AMERICAN SOCIETY FOR MICROBIOLOGY

Public and Scientific Affairs Board

March 11, 2016

Docket No. APHIS–2014–0095
Regulatory Analysis and Development
PPD, APHIS Station 3A–03.8
4700 River Road Unit 118
Riverdale, MD 20737–1238

The American Society for Microbiology (ASM) welcomes the opportunity to comment on proposed changes to the current federal Select Agents and Toxins list and regulations, in response to the Request for Public Comment published by the US Department of Agriculture (USDA) and its Animal and Plant Health Inspection Service (APHIS) in the *Federal Register* on January 19, 2016 (RIN 0579-AE08).

The ASM appreciates the APHIS/USDA effort to update the list of biological agents and toxins with potential threat to public health and safety, as well as the Agency's proposed rulemaking to strengthen and clarify the regulations addressing biosafety and biosecurity. The ASM supports periodic review of federal regulations in response to new scientific information or unresolved concerns over safety and security.

The ASM is submitting comments on the following specific changes proposed by the USDA based on the APHIS biennial review. In addition to removing certain USDA-listed agents, the agency proposes several amendments to the regulations to clarify the regulatory language and to address concerns related to inactivation of select agents, biosafety procedures, and confirmed identification of a select agent. We support USDA's stated intent to increase the regulations' usability.

1. *Removal of the following from the USDA list of select agents*:

- *Coxiella burnetii*
- *Rickettsia prowazekii*
- *Bacillus anthracis* Pasteur strain
- *Brucella abortus* and *B. suis*
- *Peronosclerospora philippinensis* (*Peronosclerospora sacchari*)
- *Phoma glycinicola* (formerly *Pyrenochaeta glycines*)
- *Sclerophthora rayssiae*

1752 N Street, NW • Washington, DC • 20036
tel: 202-737-3600 • fax: 202-942-9335 • email: publicaffairs@asmusa.org

ASM comment: We have no opposition to these proposed actions. We emphasize, however, that their removal from the list should neither re-label these organisms as harmless nor relax requisite safety protocols.

2. *For a select agent to be considered "non-viable," and therefore excluded from the requirements of the regulations, an entity will be required to use a validated inactivation method. As part of the inactivation procedure, an entity will be required to develop a site-specific kill curve to identify conditions of inactivation for each select agent or regulated nucleic acid. In addition, a validated sterility testing protocol to ensure that the inactivation method has rendered a select agent non-viable, or regulated nucleic acid non-infectious, will be required.*

ASM comment: We accept the requirement for developing a validated inactivation method and site-specific kill curves to identify conditions of inactivation for select agents or regulated nucleic acids.

An institution that holds and dispenses inactivated materials must validate that the killing method (or attenuation effort in the case of viable agents) is effective and should ensure that materials are QC tested in each lot that is subjected to this treatment. Beyond that, inactivated lots should be stored with documentation that demonstrates that a particular lot has met that standard. It would be impractical, however, to conduct a validated sterility test to ensure that the inactivation method has rendered a select agent non-viable *on every sample* that is inactivated. Implementing such a requirement would waste specimens where limited volumes are available, be costly in terms of technical time and resources, and is scientifically unjustified. The frequency of this testing should apply on a per lot quality control practice and inactivation methods must be re-validated whenever changes in equipment or procedures are introduced.

3. *A requirement for a reference laboratory, which conducts testing to confirm the identification of a select agent or toxin, to inform the specimen provider of a confirmation, so the specimen provider will be aware they are in possession of a select agent or toxin and are subject to the select agent regulations.*

ASM comment: Existing standards indicate that when a clinical laboratory encounters a suspected select agent, the laboratory refers it to a reference laboratory within the laboratory response network (LRN) (generally the respective public health systems or directly to the CDC). It is essential that the "reference laboratory" inform the submitting laboratory that they have identified a select agent. The submitting laboratory would have to register as a select agent laboratory or would have to destroy the organism and send a paperwork account of this to the CDC. If the submitting laboratory was not informed of the 'unknown' organism's final identification, the laboratory might have the organism stocked in the laboratory and not know they are in violation of the CDC.

4. *A requirement that the biosafety and incident response plans be submitted for initial select agent registration, renewal of registration, or when requested by Federal Select Agent Program (FSAP).*

ASM comment: We accept this requirement as appropriate for all biocontainment laboratories handling select agents and toxins.

5. *New specific requirements in the biosafety section would include: a written risk assessment for each registered select agent or toxin; written safety procedures to protect entity personnel, the public, and the environment from exposure to the select agent or toxin; written decontamination procedures; and written waste management procedures.*

ASM comment: We accept this requirement as appropriate for all biocontainment laboratories handling select agents and toxins.

6. *A requirement that a laboratory-specific biosafety manual must be accessible to individuals entering a laboratory registered for select agents or toxins.*

ASM comment: We accept this requirement and suggest that it is already in place. We therefore question the need for specific mention as a new requirement.

7. *Amend existing requirements for the security plan so that the security plan's description of how the entity authorizes the means of entry into areas where select agents or toxins are stored or used would include description of centralized access control management systems (e.g., keycards) and/or key management (mechanical keys).*

ASM comment: We accept this requirement as appropriate for all biocontainment laboratories handling select agents and toxins.

8. *Require that required drills or exercises be documented to include how the drill or exercise tested and evaluated a plan, any problems identified and corrective actions that were taken, and the names of the individuals who participated in a drill or exercise.*

ASM comment: We accept the need for annual drills or exercises to test and evaluate the effectiveness of existing plans and we acknowledge the value of documentation of the event. We question, however, the value or need to identify the names of individuals who participated in the drill or exercise, beyond identification of the individual responsible for the conduct and documentation of the drill or exercise. We suggest that the requirement for a record of the participating individuals be removed, replaced with the name of a single responsible individual.

9. *The rulemaking would codify existing policy that all individuals who have received FSAP approval to have access to select agents and toxins will be required to have training that addresses the particular needs of the individual and the risks posed by the select agent or toxin, regardless of whether they routinely access select agents or toxins.*

ASM comment: We accept the need for training for all individuals handling select agents.

10. *Visitor access to select agents and toxins.*

ASM comment: We applaud the modification of existing regulations to allow scientists registered to work with select agents at a registered entity to work with select agents at another registered entity. This will greatly enhance inter-laboratory collaborations and make optimum use of unique resources available at limited entities.

11. *Records for long-term storage.*

ASM comment: We understand the requirement to promptly notify the appropriate federal, state and local law enforcement agencies of theft or loss of select agents and toxins. We also understand the need to know which select agents an institution possesses and where they are stored. However, an enormous amount of time and effort is spent during inspections validating that inventories (amounts of organisms) are accurate. This has resulted in the loss of valuable virus isolates due to unintentional thawing, the failure of ultralow temperature freezers due to repeated opening and the resulting loss of ultra-low temperature, and inefficient use of scientists' time as inspectors count vials. It is illogical to measure the volumes of stored vials of bacteria and viruses in the manner that toxins or other non-replicative select agents are inventoried. It is important to indicate the nature of the pathogens stored, the numbers of vials in freezer stocks, but even the most fastidious record keeping would not demonstrate that vials of replicative organisms had not been accessed. Current select agent practices allow for these stocks to be maintained in tamper-evident stocks (security ties on freezer boxes, etc.) so that vials are not individually removed, thawed, and measured. This is a logical step that does not eliminate the need to inventory, but which does not degrade samples while still allowing detection of samples that may have disappeared.

The ASM understands that biosafety and biosecurity are of the highest priority when dealing with select agents and toxins. Periodic reviews and updates are important to both public health and national security. We appreciate USDA/APHIS efforts and this opportunity to comment on the proposed changes.

Sincerely,

Lynn W. Enquist, Ph.D., President, American Society for Microbiology
Stefano Bertuzzi, Ph.D., CEO, American Society for Microbiology
Ronald M. Atlas, Ph.D., Public and Scientific Affairs Board