

UNITED STATES ANIMAL HEALTH ASSOCIATION - 2008 RESOLUTION

RESOLUTION NUMBER: 21 APPROVED

SOURCE: COMMITTEE ON BRUCELLOSIS

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

BACKGROUND INFORMATION:

In 2005, the United States Animal Health Association (USAHA) *Laramie Agenda* identified the need for improved brucellosis vaccines, vaccine delivery systems, and diagnostics for wild bison and elk in order to advance the elimination of brucellosis from wildlife in the Greater Yellowstone Area (GYA). *Brucella abortus* (*B. abortus*) has been designated as a select agent by the United States Department of Agriculture (USDA) and the United States Department of Health and Human Services (USDHHS). The select agent rule makes it significantly more difficult to expand this body of knowledge by imposing restrictions that prevent further research on *B. abortus* because of increased expense and limitations on approved laboratory space needed for live animal trials and vaccine studies.

The Federal Select Agent Program is planning to publish an Advanced Notice of Proposed Rulemaking (ANPR) within the next year to allow the public to comment on the entire list of select agents, and based on public comments, decisions can be made to add or remove select agents.

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 review the criteria used to designate *Brucella abortus* (*B. abortus*) as a select agent. USDA-APHIS-VS should participate in and support the publication of the Advanced Notice of Proposed Rulemaking (ANPR), and include in the ANPR the rationale for removing *B. abortus* from the select agent list.

RESPONSE:

USDA, APHIS, Veterinary Services

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 Department of Agriculture 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; scientific experts from several USDA units offered guidance on the evaluation. The most recent review of the select agent list was published in the Federal Register on October 16, 2008. APHIS, in conjunction with CDC, will be developing an Advanced Notice of Proposed Rulemaking (ANPR) for the biennial review in 2010; however, the ANPR will list questions for comment from the public and does not support or outline any specific action or requirement. Rather, the ANPR is a tool to gain information from the public to help support and develop the proposed rulemaking. We would welcome comments from any members of USAHA at that time.