



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

42 CFR Part 73

[Docket No. CDC-2021-0003]

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

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice of availability and request for comment.

SUMMARY: The Centers for Disease Control and Prevention (CDC) in the Department of Health and Human Services (HHS) is opening a public docket to obtain comment on a draft *Brucella* policy statement. This draft policy statement, when finalized, will aid individuals and entities in the development of biosafety plans for outdoor large animal studies involving swine, elk, bison, and cattle to further brucellosis research in a manner that complies with the HHS and U.S. Department of Agriculture (USDA) select agent regulations. In a companion document published in this issue of the *Federal Register*, USDA has proposed the same policy for comment.

DATES: Submit written or electronic comments by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments, identified by Docket No. CDC-2021-0003 by either of the methods listed below. Do not submit comments by email. **CDC does not accept acomments by email.**

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.
- Mail: Division of Select Agents and Toxins, Centers for Disease Control and Prevention, 1600 Clifton Road N.E., Mailstop H21-7, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket No. CDC-2021-0003 for this rulemaking. All relevant comments received will be posted without change to <http://www.regulations.gov>, including any personal information provided.

Docket Access: For access to the docket to read background documents or comments received, or to download an electronic version of the draft policy statement, go to <http://www.regulations.gov>. Please be aware that comments and other submissions from members of the public are made available for public viewing without changes.

FOR FURTHER INFORMATION CONTACT: Samuel S. Edwin Ph.D., Director, Division of Select Agents and Toxins, Centers for

Disease Control and Prevention, 1600 Clifton Road N.E., Mailstop H21-7, Atlanta, Georgia 30329. Telephone: (404) 718-2000.

SUPPLEMENTARY INFORMATION:

A. Legal Authority

HHS/CDC is promulgating this policy under the authority of sections 201-204 and 221 of Title II of Public Law 107-188, 116 Stat 637 (42 U.S.C. 262a).

B. Background

Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Response Act) (42 USC §262a(a)(1)), the HHS Secretary regulates a list of biological agents and toxins that have the potential to pose a severe threat to public health and safety. The biological agents and toxins listed in 42 CFR §73.3 (HHS select agents and toxins) have the potential to pose a severe threat to human health and safety and are regulated only by HHS/CDC. The biological agents listed in §73.4 (overlap select agents and toxins) have not only the potential to pose a severe threat to human health and safety; but have been determined by the USDA, pursuant to USDA's authority under the Agriculture Bioterrorism Protection Act of 2002 (7 USC §8401), to have the potential to pose a severe threat to animals and animal products. Accordingly, these biological agents are jointly regulated by HHS/CDC and USDA as "overlap" select agents. The Bioterrorism Response Act defines the term "overlap agent or toxin" to mean a

biological agent or toxin that is listed pursuant to 42 USC §262a and is listed pursuant to 7 USC §8401. See 7 USC §8411.

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* found 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 select agent regulations (42 CFR §73.4 and 9 CFR §121.4). Accordingly, any outdoor research studies must

comport with the select agent and toxin regulations. Therefore, HHS/CDC and USDA are issuing a FSAP draft 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 regulations. We are making this policy document available to the public at the Supporting & Related Materials tab of the docket and at <https://www.selectagents.gov/regulations/policy/animalstudy.htm> for review and comment.

Copies of the policy document 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.

Sandra Cashman,

Executive Secretary,

Centers for Disease Control and Prevention.