regulations restrict possession, transfer, and use of select agents and toxins to protect the Nation from terrorist attacks. The restrictions have been highly effective in limiting access to dangerous agents and toxins by unauthorized individuals. Unfortunately, opportunities for important research on *Brucella abortus*, a disease endemic in Greater Yellowstone Area (GYA) wildlife, has also been severely limited by these same regulations. The National Academy of Sciences recently published a report titled, "Revisiting Brucellosis in the Greater Yellowstone Area," and concluded that brucellosis research is not only critical but should be expanded in response to the spread of brucellosis in the GYA.

Brucella abortus research restrictions have recently been clarified in an August 18, 2017, memo from the Department of Health and Human Services and the United States Department of Agriculture titled, "FSAP Policy Statement: Non-Exclusion of Study-Related Activities Involving Naturally Infected Animals." The memo clarified that it is not permissible to:

- "Remove an animal which is naturally infected with a select agent from its natural environment to an artificially established environment for the purpose of the intentional exposure or introduction of a select agent to a naïve or experimental animal, or
- Introduce a naïve animal to a natural environment where there is an animal which is naturally infected with a select agent for the purpose of the intentional exposure or introduction of a select agent to the naïve or experimental animal."

These limitations leave the Biosafety Level 3 (BSL-3) Agricultural Research Service facility at Ames, Iowa as the only United States facility capable of conducting brucellosis pathogenesis studies in a laboratory setting. Further, these restrictions preclude any pathogenesis studies under field conditions based on natural transmission of disease in either wildlife or livestock. Therefore, studying vaccine response in cattle, elk, or domestic bison in the GYA due to natural infection is no longer possible.

As the disease is continuing to expand, the tools previously available to address the problem have become unavailable.

RESOLUTION:

The United States Animal Health Association (USAHA) strongly urges that within the Select Agent regulations, the United States Department of Agriculture (USDA) and the Department of Health and Human Services (DHHS) permit brucellosis research studies on pathogenesis under field conditions in endemic areas based on natural transmission of disease. Further, the USAHA urges the USDA and DHHS to vigorously work to remove *Brucella abortus* from the select agent list.

INTERIM RESPONSE:

The United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service, Veterinary Services recognizes the concerns of the United States Animal Health Association and appreciates the opportunity to respond. The Agriculture Select Agent Service (AgSAS) recognizes the importance of continued research to evaluate vaccine efficacy and pathogenesis of brucellosis. After careful evaluation of the biosafety and biocontainment factors of various brucellosis studies involving livestock and naturally infected animals, AgSAS – along with their partners in the Department of Health and Human Services (DHHS) – issued “FSAP Policy Statement: Non-Exclusion of Study-Related Activities Involving Naturally Infected Animals” on August 18, 2017.

The policy statement specifically addresses the use of negative or naïve animals for the purpose of intentional transmission studies by exposure to and comingling with naturally infected animals. This policy addresses the concern of transferring select agents to a negative animal in studies not performed in compliance with the select agent regulations. AgSAS offers to review new study proposals, to ensure compliance with the select agent regulations.

USDA continues to collaborate with DHHS on consideration of delisting *Brucella abortus*, which will assist in future brucellosis research efforts.