



DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS-2020-0094]

Notice of Availability of a Draft Federal Select Agent Program Policy Statement for Biosafety for Large Animal Study-Related Activities with *Brucella abortus* and *Brucella suis* Using Outdoor Containment Spaces

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice of availability.

SUMMARY: We are advising the public that the Animal and Plant Health Inspection Service (APHIS) is making a draft Federal Select Agent Program (FSAP) policy statement related to brucella available. This policy statement will aid individuals and entities on how to develop biosafety plans for outdoor host animal studies involving swine, elk, bison, and cattle to further brucellosis research in accordance with the select agent and toxin regulations, as well as how to submit such plans to FSAP (administered jointly by the Centers for Disease Control and Prevention (CDC) and APHIS) for approval. We are making this draft policy statement available to the public for review and comment. This notice is being issued as a companion to a notice issued by CDC, which is also published in today's *Federal Register*.

DATES: We will consider all comments that we receive on or before [Insert date 30 days after date of publication in the Federal Register].

ADDRESSES: You may submit comments by either of the following methods:

- Federal eRulemaking Portal: Go to <http://www.regulations.gov/#!docketDetail;D=APHIS-2020-0094>.
- Postal Mail/Commercial Delivery: Send your comment to Docket No. APHIS-2020-0094, Regulatory Analysis and Development, PPD, APHIS, Station 3A-03.8, 4700 River Road Unit 118, Riverdale, MD 20737-1238.

The draft policy statement and any comments we receive may be viewed at <http://www.regulations.gov/#!docketDetail;D=APHIS-2020-0094> or in our reading room, which is located in room 1620 of the USDA South Building, 14th Street and Independence Avenue SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 799-7039 before coming.

The draft policy statement is also available at the following internet address:

<https://www.selectagents.gov/regulations/policy/animalstudy.htm>.

FOR FURTHER INFORMATION CONTACT: Dr. Jacek Taniewski, DVM, Director, Division of Agricultural Select Agents and Toxins, ERCS, APHIS, 4700 River Road, Riverdale, MD 20737; (301) 851-3352; jacek.taniewski@usda.gov.

SUPPLEMENTARY INFORMATION:

Background

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (42 U.S.C. 262a) and the Agricultural Bioterrorism Protection Act of 2002 (7 U.S.C. 8401) provide for the regulation of certain biological agents and toxins that have the potential to pose a severe threat to human, animal, and plant health, or to animal and plant products. The Animal and Plant Health Inspection Service (APHIS) has the primary responsibility for implementing the provisions of the Agricultural Bioterrorism Protection Act of 2002 within the U.S. Department of Agriculture (USDA). The Centers for Disease Control and Prevention (CDC) has the primary responsibility for implementing the provisions of The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 within the Department of Health and Human Services (HHS). Together, APHIS and CDC comprise the Federal Select Agent Program (FSAP) and oversee the possession, use, and transfer of biological agents and toxins, referred to as select agents and toxins. In accordance with the referenced Acts, APHIS and CDC promulgated the select agent and toxin regulations found in 7 CFR part 331, 9 CFR part 121, and 42 CFR part 73.

Overlap select agents and toxins, listed in 9 CFR 121.4 and 42 CFR 73.4, are those select agents and toxins that have been determined to pose a severe threat to public health and safety, to animal health, or to animal products. Overlap select agents and toxins are subject to regulation by both APHIS and CDC.

Brucellosis, also known as contagious abortion or Bang's disease, is a contagious, costly disease that has significant animal health, public health, and international trade consequences. While most often found in ruminant animals (e.g., cattle, bison, cervids, and swine), brucellosis can affect other animals and is transmissible to humans. Brucellosis is caused by a group of bacteria known scientifically as the genus *Brucella*. Two species of *Brucella* are of particular concern in the United States: *B. abortus*, principally affecting cattle, bison, and cervids, and *B. suis*, principally affecting swine and reindeer, but also cattle and bison.

Brucellosis can be costly to agriculture production. In 1952, prior to established efforts to eradicate the disease, agriculture production losses due to brucellosis exceeded \$400 million. A cautionary indicator of the need for greater understanding of the disease is the expanding range of endemic *B. abortus* in the Greater Yellowstone Area and *B. suis* in feral swine populations throughout various areas of the United States. This disease expansion emphasizes the critical need for improved diagnostics, along with vaccine development for both *Brucella* species, which could be furthered by outdoor research studies.

Both *B. abortus* and *B. suis* are currently listed as overlap select agents in APHIS' and CDC's select agent and toxin regulations (9 CFR 121.4(b) and 42 CFR 73.4(b), respectively). Accordingly, any outdoor research studies must comport with the select agent and toxin regulations. Therefore, APHIS and CDC are issuing a draft FSAP policy statement on biosafety for large animal outdoor containment studies with *B. abortus* and *B. suis* to aid individuals and entities in the development of biosafety plans for such studies that meet the requirements of the select agent and toxin regulations. We are making this draft policy statement available to the public for review and comment on regulations.gov (see ADDRESSES above) and at

<https://www.selectagents.gov/regulations/policy/animalstudy.htm>. We will consider all comments that we receive on or before the date listed under the DATES section at the beginning of this notice.

Copies of the draft policy statement are also available for public inspection at USDA, room 1620, South Building, 14th Street and Independence Avenue SW., Washington, DC, between 8 a.m. and 4:30 p.m., Monday through Friday, except holidays. Persons wishing to inspect copies are requested to call ahead on (202) 799-7039 to facilitate entry into the reading room. In addition, copies may be obtained by calling or writing to the individual listed under FOR FURTHER INFORMATION CONTACT.

Authority: 7 U.S.C. 8401; 7 CFR 2.22, 2.80, 371.3, and 371.4.

Done in Washington, DC, this 11th day of January 2021. .

Mark Davidson,

Administrator, Animal and Plant Health Inspection Service.

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