

UNITED STATES ANIMAL HEALTH ASSOCIATION - 2009 RESOLUTION

OCTOBER 14, 2009, SAN DIEGO, CA

RESOLUTION NUMBER: 36 **APPROVED**

SOURCE: COMMITTEE ON BRUCELLOSIS

SUBJECT MATTER: REVIEW OF SELECT AGENT STATUS FOR *BRUCELLA ABORTUS*

BACKGROUND INFORMATION:

Introduction: With the reclassification of the state of Montana from brucellosis Class Free to Class A in 2008, the Greater Yellowstone Area (GYA) states of Idaho, Montana and Wyoming have sustained livestock brucellosis infections from a brucellosis infected wildlife reservoir that resulted in loss of status during the last 10 years. These reclassifications have cost the nation millions of dollars in additional testing costs, loss of trade and decreased market value. Further research in vaccine development and other aspects of *Brucella abortus* (*B. abortus*) control is needed.

Benefits of additional research: Greater understanding of vaccine technology, transmission, immune system response including diagnosis of animals in the “dormant” state of *B. abortus* infection are critical to:

- Accomplish the goal of the brucellosis eradication program;
- Implement regionalization of brucellosis disease management;
- Collect and archive samples for studies on Differentiating Infected from Vaccinated Animals (DIVA) diagnostics;

Further, increased understanding of *B. abortus* will assist management of *Brucella suis* and *B. abortus* in feral swine.

Current Limitations: Although further efforts in vaccine research and other aspects of *B. abortus* control are needed, current regulations and restrictions have nearly abolished these efforts. Guidelines from the Center for Veterinary Biologics for challenge studies necessitate 20 challenged animals, and 10 control animals, however, there are no facilities in the nation that can accommodate research on *B. abortus* in a covered research facility as is required by the Select Agent rule.

Building new facilities is costly, dependent on congressional appropriations, and not able to meet current research needs in a timely manner. Alternatively, the Outdoor Facilities Requirements developed by the United States Department of Agriculture (USDA), in principle, allows research on *B. abortus* to be conducted outside, however, the logistical and economic burdens make the implementation of the requirements impractical.

Summary: It is essential that *B. abortus* research be enhanced to better protect captive and free-ranging bovids and cervids, as well as to accomplish the USDA goal of eradicating *B. abortus* from the United States.

Delisting *B. abortus* from the select agent list is supported by characteristics of the organism which include: 1) little potential for aerosol transmission; 2) disease is treatable with readily available antibiotics; 3) the agent can easily be acquired from infected wildlife populations regardless of Select Agent status; 4) availability of highly sensitive and specific diagnostic tests for humans and livestock. These characteristics have allowed thousands of infected ungulates to roam the landscape in the GYA, with no public health consequences, but dramatic ramifications following rare transmissions to livestock,

and 5) based on existing need relative to the minimal potential for public health and national security risk.

RESOLUTION:

The United States Animal Health Association (USAHA) urges the United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS), Veterinary Services (VS) and the United States Department of Health and Human Services (USDHHS), Centers for Disease Control and Prevention (CDC) to support additional research on *Brucella abortus* (*B. abortus*) by removing *B. abortus* from the Select Agent List.

RESPONSE:

DHHS, CDC

As you may know, the "Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Subtitle A of Public Law 107-188 (42 U.S.C. 262a; the Bioterrorism Act)," requires the HHS Secretary to review and republish the Select Agent list on a biennial basis. HHS has already begun that review and plans to soon publish in the *Federal Register* an advanced notice of proposed rulemaking to ask for public input regarding, among other things, whether any of the currently listed select agents should be removed from the list. I have forwarded your letter to Dr. Robbin Weyant, Director of the Centers for Disease Control and Prevention's (CDC) Division of Select Agents and Toxins, so that your request can be incorporated into the current evaluation process. To that end, CDC would also be interested in your organization's views regarding *B. abortus* and the criteria listed in the Bioterrorism Act; including whether you believe *B. abortus* could be weaponized for use against humans.

Please be aware that there are attenuated strains of *B. abortus* (Strains RB51 and 19) that are excluded from the Select Agent regulations because these strains do not pose a severe threat to public health and safety. Information regarding excluded strains of select agents can be found at: <http://www.selectagent.gov/Select%20Agents%20and%20Toxins%20Exclusions.html>.

INTERIM RESPONSE

The U.S. Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS), Veterinary Services recognizes the United States Animal Health Association's (USAHA) concerns. Subtitle B, section 212(a)(2) of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, requires the USDA to conduct a biennial review of the list of select agents and toxins and to revise the list as necessary. APHIS quantitatively and objectively evaluates each agent using a method developed in accordance with the law. This process involves bringing together scientific government experts to evaluate each agent using certain criteria. The last review was completed and published in the *Federal Register* on October 16, 2008. Currently, APHIS is conducting another review of the select agent list. It is expected that APHIS, in conjunction with the Centers for Disease Control and Prevention, will develop a proposed rule, which will be open for public comment, from this biennial review in late 2010, which will make changes to the list of select agents.

Before implementing the select agent regulations, APHIS regulated the interstate movement and importation of *Brucella* in accordance with the Virus-Serum-Toxin Act and the Animal Health Protection Act. All importation and interstate movement of *Brucella* must occur under a USDA permit. In addition, laboratory inspections are required and APHIS will determine, based on the nature of the work and agent, what type of bio-safety level the facility will need to meet for the intended work. As a component of the containment requirements, maintaining a secured entry into laboratories and security on inventories of the agents was also required, in addition to controlling access to the agents.

Appropriate bio-safety protocols and facility requirements must be met to prevent dissemination of the agent into the environment.