**Draft letter from NASAHO regarding Select Agent status of *Brucella* species and Coxiella burnetii**

April 6, 2020

**USDA APHIS, Regulatory Analysis & Development, PPD, APHIS**

Station 3A-03.8

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Reference: Comments on Select Agent Rule, Docket No.APHIS-2019-0018

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**Division of Select Agents and Toxins, Centers for Disease Control and Prevention**

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Reference: Comments on Select Agent Proposed Rule, Docket ID:CDC\_FRDOC\_0001

To whom it may concern:

The limitation on research due to the select agent status of *Brucella* species and Coxiella burnetii has restricted the capacity of research institutions to study these organisms under field conditions, a necessary step to develop effective vaccines and diagnostic tools. The continued expansion of wildlife reservoirs of *Brucella* spp. without efficacious vaccines and sensitive, specific diagnostic tools will result in additional costs to producers, state and federal disease control programs as well as a continued threat to public health. The continued existence and spread of Coxiella burnetii (Q Fever) as an endemic disease in livestock and wildlife poses undue risk to public health.

There is a critical need to develop vaccines, therapies, and diagnostic tools necessary for disease surveillance, control measures and eventual eradication of Brucella abortus in the Greater Yellowstone Area (GYA) and B. suis and Coxiella burnetii in endemic areas of the US. Research should be allowed in appropriate laboratory and field settings so that these bacterial species can eventually be contained or eliminated in susceptible populations.

Select Agent regulations restrict possession, transfer, and use of select agents and toxins to protect the Nation from terrorist attacks. The restrictions have been highly effective in limiting access to dangerous agents and toxins by unauthorized individuals. Unfortunately, these same restrictions have limited opportunities for important research on *Brucella* species, including *B. abortus*, *B. melitensis*, and *B. suis*. *Brucella* *abortus* is a disease endemic in GYA bison and elk, while *Brucella* *suis* is endemic in feral swine populations throughout the United States. The same can be said of Coxiella burnetii. These organisms are already in the natural environment in the U.S while *Brucella* *melitensis* is a foreign pathogen that has successfully been kept out of domestic livestock and wildlife populations in the United States.

A recent paper published by Olsen et. al provides scientific evidence supporting that *Brucella* species can be removed from the biological select agent and toxins list based on clinical, biological, and epidemiological properties of the bacteria. In particular, the paper highlights that *Brucella* species are readily available in endemic areas, thus easily attained by individuals or groups with nefarious intentions. Previous reports estimating human morbidity and mortality in the event of a *Brucella* bioweapons attack did not adequately consider the fact that Brucellosis is the most common zoonotic infection reported in humans annually worldwide. When a human is infected, the bacteria is not likely to spread further (considered a “deadend host”). Additionally, previous reports have listed the infectious dose for *Brucella* to be 10 to 100 bacteria, but research in closed environments indicate that aerosol exposure to a much higher concentration of bacteria is required to result in infection. Use of *Brucella* under natural conditions as a bioweapon would likely result in a limited to negligible rate of infection in humans or animals.

Costs associated with the effective eradication of swine and bovine brucellosis in the United States between 1934 and 1998 are conservatively estimated to be over $3 billion dollars. The persistence of Brucellosis in wildlife reservoirs with an expanding terrain both within the GYA and the greater United States has resulted in potential incursions of the disease into the national domestic cattle and swine herds.

The National Assembly of State Animal Health Officials strongly 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 remove the Brucella species (*B.* *abortus*, *B. suis*, and *B. melitensis)* and Coxiella burnetii from the biological select agent and toxins list, thereby supporting additional research to control these natural pathogens. While we support removal of these species from the Select Agent and Toxin List, we encourage authorities to retain the diseases caused by these agents as reportable diseases with appropriate regulatory disease control responses.

We thank you for your consideration and ask that the science be considered and that risks be weighed against the benefits to research and industry if the agents are delisted.

 Thank you.

Dr Annette Jones

President of the National Assembly of State Animal Health Officials

*The National Assembly of State Animal Health Officials (NASAHO, or the National Assembly) is an organization comprised of the state and territorial animal health officials of the United States. Our mission is to work collectively to safeguard animal and public health as well as the food supply. We accomplish this by working with federal, state, and industry partners to develop science-based policies to address issues that affect public and animal health, public safety, and commerce. We strive to use the best available science to formulate our positions and to reach consensus among all members whenever possible.*

 *The National Assembly is uniquely qualified to assess the impact of animal health threats in our individual states and territories, as well as how those threats will affect our nation. We are aware of available resources to mitigate threats, as well as gaps that represent vulnerabilities to those threats and our abilities to address them. We are hopeful that you will consider us to be a valuable resource in addressing any animal health related issues.*