ABSA INTERNATIONAL
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March 14, 2016

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

RE: Agricultural Bioterrorism Protection Act of 2002; Biennial Review and Republication of the Select Agent and Toxin List; Amendments to the Select Agent and Toxin Regulations. Docket No. APHIS-2014-0095.

Dear Dr. Isaac,

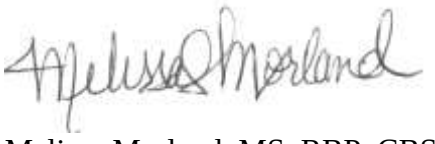
The American Biological Safety Association (ABSA) International welcomes the opportunity to comment on the proposed biennial review of the Select Agent and Toxin List, released on January 19, 2016. ABSA International provides a critical expertise for this topic as many of its members are extensively involved in implementing the Federal Select Agent Program and fulfilling certain roles specified therein.

ABSA International has reviewed the amendments to the Select Agent regulations and provides the following comments for your consideration on the attached Specific Comments Table.

Specific comments for the Biennial Review of the Select Agent and Toxin list and Amendments include requested definitions, clarifications, and further guidance to ensure programs are maintained with integrity. Prevalent concerns and comments are provided regarding proposed changes under the Topics: exclusions and inactivation; security; biocontainment / biosafety; risk assessments; training; and records.

ABSA appreciates the biennial review of the Select Agent program and the proposed modifications that aim to increase the usability of the select agent regulations. The attached comments are respectfully offered for your consideration.

Sincerely,



Melissa Morland, MS, RBP, CBSP
President, American Biological Safety Association

Table: Specific Comments

Table used to make comments specific to document sections and/or paragraphs

Section Name and/or Section Number	Paragraph/ Figure/Table/Note	Type of comment	Comment (justification for change)	Proposed change
Exclusions & Inactivation; Definitions	Page 2763, Paragraph 2; 7 CFR 331.1; 9 CFR 121.1	Technical	Include the word "validated" in the definition of the inactivation method	The definition of inactivation would be established as ''a validated method to render a select agent non-viable but retain characteristic of interest for future use, or to render any nucleic acids that can produce infectious forms of any select agent virus non-infectious for future use.''
Exclusions & Inactivation; Definitions	Page 2763, paragraph 2, 7 CFR 331.1; 9 CFR 121.1	Technical	A validated sterility test that is designed and validated in-house appears to be acceptable. Please specify the criteria to be used to show that a test was "validated".	Define "validated sterility test"
Exclusions & Inactivation; PPQ Select Agents and Toxins; VS Select Agents and Toxins	Page 2764; 7 CFR 331.3; 9 CFR 121.3 (d)(2)(i)(B) (d)(2)(i)(E)(2)	General	The term "safety margin" used in these paragraphs needs to be defined as it is a subjective term that may vary depending on context. Additionally, the need for a "safety margin" is unclear when there is a requirement to determine a kill curve which identifies the conditions to achieve 100% kill of the select agent or toxin. Use of the "safety margin" term seems unnecessary.	Remove reference to the term "safety margin" in these paragraphs or insert a definition of the term so it is clear what is desired when requiring users to "inactivate by a safety margin".
Exclusions & Inactivation	Page 2764	Technical	Guidance is requested for determining an acceptable kill curve and the specifications for acceptable data.	
PPQ Select Agents and Toxins; VS Select Agents and Toxins	7 CFR 331.3 (d)(2)(i)(E); 9 CFR 121.3 (d)(2)(i)(E)	General	Two things are unclear in the proposed change asking for annual reviews of the documents described in subparagraphs (1)-(3) of this paragraph. First, it is unclear what constitutes a review of these documents; and second, what documentation is required to demonstrate compliance with this review requirement. Please specify the intention, whether it be to require the kill-curve and sterility procedure to be repeated and verified annually, or if this is a review of the data and written procedures, etc.	Add language clarifying the expectations of the "review" and specify the documentation that is required to demonstrate compliance.
Exclusions & Inactivation; PPQ Select Agents and Toxins; VS Select Agents and Toxins; Overlap Select Agents and Toxins	Page 2764, Paragraph 5; 7 CFR 331.3 (d)(2); 9 CFR 121.3 (d)(2); 9 CFR 121.4 (d)(2);	Technical	The inclusion of "Toxins" is not consistent throughout the document	Propose amending 7 CFR 331.3(d)(2), 9 CFR 121.3(d)(2), and 9 CFR 121.4(d)(2), which currently exclude nonviable select agents or non-functional toxins from the requirements of the regulations, in order to clarify the policy that an entity must use a validated method to render a select agent nonviable, a toxin as non-functional or regulated nucleic acids non-infectious for future use.

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Exclusions & Inactivation; PPQ Select Agents and Toxins; VS Select Agents and Toxins; Overlap Select Agents and Toxins	Page 2763, paragraph 2; 7 CFR 331.3(d)(2); 9 CFR 121.3(d)(2); 9 CFR 121.4(d)(2);	Technical	Include a requirement for inactivation process to be repeatable	We are proposing that inactivation include the use of one of the following: The exact conditions of a commonly accepted method that has been validated as applied (e.g., autoclaving), a published method with adherence to the exact published conditions (i.e., extrapolations or deductions are to be avoided), or in-house methods, only if validation testing includes the specific conditions used and appropriate controls. The process must generate data that demonstrates consistent repeatability.
Exclusions & Inactivation; PPQ Select Agents and Toxins; VS Select Agents and Toxins; Overlap Select Agents and Toxins	Page 2764, paragraph 1; 7 CFR 331.3(d)(2); 9 CFR 121.3(d)(2); 9 CFR 121.4(d)(2);	Technical	Include toxins as part of the validation requirements	In addition, a validated sterility testing protocol would have to be conducted in order to ensure that the inactivation method has rendered a select agent nonviable, a toxin non-functional, or regulated nucleic acids non-infectious.
Exclusions & Inactivation; PPQ Select Agents and Toxins; VS Select Agents and Toxins; Overlap Select Agents and Toxins	Page 2764, paragraph 2; 7 CFR 331.3(d)(2); 9 CFR 121.3(d)(2); 9 CFR 121.4(d)(2)	Technical	Need to consistently address toxins throughout the document.	In addition, we are proposing that an entity be required to report any viability of a select agent, functionality of a toxin, or infectivity of regulated nucleic acids that can produce infectious forms of any select agent virus that was subjected to a validated inactivation protocol to APHIS or CDC.

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Biocontainment/ Biosafety Plan; Biosafety	Page 2765; 7 CFR 331.12(a)(1), (a)(1)(i), (a(1)(ii); 9 CFR 121.12(a)(1), (a)(1)(i), (a(1)(ii)	General	The additional requirement of written risk assessments for all procedures involving select agent or toxins is excessively burdensome to researchers and the RO/ARO and should be removed, especially in light of the rationale given in the description of the proposed changes on page 2765 under the "Biocontainment/Biosafety Plan" section (the anthrax incident at Royal Campus and the cross-contamination of a shipment of LPAV). The concerns in the aftermath of these events are already addressed by the proposed changes in Section 331.4 and 121.4 requiring validation of inactivation procedures. The existing requirements for a biosafety manual and site-specific risk assessment are sufficient in the context of the new requirement to submit the biosafety manual for renewal of registration and when requested by HHS or APHIS [331.12(a) and 121.12(a)]. Should the requirements for these written risk assessments remain, guidance is requested for the format of these additional documents.	Remove requirement to have written risk assessments for every procedure involving select agents and toxins as described in paragraph (a)(1) and sub paragraphs of sections 7 CFR 331.12 and 9 CFR 121.12.
Training	Page 2766; 7 CFR 331.15 (a), (a)(1); 9 CFR 121.15 (a),(a)(1)	General	Individuals with direct and routine access to select agents and toxins include a range of personnel including laboratory workers, maintenance staff, RO and AROs, possibly custodial staff, and personnel that access the registered space under full escort. No qualification is described regarding the level of training to be conducted on the topics listed in paragraph (a). Personnel at these various positions would not be equipped with the technical level that these topics may detail but awareness training, basic knowledge of the facility, emergency response, and security awareness relevant to the trainee's role and access is recognized.	Request clarification in the regulatory text to assure the acceptability to design training at a level appropriate to the registered person's role and capability of access to the agent or toxin. Alternatively, a new paragraph or sub-paragraph should be added to this section that acknowledges that the spectrum of training requirements and content should be based on the individual's role and level of access to agents, rather than requiring the same level of training for all registered persons as well as escorted persons.
Records	Page 2766	General	The requirement to keep laboratory notebooks for inspection purposes is concerning from an intellectual property standpoint. Clarification is requested as to the information needed from the notebooks other than vetting usage if there is an issue with inventory.	Provide language that protects intellectual property interests and specifies information required for more than inventory purposes.