ABSA INTERNATIONAL
The Association for Biosafety and Biosecurity
1200 Allanson Road • Mundelein, IL 60060-3808 • 866-425-1385 • Fax: 847-566-4580 • E-mail: info@absa.org • Web Site: www.absa.org

Samuel S. Edwin, Ph.D.
Director, Division of Select Agents and Toxins
Centers for Disease Control and Prevention

Adis Dijab, DVM
National Director, Agriculture Select Agent Services
Animal and Plant Health Inspection Service

Dear Dr. Dijab and Dr. Edwin,

The American Biological Safety Association (ABSA) International welcomes the opportunity to review the draft Federal Select Agent Program (*FSAP*) *Policy Statement: Select agent contained in formalin-fixed, paraffin-embedded tissue* released July 31, 2018. ABSA International provides a critical expertise for this topic as many of its members are extensively involved in implementing the FSAP at their entities and fulfilling certain roles therein.

ABSA International recognizes the intent of the draft policy to significantly decrease the regulatory burden and supports the overall policy statement. The comments below are respectfully offered for your consideration:

Policy Statement:

"FSAP has determined that a select agent or regulated nucleic acids that can produce infectious forms of any select agent virus contained in a formalin-fixed, paraffin-embedded (FFPE) tissue has been effectively inactivated if the FFPE process used is a recognized method (e.g., a previously published method shown to be effective such that validation does not have to occur in-house for FFPE tissues) for that particular agent or regulated nucleic acids. It is therefore the policy of the FSAP that such material is not subject to the select agent regulations found in 7 C.F.R. Part 331, 9 C.F.R. Part 121, or 42 C.F.R. Part 73."

- *Concern*: FSAP has repeatedly indicated that in-house validation is required for all inactivation procedures. ABSA International supports eliminating this requirement but is concerned that more will be required than is described in this policy. The language in the policy is requested to be revised to add clarity.

- *Question*: Clarification is also requested on how to determine what qualifies as an FSAP-approved "recognized method". The example given is not fully clear. Does this refer only to a method published in a peer-reviewed journal, or does any method that was validated by a facility then shared with others qualify (even if not published)? Does the publication need to include the detailed validation data?
- *Question*: Entities will be concerned that the FSAP inspector does not consider their method "recognized" and therefore will cite the entity for not validating the method in-house. How will inspectors determine that a method meets this policy and how will this determination be consistently applied to all entities?
- *Question*: What will be considered adequate documentation that pertinent material is no longer under the select agent regulations if the inactivation procedure or process is conducted in-house?
- *Comment*: The scope of this policy statement is narrowly applied to formalin-fixed paraffin-embedded tissue infected with select agents and/or regulated nucleic acids. Given that the formalin-fixation step is the effective inactivation procedure, it is unclear why paraffin embedding is a required condition.
- *Comment*: It is unclear why select agents (except spore-forming) or regulated nucleic acids in tissue cell culture or suspension would not also be considered effectively inactivated by formalin; and therefore, not subject to select agent regulations. Expanding the policy to all formalin-fixed tissues is encouraged for consideration.

Authority:

"Sections 3(d)(6) and 4(d)(6) of the select agent regulations provide that a select agent or toxin that meets the following criteria is excluded from the requirements of the select agent regulations: a select agent or regulated nucleic acids that can produce infectious forms of any select agent virus not subjected to a validated inactivation procedure or material containing a select agent not subjected to a procedure that removes all viable select agent cells, spores, or virus particles if the material is determined by FSAP to be effectively inactivated or effectively removed."

- *Concern:* The draft text for the authority statement is confusing as the text leads one to understand that material that was *not* subjected to a validated inactivation process or procedure would be considered effectively inactivated or select agent effectively removed. While the text was confirmed to be accurately quoted from the CFR, the paragraph excludes from regulation those select agents or toxins (and materials containing the same) that *were* subjected to a validated and effective inactivation procedure or process.
- *Recommendations*:
    1. Revise the Authority statement to meet intent.
    2. Review and consider revising 42 CFR 73.3(d)(6) and 42 CFR 73.4(d)(6) to remove the word "not" from the two locations it occurs.

- *Concern*: The exclusion listed in the first sentence is "from the requirements of the select agent regulations". The CFR Sections 3 and 4, state that the exclusion is from "the requirements of this part". Excluding the inactivated materials from all select agent requirements may imply a broader than the intent of the regulations.

- *Recommendation*: Consider specifying that the exclusion is from the "part" referred to in the CFR and not the entire select agent regulations. It is presumed that the select agent or toxin would be required to be in compliance with the select agent regulations until the material is inactivated and properly documented.

ABSA International appreciates the opportunity provided by FSAP to review the draft *FSAP Policy Statement: Select agent contained in formalin-fixed, paraffin-embedded tissue*. We recognize and appreciate the work involved in maximizing program safety and efficiency, and efforts to reduce the regulatory burden. Please contact me with any questions or to request clarification.

Respectfully,

Patrick Condreay, PhD, RBP
President, ABSA International