

# Recommended Changes as Proposed in NPRM: Possession, Use and Transfer of Select Agents and Toxins

Docket no: CDC-2015-0006

Summary and Discussion Guide for APHL Members

Developed by APHL Public Policy Program; Last Updated 1/20/16

## Proposed Recommendations:

1. Removes six select agents from HHS list of select agents largely due to comments received during the Advanced Notice of Proposed Rulemaking period:
  - a. *Coxiella burnetii*
    - i. HHS still seeks specific comments on whether *C. burnetii* should be removed
  - b. *Rickettsia prowazekii*
    - i. HHS still seeks specific comments on whether *R. prowazekii* should be removed
  - c. *Bacillus anthracis* Pasteur strain
  - d. *Brucella abortus*
  - e. *Brucella melitensis*
  - f. *Brucella suis*
2. Adds specific requirements to address the inactivation of select agents (page 2808, Section C.). Added definitions include:
  - a. Inactivation: for an agent to be “non-viable,” an entity must use a validated method which is scientifically sound. Inactivation procedures may include:
    - i. Use of the exact conditions of an accepted method that has been validated, such as autoclaving;
    - ii. A published method with adherence to the exact published conditions; or
    - iii. For in-house methods, validation testing should include the specific conditions used and appropriate controls
  - b. Kill Curve: each entity will be required to develop a site specific kill curve for each select agent to identify conditions of inactivation.

FEEDBACK: Provide ideas as to whether there are other methods that should be required to validate the rendering of a select agent “non-viable” or regulated nucleic acids that can produce infectious forms of any select agent virus non-infectious
3. Adds provision of "due diligence" related to the transfer of toxins (page 2808, Section D.)
  - a. Will require a person transferring toxins in amounts which would otherwise be excluded from the provision to:
    - i. Use due diligence to assure that the recipient has a legitimate need to handle or use such toxins; and
    - ii. Report to the FSAP if they detect a known or suspected violation of Federal law or become aware of suspicious activity related to the toxin
    - iii. Proposes adding more specific documentation requirements to the toxin exclusion provision to require the transferor to document the identity of the recipient and legitimate need claimed by the transferee

4. Expands Toxin Permissible Limits (page 2808, Section D)
  - a. Reviews the listed exclusion limits for select toxins. Generally, the NPRM is proposing an increase in regulatory exclusion limits.
  - b. See list of limits on page 2809

**FEEDBACK: Should current regulatory exclusion limits be maintained? Or as outlined in the NPRM, can they be increased?**

**Should DAS and T-2 be removed from the toxin list given the newly proposed high exclusion limit?**

5. Exclusion of Original Food Samples and Clinical Samples (page 2809, Section D)
  - a. Proposes to exclude the original food sample or clinical sample identified to contain an HHS select toxin to be consistent with the rationale for the current exclusion for animals exposed to toxins
  - b. Rationale of the exclusion (page 2810):
    - i. The amount of toxin is highly variable, which would require large amounts of food and clinical samples to quantify and purify;
    - ii. Laboratory procedures to extract toxin from samples are inefficient with most extractions producing low yields;
    - iii. The resources that would be required to quantify toxins in clinical samples and food samples make sample quantification prohibitively expensive;
    - iv. Procedures in these laboratories, based on the requirements of their public health missions, are designed only for toxin detection and not for purification and quantification

**FEEDBACK: Do you agree with the rationale that the original food sample or clinical sample identified to contain an HHS select toxin should be excluded from the select agent regulation?**

6. Exclusion of Toxin Produced as a Byproduct (page 2810, Section D)
  - a. Proposes to exclude toxins that are produced as a byproduct, so long as the toxin has not been intentionally collected, purified or otherwise extracted and the material containing the toxin is inactivated and properly disposed of within 30 days of the initiation of the culture.
  - b. Will allow laboratories whose main purpose is to conduct outbreak investigations, food studies, and molecular characterization to do so effectively.

**FEEDBACK: Do you agree with this exclusion?**

7. Requirements to Destroy Materials After Identification of Select Toxin (page 2810, Section E)
  - a. The current regulation requires laboratories that have identified a select toxin-positive specimen to report to FSAP. The laboratory then must transfer or destroy the material within 7 days

**FEEDBACK: Should the 7 day timeframe be expanded?**

- b. Proposes to extend the exemption time period to 30 days for BoNT and Staphylococcal enterotoxin (subtypes A-E) to allow clinical and diagnostic laboratories sufficient time to complete their investigations without having to transfer or destroy the sample.

**FEEDBACK: Do you agree with this extension?**

8. Patient Care (page 2810, Section E)

- a. Proposes that HHS/CDC will not regulate material containing a select agent or toxin when it is in a patient care setting and is not being otherwise collected, tested or retained for non-patient care purposes. Once delivery of patient care concludes, select agent or toxin regulations fall into place.

**FEEDBACK: Do you agree with this exclusion?**

9. Responsible Officials (RO) (page 2810, Section G)

- a. Proposes ROs must now document the corrective actions taken by the entity to address any deficiencies identified during an inspection

10. Security, Biosafety, and Incident Response Plans (page 2811, Section I)

- a. Proposes requiring the documentation of drills or exercises to include how the drill or exercise tested and evaluated the plan, any problems identified and any corrective actions that were taken
- b. Proposes an added requirement that the biosafety and incident response plans be submitted for initial registration, renewal of registration or when requested by FSAP

**FEEDBACK: Do you agree with these proposed requirements?**

11. Biosafety (page 2811, Section I)

- a. Proposes adding a requirement that a laboratory-specific biosafety manual must be accessible to individuals
- b. Proposes that the biosafety plan should be designed according to a site-specific risk assessment in accordance with the risk of a select agent, given its intended use

**FEEDBACK: Do you agree with these proposed requirements?**

**Please provide any additional ideas regarding any specific biosafety measure that should be required to prevent laboratory associated infections or accidental or intentional release of select agents and toxins**

12. Security (page 2811-2812, Section I)

- a. Proposes to include a description of centralized access control management systems in the laboratory's security plan
- b. Proposes ROs must be notified of any loss of computers, hard drives, or other data storage devices that contain information that could be used to gain access to select agents or toxins

**FEEDBACK: Do you agree with these proposed requirements?**

13. Training (page 2812, Section J)

- a. Proposes requirement that all individuals who have received approval to have access to select agents and toxins have training that address the particular needs of the individual and the risks posed by the select agent or toxin regardless of whether they have access to the select agent or toxin.

FEEDBACK: Do you agree with these proposed requirements?

14. Records (page 2812, Section K)

- a. Proposes the requirement for records to be created and maintained for the destruction of a select agent held in long-term storage
- b. Proposes to expand the scope of records required to be maintained (biocontainment certifications, laboratory notebooks, institutional biosafety and/or animal use committee minutes and approved protocols, etc)

FEEDBACK: Do you agree with these proposed requirements?

- c. Records for Long-Term Storage

FEEDBACK: HHS/CDC is soliciting any alternative regulatory requirements that could be constructed such that a registered entity would know whether it had a theft or loss of a select agent or toxin without that registered entity first having “an accurate, current inventory for each select agent...held in long term storage”