

Executive Summary: Public Comments and Response to Public Comments

Revised Regulations: Possession, Use, and Transfer of Select Agents and Toxins

Purpose of the Regulatory Action:

The final rule is based on the Advanced Notice of Proposed Rulemaking (ANPRM) (75 FR 42363; July 21, 2010) and Notice of Proposed Rulemaking (NPRM) (76 FR 61206; October 3, 2011). The NPRM solicited comments regarding (1) the appropriateness of the current HHS list of select agents and toxins; (2) whether there are other biological agents or toxins that should be added to the HHS list; (3) whether biological agents or toxins currently on the HHS list should be deleted from the list; (4) whether the HHS select agents and toxins list should be tiered based on the relative bioterrorism risk of each biological agent or toxin; and (5) whether the security requirements for select agents or toxins in the highest tier should be further stratified based on type of use or other factors. The final rule, which is set forth at 42 CFR part 73, implements provisions of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Act) and is designed to protect public health and safety. In addition, the final rule accounts for the Executive Order 13546 (*Optimizing the Security of Biological Select Agents and Toxins in the United States*) that directed the HHS Secretary to (1) designate a subset of the select agents and toxins list (Tier 1) that presents the greatest risk of deliberate misuse with the most significant potential for mass casualties or devastating effects to the economy, critical infrastructure; or public confidence; (2) explore options for graded protection for these Tier 1 agents and toxins to permit tailored risk management practices based upon relevant contextual factors; and (3) consider reducing the overall number of agents and toxins on the select agents and toxins list. The final rule also addresses recommendations by the Federal Experts Security Advisory Panel on the designation of Tier 1 agents and toxins, reduction in the number of agents on the Select Agent List, establishment of suitability standards for those having access to Tier 1 select agents and toxins, and establishment of physical security and information security standards for Tier 1 select agents and toxins.

For the NPRM, we provided for a 60-day comment period for written comments that ended December 2, 2011. We also extended the comment period for additional 30-day period that ended January 17, 2012. The final rule also addresses the relevant issues that were raised by the 112 written comments.

Summary of the Major Changes:

The changes were made to improve CDC's ability to help ensure that BSAT are secured according to level of risk:

1. Modification of the Select Agent and Toxin list
 - a. These agents would be considered select agents: SARS-associated coronavirus (SARS-CoV), Lujo and Chapare viruses to the list of HHS only agents based on scientific data and risks associated with these viruses.
 - b. These agents would no longer be considered select agents or toxins: Cercopithecine Herpesvirus 1 (Herpes B virus), *Clostridium perfringens* epsilon toxin, *Coccidioides posadasii/Coccidioides immitis*, Eastern Equine Encephalitis virus (South American type only), Flexal virus, West African clade of Monkeypox viruses, *Rickettsia prowazekii*, *Rickettsia rickettsia*, *Shigatoxins* and *Shiga-like ribosome inactivating proteins*, and specific subtypes of Venezuelan Equine Encephalitis Virus. Also, reorganized the list of Conotoxins, Staphylococcal enterotoxins and Tick-borne encephalitis complex viruses that would be considered a select toxin.
2. Tiering of the Select Agent and Toxin list to optimize security of BSAT that pose a higher risk to public health and safety and to permit graded management of risk.
 - a. Tier I agents include:
 - i. HHS Agents and Toxins
 1. Ebola virus

2. *Francisella tularensis*
 3. Marburg virus
 4. Variola major virus
 5. Variola minor virus
 6. *Yersinia pestis*
 7. Botulinum neurotoxin
 8. Toxin-producing strains of *Clostridium botulinum*
- ii. Overlap agents
1. *Bacillus anthracis*
 2. *Burkholderia mallei*
 3. *Burkholderia pseudomallei*

3. Establish physical security standards for select agents and toxins with the greatest risk of deliberate misuse and the most significant potential for mass casualties or devastating effect to the economy, critical infrastructure, or public confidence and establish personal reliability standards for persons who work with these agents; and

4. Miscellaneous revisions to the regulations concerning select agents and toxins including the addition of definitions and clarification of language concerning security, training, biosafety, and incident response.

Costs of the Rule:

Benefits of the Rule: These changes are proposed to improve DSAT's ability to help ensure that BSAT are secured according to level of risk. The proposed changes will increase the biosafety and biosecurity safeguards in place by entities that possess BSAT with the highest risk of misuse, while reducing the burden on some entities that possess BSAT with a lower risk of misuse.