COLLEGE OF VETERINARY MEDICINE
& BIOMEDICAL SCIENCES
Department of Veterinary Pathobiology

TEXAS A&M UNIVERSITY

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Centers for Disease Control and Prevention
Division of Select Agents and Toxins
1600 Clifton Road, MS A– 46
Atlanta, GA 30333.

Gentlemen;

The responses expressed below are my personal opinions based on more than 25 years of research with *Brucella* species and are not meant to reflect the opinions of Texas A&M University or any other individuals working at TAMU or within the TAMU system.

The responses below are provided in answer to the solicitation in 42 CFR Part 73 RIN 0920–AA34 Public Health Security and Bioterrorism Preparedness and Response Act of 2002; Biennial Review and Republication of the Select Agent and Toxin List in which HHS has requested whether any biological agent or toxin should be added to or removed from the list and whether a ‘‘tier’’ of select agents developed based on the relative bioterrorism risk of each agent or toxin in an effort to ‘‘stratify’’ the security requirements for agents in the highest tier.

It is clear from the current stratification of the select agent list that there has always been recognition of differences between agents, resulting in the distinction between categories A, B and C. Unfortunately, the regulations as written did not specify their application according to agent class. In fact, the only evidence that this was ever taken into consideration is based on funding priorities applied to select agent research. The basis for their distinction into categories A, B and C were (it was thought) meant to reflect their bioterror or biowarfare threat and is presumably based on the impact the release of such an agent would have based on factors elaborated below. I would like to suggest that these same factors should be applied for consistency to all considerations regarding security and safety.

Criteria that were presumably used in developing the list of A, B and C agents, include the mortality and morbidity associated with human infection which is controlled in part by the availability of interventions used to arrest or prevent infection in individuals resulting from a primary event, and to prevent the secondary spread of infection, i.e., therapeutics and vaccination. Infection may spread from the primary site of infection resulting from secondary transmission including human-human, human-animal, or vector borne spread of disease to other individuals or the community at large via insects, birds or other vectors. In addition, analysis should also include a determination of the stability of the agent in the environment that is not only limited to physical stability, but also includes the

potential for chronic infection and potential reemergence. Since the potential for secondary spread is agent specific, these factors should be evaluated individually to prevent against unwarranted measures and adverse public reaction.

For agents that are not transmissible between humans or known to be spread naturally by vectors, restrictions placed on experimentation may be doing greater harm to public safety than a potential accidental release given that may be readily contained by properly trained personnel. An additional factor that should govern the level of security is the natural prevalence of the agent in the environment. Several of the agents listed are endemic in certain areas and may be readily collected making extreme security requirements ineffectual.

Perhaps any re-evaluation of the use of these criteria are best considered with specific examples. One example of an agent that might be placed at a lower tier is the *Brucella* species. The reasons include the fact that infection requires contact of the agent with mucous membranes and typically occurs as a result of consumption of infected animals tissue/excretion. However, the organism is stable in aerosol and infectious at low dose making it a considerable risk for primary exposure. But it is sensitive to mild heat @ 60°C, sunlight and disinfectants, and does not form spores. Thus, although primary exposure is of concern, delivery would require a concerted effort to weaponize the agent. Secondary spread may be expected to be quite limited based on only a single report of possible sexual transmission between humans. Brucella transmission to humans from animals is a well-known phenomenon, but transmission from humans to animals has not been documented. The prevalence of the agent globally (the number one cause of zoonotic infection) means that it is readily available outside the lab, even within the U.S. (feral swine, elk, bison, reindeer). Thus, although potential for misuse may be exacerbated by persistence in the environment including animal hosts, the ready availability of the agent and the limited potential for secondary spread argue against inclusion in an elevated security tier.

Finally, the ability of biological select agents to replicate renders counting vials a meaningless exercise. Quantities of agent may be removed that are undetectable and amplified to provide lethal doses of agent. Thus, the fact that a vial may be present and accounted for provides no certainty of security and absorbs a great deal of valuable time to maintain. Accountability is best served by controlling access to qualified and trained personnel. Furthermore the requirements placed on these laboratories cannot be readily absorbed by the budgets provided. Federal funding should be made available to ensure appropriate facility operation.

To summarize, it is my opinion that any changes made to the security requirements should be risked-based. Constant training and inspection of personnel has focused on risk-based analysis which may or may not be suspended for unspecified reasons. Work is performed by reasonable and conscientious individuals who have a vested interested in preventing against accidental release or misuse and consistency is critical to their understanding and participation.

Sincerely,

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