
RESOLUTION NUMBER: 32

APPROVED

SUBJECT MATTER: Removal of Select Agent Status for *Brucella* species

BACKGROUND INFORMATION:

In order to protect the nation from terrorist attacks, select agent regulations restrict possession, transfer, and use of select agents and toxins. The restrictions have been highly effective in limiting access to dangerous agents and toxins by unauthorized individuals. Unfortunately, these same restrictions have limited opportunities for important research on *Brucella* spp., including *B. abortus*, *B. melitensis*, and *B. suis*. *B. abortus* is a disease endemic in Greater Yellowstone Area (GYA) wildlife, while *B. suis* is endemic in feral swine populations throughout the United States (US), and *B. melitensis* is a foreign animal disease that has successfully been kept out of domestic livestock and wildlife populations in the United States.

A recent paper published by Olsen et. al documents that *Brucella* spp. can be removed from the biological select agent and toxins list based on clinical, biological, and epidemiological properties of the bacteria. In particular, the paper highlights that *Brucella* spp. are readily available in endemic areas, thus easily attained by individuals or groups with nefarious intentions. Previous reports estimating human morbidity and mortality in the event of a *Brucella* bioweapons attack did not adequately consider the fact that brucellosis is the most common zoonotic infection reported in humans annually. Humans are considered dead end hosts for *Brucella* and are typically infected from exposure to animal reservoirs or animal products. Additionally, previous reports have listed the infectious dose for *Brucella* to be 10 to 100 bacteria, but research in closed environments indicate that aerosol exposure to a much higher concentration of bacteria is required to result in infection; thus, use of *Brucella* under natural conditions as a bioweapon would likely result in a limited to negligible rate of infection in humans or animals.

Costs associated with the effective eradication of swine and bovine brucellosis in the US between 1934 and 1998 are conservatively estimated to be over 3 billion dollars. The persistence of brucellosis in wildlife reservoirs with an expanding terrain both within the GYA and the greater US has resulted in potential incursions of the disease into the national domestic cattle and swine herds. A limitation on research due to the select agent status of *Brucella* spp. has reduced the capacity of research institutions to study *Brucella* under field conditions, a necessary step to develop effective vaccines and diagnostic tools. The continued expansion of wildlife reservoirs of *Brucella* spp. without efficient vaccines and sensitive, specific diagnostic tools will result in additional costs to producers, and state and federal governments for disease control programs.

RESOLUTION:

The United States Animal Health Association (USAHA) urges the United States Department of Homeland Security (DHS) to support the United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS) and the United States Department of Health and Human Services, Centers for Disease Control and Prevention in the removal of *Brucella abortus*, *Brucella suis*, and *Brucella melitensis* from the biological select agent and toxins list, thereby enabling needed *Brucella* spp. research and diagnostics.

INTERIM RESPONSE:

USDA, APHIS, Veterinary Services recognizes the concerns of USAHA and appreciates the opportunity to respond. USDA concurs with USAHA's recommendation to urge DHS to support the removal of select agent status for *Brucella* species to enable research and diagnostic work. USDA will continue to work with DHS and the Centers for Disease Control and Prevention on options to achieve this goal.

FINAL RESPONSE:

USDA, APHIS, Veterinary Services recognizes the concerns of USAHA and appreciates the opportunity to respond. APHIS concurs with USAHA's recommendation to urge DHS to support the removal of *brucella* species from the select agent (SA) list to enable research and diagnostic work. In March 2020, APHIS and CDC published an Advanced Notice of Proposed Rule Making notifying the public of the intention to remove *brucella* species and other pathogens from the SA list. APHIS received over 220 comments supporting removal of *brucella* from the SA list. APHIS is moving forward with the proposed rule to remove *brucella* from the SA list and will continue to work with CDC and DHS to explore options to achieve this goal.