ABSA INTERNATIONAL
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March 30, 2024

Subject: *Comments and Recommendations for HHS/USDA Proposed Rulemaking – Select Agent Regulations (Review of Proposed Rules – published in the Federal Register Vol 89, No. 20, dated January 30, 2024)*

Dear Sir/Madam,

On behalf of the American Biological Safety Association International (ABSA-International), we extend our gratitude for the opportunity to offer insights and recommendations on the proposed rule issued on January 30, 2024, by the Department of Agriculture Animal and Plant Health Inspection Service titled Agricultural Bioterrorism Protection Act of 2002; Biennial Review and Republication of the Select Agent and Toxin List, Docket No APHIS-2019-0018 D. D Docket No APHIS-2019-0018.

After a careful review of the document ABSA-International, through its Technical & Regulatory Committee, has meticulously reviewed the proposed rule and assembled the following comments and recommendations in the Request for Comment published in the Federal Register starting on page 5795 to contribute to the clarity and effectiveness of the regulations:

1.- Advance Notice of Proposed Rulemaking

a) *Discovery of Select Agents or Toxins:* ABSA-International supports the establishment of mechanisms for reporting the discovery of unknown Select Agents or Toxins. However, we recommend clear delineation of the criteria for using reporting forms, standardized reporting forms, and guidance on submission timeframes.

b) *Regarding the exemptions for research laboratories:* Clarification is needed on exemptions for research laboratories where Select Agents or Toxins are identified in environmental specimens, including different scenarios such where viable Select Agents or Toxins may be identified by a research laboratory (e.g., cultures with improper or incomplete validation data, not-fully inactivated samples and incorrect or misidentified strains).

c) A clarification regarding what applies to research activities is highly appreciated under exemption as specimens used for "diagnosis or verification" may not fully encompass the intent in cases of research.

d) Clear guidance is needed regarding the disposal of Select Agent waste during patient care to ensure consistency with existing protocols.

2.- Inactivation procedures

a) Separation of definitions: We recommend clarification on the rationale behind separating definitions for validated inactivation and removal procedures (P 5813) suggesting the adoption of the standardized definitions included in the CDC/NIH Biosafety in Microbiological and Biomedical Laboratories (BMBL) 6th Edition. We would like to highlight as well, that the BMBL also considers three additional and relevant terms associated with inactivation and removal procedures like i) institutional verification, ii) verification, and iii) viability testing protocol.

b) Outsourcing validation (P5799): Clarification is highly appreciated on whether labs can outsource validation of inactivation procedures, along with minimum requirements for such outsourcing.

3.- Loss, release, and theft

a) Definitions such as "reasonably anticipated" and "release" will require explicit clarification to avoid confusion and ensure accurate reporting (P5799) bullet point 1, 3 and 5.

b) Regarding bullet point 2 (P5799), we suggest rewording the existing definition to "An incident resulting in an unplanned animal/plant exposure to a select agent or toxin" in order to avoid confusion of an accidental or intentional exposure of an animal, plant and not a planned, approved and properly contained exposure experiment.

c) Regarding bullet point 3 (P5799), we kindly request clarification on this point as in the case of a release of biological materials from primary containment (e.g., biosafety cabinet), work may still be inside a lab engineered for containment as well as, other engineering controls. Therefore, we appreciate clarification on which layer of containment barrier will require reporting.

d) Regarding bullet point 4 (P5799), we kindly request clarification on "*The failure of or breach in personal protective equipment in the presence of a select agent or toxin*". The aforementioned definition could lead to confusion, and a clear exemplification of in which cases it could be considered an exposure

4.- Registration

a) We respectfully recommend that facilities that do not possess select agents are automatically removed from the program after 3 years of non-possession. The proposed times are based on the typical cycle for Institutional Biosafety Committee (IBC) and Institutional Animal Care and Use Committee (IACUC) protocols.

b) Standardized decommissioning checklist: A standardized checklist for decommissioning labs with Select Agents is recommended for consistency and efficiency.

5.- Recordkeeping

Regarding registration, clarity is kindly appreciated on whether HHS or APHIS must approve submitted amendments prior to implementation.

6.- Training

a) Guidance and terminology: Extensive guidance and updated terminology are necessary to meet new requirements mandated by the PREVENT Pandemics Act.

There are several potential concerns associated with this act such as the regulatory burden on entities working with Select Agents and Toxins. Compliance with revision could be resource-intensive and time-consuming for entities with minimal to no beneficial risk mitigation. The definition of "close proximity' is critical for determining who at an entity could fall under this requirement.

b) Identification of personnel: The regulated community will appreciate guidance that includes examples and definitions that aid in the identification of individuals who are not authorized by the FSAP but are in "close proximity" (i.e., administrative staff, other lab staff) to areas where select

agents or toxins are transferred, possessed, or used as well as, their need for training and administrative oversight.

7.- Definitions for several terms:
a) Regarding the definition of "owner/controller" and the "Principal Investigator, PI," clarity is appreciated to emphasize respective responsibilities. Our working group propose the following definition for PI "*Principal investigator means the one individual who is designated by the entity to direct a project or program and who is responsible to the entity for the scientific and technical direction of that project or program and who is responsible for ensuring laboratory staff and visiting scientists comply with the Regulations and any additional entity-specific or government policies or guidelines*". This definition is consistent with the roles and responsibilities of the PI as defined in the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines), April 2019.

8.- Removal of overlapping Select Agents
a) We support the removal of *Brucella abortus*, *Brucella suis*, and *Brucella melitensis* from the Select Agents and Toxins list. However, guidance will be needed for the regulated community currently registered for these agents regarding the process for removal of registered space and/or *Brucella* from registration while active work is ongoing with *Brucella*.

9.- Miscellaneous
a) Revisions to Exemption Text: We respectfully request revising the text to exemptions for Select Agents and Toxins across various regulations through consultation with the subject matter experts including members of ABSA International:
-Part 121 (121.5 Exemptions for VS select agents and toxins)
-Part 331 (331.5 Exemptions)
-Part 73 (73.5 Exemptions for HHS select agents and toxins)

We believe that addressing these points will not only strengthen biosafety and biosecurity practices within institutions handling select agents but also streamline regulatory processes for the government. Clear and consistent guidelines will facilitate compliance, enhance risk management, and contribute to safeguarding public health and safety.

Thank you for considering our input on this critical matter. ABSA-International stands ready to provide further assistance or clarification as needed. We look forward to the implementation of regulations that promote both safety and scientific progress.

Sincerely,

Luis Ochoa Carrera, MSc
President, ABSA-International