Appendix F—Select Agents and Toxins

Following the anthrax attacks of 2001 that resulted in five deaths, Congress significantly strengthened federal oversight of biological agents and toxins that have the potential to pose a severe threat to public health; animal and plant health; and animal and plant products (Select Agents and Toxins). The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Response Act) required the Department of Health and Human Services (HHS) to regulate the possession, use, and transfer of select biological agents and toxins that have the potential to pose a severe threat to public health and safety. Subtitle B of Title II of the Bioterrorism Response Act (cited as the Agricultural Bioterrorism Protection Act of 2002) granted comparable regulatory authorities to the U.S. Department of Agriculture (USDA) over select biological agents and toxins that have the potential to pose a severe threat to animal and plant health or products. The Bioterrorism Response Act also requires HHS and USDA to coordinate activities regarding the zoonotic agents regulated by both Departments.

These activities are implemented through the Federal Select Agent Program (FSAP). FSAP is managed jointly by the Centers for Disease Control and Prevention's (CDC) Division of Select Agents and Toxins (DSAT) and the Animal and Plant Health Inspection Service's (APHIS) Agriculture Select Agent Services (AgSAS). FSAP regulates the acquisition, use, storage and transfer of Select Agents and Toxins through the development, implementation, and enforcement of the federal Select Agent regulations—7 CFR Part 331 (APHIS-PPQ), 9 CFR Part 121 (APHS-VS), and 42 CFR Part 73 (CDC).

FSAP provides national oversight of the safety and security of potentially dangerous biological Select Agents and Toxins. Key elements of the Select Agent regulations include:

- All entities that possess, use, or transfer Select Agents and Toxins must be registered with FSAP.
- All individuals who have access to Select Agents and Toxins must first be approved by FSAP after a security risk assessment (SRA) performed by the Federal Bureau of Investigation's (FBI) Criminal Justice Information Services Division (CJIS) to help guard against access to the agents and toxins by those who may wish to misuse them.
- Enforcement actions for regulatory violations may be taken to address present risks and increase future compliance through administrative actions and/or civil monetary penalties. An entity may be referred to the HHS Office of the Inspector General (OIG) or APHIS Investigative and Enforcement Services (IES), or the FBI may be notified of the incident for potential further investigation, as appropriate.

- An entity's registration may be denied, suspended, or revoked if it is determined that such action is necessary to protect human, animal, or plant health, or animal or plant products.
- Each registered entity must designate a Responsible Official (RO), an individual with the authority and responsibility to act on behalf of the entity and charged with ensuring compliance with the Select Agent regulations. The RO is able to respond to onsite incidents involving Select Agents in a timely manner, ensures annual inspections are conducted for each space where Select Agents are stored or used, reviews the entity's validated inactivation procedures and investigates any failures, and reports the identification and final disposal of any Select Agent or Toxin in a diagnostic specimen or proficiency test. Alternate Responsible Official(s) (ARO) may be designated to serve when the RO is not available; AROs have the same responsibilities as ROs.
- Each registered entity must develop and implement a written security plan sufficient to safeguard their Select Agents and/or Toxins against unauthorized access, theft, loss, or release.
- Each registered entity must develop and implement a written biosafety plan commensurate with the risk of their Select Agents and/or Toxins, given their intended use.
- A registered entity must receive pre-approval for *Restricted experiments* that pose heightened safety and security risks. See Section 13 of the Select Agents and Toxins regulations for additional information.
- Each registered entity must develop and implement a written incident response plan specific to the hazards associated with their Select Agents and/or Toxins.
- Each registered entity must provide information and training on biosafety, security, and incident response to individuals with access to Select Agents and Toxins.
- Any instances of the theft, loss, or release of a Select Agent or Toxin must be promptly reported to FSAP in accordance with the Select Agent and Toxin regulations.
- An entity may only transfer a Select Agent or Toxin to another entity registered to possess that agent or toxin, and the transfer must be preauthorized by FSAP.
- Each registered entity must maintain complete records and documentation including, but not limited to: inventories, exposures, lists of individuals with approved access, and entry into areas containing Select Agents or Toxins.
- FSAP may conduct inspections of an entity without prior notification and prior to issuing a certificate of registration.

- There are specific exemptions or exclusions to the regulations including specific attenuated strains or Select Toxins modified to be less potent or toxic.
- Entities must use validated inactivation procedures to inactivate Select Agents. Please refer to the appendix on Inactivation and Verification.

As of January 2017, FSAP regulates 66 Select Agents and Toxins. The list of Select Agents and Toxins is reviewed at least every two years to determine if agents or toxins need to be added to or deleted from the list.

For more information on the regulations and guidance documents for implementation of a Select Agent program, please visit https://www.selectagents.gov.