

FAX

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**FROM: U.S. Department of Agriculture
Animal and Plant Health Inspection Service
Legislative and public Affairs
Executive Communications**

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July 10, 2012

The Honorable Jon Tester
United States Senate
Washington, D.C. 20510

Dear Senator Tester:

Thank you for your May 29, 2012, letter requesting a review of the classification of *Brucella abortus* as a select agent. Both the Centers for Disease Control and Prevention (CDC) and U.S. Department of Agriculture (USDA) appreciate your concern about this issue and recognize the challenges researchers face in working with select agents. Enclosed are a brief history of the select agent review process for *B. abortus* and responses to your specific questions.

Scientific evidence continues to show that *B. abortus* is a potential severe threat to animal and human health. The most recent review of the select agent list by our agencies, in consultation with the Departments of Homeland Security, Defense, and Justice, and subject matter experts, recommends continued inclusion of *B. abortus* on the select agent list. The bacteria's ease of production, high infectivity via the aerosol route, low infectious dose, and the absence of an available brucellosis vaccine for humans support this recommendation.

The Department of Health and Human Services and USDA are reviewing public comments on the proposed list and expect to publish a final rule on *B. abortus* and other pathogens this fall. In the unlikely event that *B. abortus* is removed from the select agent list, research laboratories will still need to meet stringent biosecurity and biosafety requirements to guard against unintentional release of the agent into the environment. Even with these stringent biosecurity requirements, robust biological product research and development continues. These products are important components of ongoing brucellosis eradication efforts in livestock in the U.S.

Changes in the USDA- Animal and Plant Health Inspection Service (APHIS) regulatory program for the control and elimination of brucellosis are designed to focus resources and expertise on eliminating the disease reservoir in the greater Yellowstone area. USDA is also working with states and the livestock industry to demonstrate to trading partners that the U.S. is free of this disease. The continued characterization of *B. abortus* as a select agent is not at odds with the changes we are making to strengthen the brucellosis program, or our goal of eliminating brucellosis from the greater Yellowstone area.

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Thank you again for sharing your concerns. CDC and APHIS are committed to protecting human and animal health while allowing safe research and development. If you have additional questions, please feel free to contact Barbara Rogers in the CDC Washington Office at BRogers@cdc.gov or (202) 245-0600. A similar response is being provided to Senator Max Baucus, who cosigned your letter.

Sincerely,



Kevin Shea
Acting Administrator,
USDA-APHIS



Thomas R. Frieden, M.D., M.P.H.
Director, CDC

Enclosure

CDC and USDA-APHIS Response to Senators Baucus and Tester regarding *B. abortus*

Review process history

B. abortus was included in the first select agent list published in 1996 during the implementation of section 511(e) of the *Antiterrorism and Effective Death Penalty Act*. *B. abortus* remained on the select agent list during the promulgation of the current select agent regulations implementing the provisions of the *Public Health Security and Bioterrorism Preparedness and Response Act of 2002* (the Bioterrorism Response Act), which requires the HHS and USDA secretaries to biennially review and republish the select agent list. *B. abortus* has been retained as a select agent after two subsequent biennial reviews that included the opportunity for public comment. The departments are currently conducting the latest biennial review.

As part of the current review, we published a proposed select agent list on October 3, 2011 (76 FR 61206), which proposed that *B. abortus* be retained as an HHS and USDA select agent. The public comment period for this biennial review closed on January 17, 2012. HHS and USDA expect to publish the final rule this fall.

In addition to public input received as part of the biennial review process, CDC and APHIS also consider recommendations from subject matter experts, including the Intra-Governmental Select Agents and Toxins Technical Advisory Committee (ISATTAC) and the Federal Experts Security Advisory Panel (FESAP). ISATTAC has participated in every biennial review of the current select agent list since its inception in 2005. FESAP was established by Executive Order 13546 "Optimizing the Security of Biological Select Agents and Toxins in the United States" and it serves to advise the HHS and USDA secretaries on the designation of Tier 1 agents and toxins and the reduction in the number of agents on the select agent list.

Answers to specific questions asked in the incoming letter

What comments have your agencies received from stakeholders and scientists regarding *Brucella* pathogens generally, and specifically the appropriate level of distinction between the different species of *Brucella*?

During the public comment period for the current biennial review, which closed on January 17, 2012, HHS and USDA received 143 comments, and two mentioned *Brucella*. One commenter suggested removing *Brucella melitensis* from a subset of the list of overlap select agents and toxins whose identification by any clinical or diagnostic laboratory requires immediate reporting to APHIS or CDC via phone, fax, or e-mail. Our proposed rule already suggests making that change. Another commenter suggested moving *Brucella abortus*, *Brucella melitensis*, and *Brucella suis* to a lower tier in the commenter's proposed multi-tiered structure. Our proposed rule does not include any of these agents as Tier 1 select agents.

HHS and USDA received comments from the following professional organizations: the American Association for the Advancement of Science, the American Biological Safety Association, the American Society for Microbiology, the Association of American

Universities, the Association of Public and Land-Grant Universities, the Association of Public Health Laboratories, the Council on Governmental Relations, and the Infectious Diseases Society of America. None had comments regarding *B. abortus*

What laboratory resources are available to perform research on *B. abortus* today compared with the resources available before listing as a select agent?

A total of 168 entities are registered with the Federal Select Agent Program to possess *B. abortus*. These entities include laboratories performing research with *B. abortus*. This is an increase from the 123 entities that were registered with the Federal Select Agent Program in 2003. We are unable to determine the number of laboratories performing research with *B. abortus* before the Federal Select Agent Program was initiated.

USDA's Agricultural Research Service (ARS) continues its long-standing *Brucella* research program at the National Animal Health Laboratories in Ames, Iowa. Scientists at the National Animal Disease Center work closely with researchers in other states and institutions to try to develop control strategies for use in the greater Yellowstone region. ARS' ongoing studies include evaluating the current cattle vaccine, RB51, for its ability to reduce transmission in bison and elk. If you or your staff have questions about ARS' research efforts, please feel free to contact Dr. Eileen Thacker, National Program Leader for Animal Health, at (301) 504-5774 or eileen.thacker@ars.usda.gov.

Have there been any known attempts to use *B. abortus* as a biological weapon?

DHS advises CDC that prior to the implementation of the Biological Weapons Convention, zoonotic *Brucella* species including *B. abortus* had been part of the biological weaponization programs of several countries.

How many human cases of brucellosis have been attributed to *B. abortus* in the past ten years, and what have been the outcomes of those cases?

Since 2002, CDC has received 368 *Brucella* isolates from persons with human cases of brucellosis. CDC identified 33 of these isolates as *B. abortus*. CDC does not have access to any of the outcome data.

In addition, the Federal Select Agent Program receives information on select agent "release" reports (occupational exposures or releases of a select agent outside of the primary barriers of the biocontainment area) and "loss" reports (failure of a registered entity to account for a select agent or toxin). Since 2003, the Federal Select Agent Program has received 56 such reports that involved *B. abortus*.