



August 18, 2010

Centers for Disease Control and Prevention
Division of Select Agents and Toxins
1600 Clifton Road
MS A-46
Atlanta, GA 30333
(email: SAPcomments@cdc.gov)

RE: Comments on the changes to the list of select agents and toxins.

Dear Dr. Weyant and colleagues:

We thank you for the opportunity to comment as part of the biennial review and republication of the select agent and toxin list. The University of Texas Medical Branch (UTMB) at Galveston, Texas, maintains a large and robust research program involving select agents. In addition, UTMB is home to the Galveston National Laboratory (GNL), a recently completed modern containment laboratory where select agents and other pathogens requiring biological safety level 2, 3 and 4 containment can be safely and securely stored and handled in both basic research and translational product development. Our students, staff and scientists are directly affected by and intimately familiar with the select agent regulations and the need to maintain a safe and secure environment for handling these pathogens. Our approximately 350 individuals cleared to handle select agents strictly adhere to the select agents regulations on a daily basis, and as such they represent an informed users group with significant and highly relevant experience in this field.

We have contributed significantly to the American Society of Microbiology response to the biennial review of the select agent list, and we strongly endorse the recommendations made in their letter. We take this opportunity to further emphasize the follow points:

- We support the suggestion made by many to stratify the select agent list and the biosecurity requirements commensurate with risk. We suggest that a three-tiered system be considered, with Tier 1 dedicated solely to smallpox (variola virus), with biosecurity requirements consistent with those already in place and endorsed by the World Health Organization.*

INSTITUTE FOR HUMAN INFECTIONS AND IMMUNITY
UTMB CENTER FOR BIODEFENSE AND EMERGING INFECTIOUS DISEASES • SEALY CENTER FOR VACCINE DEVELOPMENT
WORLD HEALTH ORGANIZATION COLLABORATING CENTER FOR TROPICAL DISEASES
UTMB CENTER FOR HEPATITIS RESEARCH • McLAUGHLIN ENDOWMENT FOR INFECTION AND IMMUNITY

ROOM 6.200 GNL, 301 UNIVERSITY BOULEVARD, GALVESTON, TEXAS 77555-0610
(409) 266-6500 FAX (409) 266-6810

- We suggest that Tier 2 include the following pathogens:
 - Arenaviruses causing South American hemorrhagic fevers (Guanarito, Junin, Machupo and Sabia viruses*)
 - Bacillus anthracis*
 - Botulinum neurotoxins (including neurotoxin producing species of *Clostridium*)
 - Crimean-Congo hemorrhagic fever virus
 - Ebola viruses (all recognized “species”)
 - Francisella tularensis*
 - Lassa fever virus
 - Marburg virus
 - Reconstructed replication competent forms of 1918 influenza virus*

- We suggest that Tier 3 include the following pathogens and toxins:
 - Coxiella burnetti*
 - Eastern Equine Encephalitis virus
 - Rickettsia prowazekii*
 - Staphylococcal enterotoxins
 - Brucella abortus*
 - Brucella melitensis*
 - Brucella suis*
 - Burkholderia mallei*
 - Burkholderia pseudomallei*
 - Flaviviruses of the Tick-borne encephalitis complex (Central European TBE; Far Eastern TBE; Kyasanur Forest Disease; Omsk hemorrhagic fever; Russian spring-summer encephalitis)
 - Hendra virus
 - Nipah virus
 - Rift Valley fever virus
 - Venezuelan Equine Encephalitis virus
 - Ricin
 - Abrin

- We recommend that the following pathogens and toxins be removed from the select agent list:
 - Coccidioides posadasii/Coccidioides immitis*
 - Monkeypox virus
 - Flexal virus (South American Arenavirus)*
 - Cercopithecine herpesvirus 1 (Herpes B)
 - Several toxins as suggested by ASM: Shiga-like ribosome inactivating proteins, shigatoxin, T-2 toxin, tetrodotoxin, conotoxin, diacetoxyscirpenol, *Clostridium perfringens* epsilon toxin.

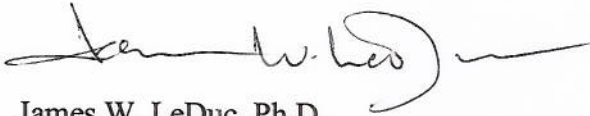
- We believe that those who work with select agents should be responsible for the safe and secure handling of the pathogens under their control; however, the requirement to account for individual vials of each pathogen is inappropriate for replicating agents. This is a costly and burdensome responsibility for laboratories and their staff that should be abolished except for Tier 1 agents (smallpox) where such accounting is mandated by WHO. We strongly recommend the elimination of this requirement for Tier 2 and Tier 3 agents.

- Finally, we endorse the recommendation by the National Academy of Sciences report on Responsible Research with Biological Select Agents and Toxins suggesting that the current Security Risk Assessment screening process should include an appeal process to consider the circumstances surrounding otherwise disqualifying factors.

*These recommendations may differ from those of ASM.

We appreciate the opportunity to comment on the biennial review of the select agent list and stand ready to assist should you have questions or require clarification on any of the points we propose.

Yours sincerely,

A handwritten signature in black ink, appearing to read "James W. LeDuc", with a long horizontal flourish extending to the right.

James W. LeDuc, Ph.D.
Professor, Microbiology and Immunology
Robert E. Shope M.D. and John S. Dunn
Distinguished Chair in Global Health
Director, Galveston National Laboratory
Director, Program in Global Health
Institute for Human Infections and Immunity

JWL:daj