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Dr. Robbin Weyant
Director, Division of Select Agents and Toxins
Centers for Disease Control
1600 Clifton Rd. MS A-46
Atlanta, GA 30333

RE: Comments on changes to the list of Select Agents and Toxins

Dear Dr Weyant,

I am writing in response to the request for comments on changes to the list of Select Agents and Toxins as announced in the Federal Register/Vol. 75, No. 139/42363. I am a Ph.D. microbiologist with 10 years of research experience on biosafety level-3 bacteria including the Select Agent pathogens *Francisella tularensis* and *Brucella* spp. I would like to provide input on the inclusion of *Brucella melitensis*, *Brucella abortus* and *Brucella suis* on the HHS List, as well as on stratification of the list. I have been leading research programs on *Francisella* and *Brucella* spp. for the last 6 years under the Select Agents Program regulations and I am currently a member of the NIAID's Rocky Mountain Laboratories Institutional Biosafety Committee. It is from this perspective and with this experience that I support a stratification of the Select Agent list and recommend that *Brucella* spp. be classified within the lowest risks agent tier of a stratified security scheme (if adopted).

I believe that biosecurity is important and I would like to recognize the work of your Division to ensure a safe and secure working environment for scientists studying Select Agents. Physical security, restricted access, adequate biosafety laboratories and practices, FBI background checks, and adequate training are necessary procedures. However, I also believe that not all Select Agents should be dealt with using the same array of specific SA security rules and regulations, since they certainly do not all present the same biological risks to human health in terms of rapid spread, high morbidity and mortality and availability of therapeutics. Additionally, natural occurrence of a Select Agent in the environment should also be an important criterion in defining biosecurity rules for laboratories possessing and working with such agents. I would therefore strongly support a stratified security scheme for Select Agents based upon criteria that have been used by the HHS Secretary when listing a pathogen as a Select Agent.



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With these criteria in mind, I would like to point out the reasons why I believe *Brucella* spp. should be considered a low risk Select Agent, and perhaps have its Select Agent status reconsidered.

- 1) Human infection with *Brucella* spp. is rarely fatal and acute brucellosis can be readily treated with available antibiotics to prevent chronic disease. Furthermore, *Brucella* spp. in nature do not readily acquire genetic material conferring antibiotic resistance, rendering the occurrence of antibiotic-resistant strains very unlikely;
- 2) Human-to-human transmission is extremely rare, so that in the case of illicit dissemination, infection would be contained to treatable, initial cases and would therefore present a very restricted risk to a human population;
- 3) Brucellosis is endemic in many areas of the world, and *Brucella* spp. are naturally present in the environment in non-endemic areas, such as the United States, where wildlife carriers (bison, elk, feral swine) often come into contact with humans yet without significant transmission. This exemplifies the low risk that *Brucella* spp. pose to human populations in non-endemic areas;

When considering the epidemiology and pathogenesis of brucellosis, it is my opinion that these pathogens pose limited threat to human health and safety, especially compared to other highly infectious, easily spreadable, fatal Select Agents, such as *Bacillus anthracis*, *Yersinia pestis* or *Francisella tularensis*. A reexamination of the Select Agents list towards a tiering of security requirements seems therefore to be warranted when comparing such pathogens, in which low transmissibility from person-to-person, low morbidity, difficulty in propagation, poor environmental stability, and susceptibility to readily available antibiotics, should justify handling of certain Select Agents at a lesser degree of security, if not removal from the list.

It is my hope that such changes will promote a research environment that is more conducive to scientific discoveries and advances on these organisms - many of which are critically understudied due to regulatory burdens - while retaining all the necessary safety associated with working with these pathogens.

Sincerely,

A handwritten signature in black ink, appearing to read "J. Celli".

Jean Celli, Ph.D.
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