February 11, 2016

Centers for Disease Control and Prevention
Division of Select Agents and Toxins
1600 Clifton Road, NE, Mailstop A-46
Atlanta, GA 30329

Animal and Plant Health Inspection Service
Agriculture Select Agent Services
4700 River Road, Unit 2, Mailstop 22, Cubicle 1A07
Riverdale, MD 20737

RE: FSAP Policy Statement: Inactivated *Bacillus anthracis*

Dear Dr. Sosin and Dr. Isaac,

The American Biological Safety Association (ABSA International) welcomes the Federal Select Agent Program (FSAP) Policy Statement entitled, “Inactivated *Bacillus anthracis*”, released on November 30, 2015. ABSA International provides a critical expertise for this topic as many of its members are extensively involved in implementing the Federal Select Agent Program and fulfilling certain roles specified therein.

ABSA International has reviewed the FSAP policy. Regarding *B. anthracis* inactivation criteria that meets the exclusion found in the select agents and toxins regulations, section 3(d)(2) and section 4(d)(2) referenced in the FSAP policy statement, ABSA International would like to provide the following comments for your consideration:

Exclusion criteria 1: ABSA supports the determination to regulate *B. anthracis* preparations that are not inactivated using a validated procedure as select agents. It is recognized that materials handled prior to the release date of the policy and materials inactivated prior to June 2, 2015, as specified in the policy may still pose a risk.

Exclusion criteria 2(b): The viability test method to inoculate and incubate a broth culture for 48 hours, prior to plating, followed by incubating the plate culture for 48 hours is an appreciated measure to recoup compromised bacteria. The validation or assessment of this method to prove a negative, the absence of viable material, is not discussed.
Validation of the viability test is encouraged, to include application to the various *B. anthracis* strains. Consideration is also encouraged to evaluate a more extended incubation period for the test method, avoiding desiccation of the growth media, to ensure that the absence of growth is clearly established. Also, as static liquid cultures, versus shaking incubations, are commonly practiced in BSL-3 laboratories to reduce risk, clarification is also desired as to whether static broth culture incubations are effective for the viability test method described.

ABSA appreciates the FSAP policy statement on inactivated *B. anthracis* and supports the measure to ensure safe and controlled handling of *B. anthracis* preparations. The above comments are respectively offered for your consideration.

Sincerely,

Melissa Morland, MS, RBP, CBSP
President, ABSA International