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Agriculture Select Agent Services
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RE: FSAP Policy Statement: Inactivated *Bacillus anthracis*

Dear Dr. Sosin and Dr. Isaac,

The American Biological Safety Association (ABSAs International) welcomes the Federal Select Agent Program (FSAP) Policy Statement entitled, "Inactivated *Bacillus anthracis*", released on November 30, 2015. ABSAs 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.

ABSAs 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, ABSAs International would like to provide the following comments for your consideration:

Exclusion criteria 1: ABSAs 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 respectfully offered for your consideration.

Sincerely,

A handwritten signature in cursive script that reads "Melissa Morland". The signature is written in dark ink and is positioned above the typed name.

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