RESOLUTION NUMBER: 30  APPROVED

SOURCE: COMMITTEE ON CATTLE AND BISON

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, 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 United States 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 United States 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 urges the United States Department of Agriculture, Animal and Plant Health Inspection Service, Veterinary Services and the United States Department of Health and Human Services, Centers for Disease Control and Prevention to remove *Brucella abortus*, *Brucella suis*, and *Brucella melitensis* from the biological select agent and toxins list, thereby enabling needed *Brucella* spp. research.

**INTERIM RESPONSE:**

The United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service, Veterinary Services (VS) recognizes the concerns of USAHA and appreciates the opportunity to respond. Agriculture Select Agent Services (AgSAS) recognizes the importance of *Brucella* spp. research to develop effective vaccines and diagnostic tools, as well as the financial impact of the disease spread for producers and agencies involved in disease control activities.

USDA continues to collaborate with the Department of Health and Human Services, which jointly regulates the Federal Select Agent Program with USDA, in consideration of delisting these agents. Throughout 2018, USDA collaborated with our federal partners, including the Department of Justice, Department of Homeland Security, Department of Defense, and others, to complete the mandated biennial review of the biological select agents and toxins list. In early 2019, USDA plans to issue an Advanced Notice of Proposed Rulemaking. We strongly encourage USAHA to provide comments and insight into the proposed revisions to the list of select agents and toxins.