

Title: Review of Requests to Exclude Attenuated Strains of Select Agents and Modified Select Toxins, Division of Select Agents and Toxins, 2003-2016

Subject of Planned Report: The Centers for Disease Control and Prevention's Division of Select Agents and Toxins (DSAT) regulates the possession, use, and transfer of select agents and toxins throughout the United States as part of the Federal Select Agent Program (FSAP). The Health and Human Services (HHS) select agent regulations also include criteria for the exclusion of select agents and toxins from the requirements of the regulations (42 CFR § 73.3 and 73.4). An entity may request the exclusion of an attenuated (reduced in virulence) strain of a select agent or a select toxin modified to be less, potent or toxic. This report describes the review of requests to exclude attenuated strains of select agents and modified select toxins by the Division of Select Agents and Toxins from 2003 to 2016.

Purpose of Planned Report: Disseminate information on the review of requests to exclude attenuated strains of select agents and modified select toxins as part of the Federal Select Agent Program.

Type of Dissemination: ISI Publication intended in a peer-reviewed journal

Timing of Review (including deferrals): 8 months (10/04/2017 to 5/25/2018)

Type of Review (panel, individual or alternative procedure): This report was reviewed by subject matter experts including the Office of the Associate Director for Laboratory Safety and Science (OADLSS), the chain of command including the Director of the Office of Public Health Preparedness and Response (OPHPR) and the CDC Office of the Associate Director for Science (OADS), and an external reviewer at the United States Department of Agriculture (USDA).

Opportunities for the Public to Comment (how and when): Not until journal embargo is lifted

Peer Reviewers Provided with Public Comments before the Review: Journal reviewers and USDA reviewer (outside of HHS)

Anticipated Number of Reviewers: Journal reviewers (2), Clearance reviewers (10), USDA (1)

Primary Disciplines or Expertise: Public Health Practice, Preparedness and Response, Microbiology, Regulatory Practice, Policy

Reviewers Selected by (agency or designated outside organization): Both

Public Nominations Requested for Reviewers: No

Charge to Peer Reviewers: Scientific accuracy and integrity

Additional elements to be added to the public posting as they become available

For each Peer Reviewer Selected: *Only listing the external reviewer at USDA*

Last Name, First Name, Middle Initial: Narda Huyke

Academic and Professional Credentials: Doctor of Veterinary Medicine

Current Position Title: Senior Veterinary Medical Officer

Organizational Affiliation(s): U.S. Department of Agriculture (USDA)

Areas of Expertise, Discipline, Relevant Experiences: Senior VMO with USDA, APHIS, Agriculture Select Agent Services (AgSAS), currently detailed as Technical Unit Director. Bachelor of Science and Doctor of Veterinary Medicine degrees from the University of Illinois. Residency in veterinary pathology, worked as laboratory animal veterinarian and in research compliance. Also worked at the National Veterinary Services Laboratories (NVSL) in the Diagnostic Virology Laboratory, for the Equine and Ovine Viruses Section and the Bovine and Porcine Viruses Section. Committee member on two Institutional Biosafety Committees and one Institutional Animal Care and Use Committee.

Recommended by Scientific/Professional Society or General Public: Subject matter expert's recommendation

Charge to Peer Reviewers: Scientific accuracy and integrity

Peer Reviewers' Comments: Sent to authors for inclusion in final version of manuscript

CDC/ATSDR's Response to Reviewers' Comments: Addressed in current version – available after journal embargo

The ISI/HISA Dissemination Itself: NA