Federal Select Agent Program Overview

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Federal Select Agent Program (FSAP)

- FSAP regulates the possession, use, and transfer of biological select agents and toxins that have the potential to pose a severe threat to public, animal or plant health, or to animal or plant products.

- Managed jointly by:
  - The Division of Select Agents and Toxins (DSAT) at the Centers for Disease Control and Prevention (CDC), part of the U.S. Department of Health and Human Services (HHS)
  - The Agriculture Select Agent Services (AgSAS) at the Animal and Plant Health Inspection Service (APHIS), part of the U.S. Department of Agriculture (USDA)
Overview and History

- 2001 anthrax attacks led to strengthening of program
- Title II of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002
  - Legal authority for the current Federal Select Agent Program
  - Required security measures in addition to biosafety measures
  - Strengthened the regulatory authorities of HHS
  - Granted comparable regulatory authorities to USDA
Establish and maintain a list of biological agents and toxins that have the potential to pose a severe threat to public health and safety. Consider:

1. Effect on human health
2. Degree of contagiousness and transmissibility
3. Availability of pharmacotherapies and immunizations
4. Other criteria, including children and vulnerable populations

Conduct a biennial review, or more often as needed.
Types of Select Agents and Toxins

- **HHS-only agents** (HHS has sole authority and responsibility to regulate)
  - May only affect public health and safety
  - Botulinum neurotoxins, *Yersinia pestis*, Smallpox virus

- **USDA-only agents** (USDA has sole authority and responsibility to regulate)
  - May only affect animal and plant health; animal and plant products
  - Foot-and-mouth disease virus, Rinderpest virus

- **“Overlap” agents**
  - Subject to regulation by both agencies because they affect both humans and animals (requires interagency coordination)
  - *Bacillus anthracis, Brucella abortus*, Rift Valley fever virus
67 select agents and toxins on the HHS and USDA lists:

- 35 HHS-only
- 21 USDA-only
- 11 Overlap (HHS/USDA)

- 14 Tier 1 agents

https://www.selectagents.gov/SelectAgentsandToxinsList.html
Tier 1 Select Agents and Toxins

- Tier 1 is a subset of the select agents and toxins list 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.

### HHS select agents and toxins
1. *Bacillus cereus* Biovar *anthracis*
2. Botulinum neurotoxin
3. Botulinum neurotoxin producing species of *Clostridium*
4. Ebola virus
5. *Francisella tularensis*
6. Marburg virus
7. Variola major virus
8. Variola minor virus
9. *Yersinia pestis*

### USDA select agents
1. Foot-and-Mouth Disease virus
2. Rinderpest virus

### Overlap select agents
1. *Bacillus anthracis* (excluding Pasteur strain)
2. *Burkholderia mallei*
3. *Burkholderia pseudomallei*
U.S. Federal Biosafety & Biosecurity Oversight
Key Regulatory Functions & Activities

- Promulgate the select agent regulations
- Provide oversight of possession, use, and transfer
- Conduct inspections and approve registrations
- Approve individual access to select agents & toxins
- Receive reports of a theft, loss, or release
- Take appropriate enforcement actions
- Serve as a resource on compliance with the regulations
Types of Entities Registered with FSAP, 2016

- Academic: 32%
- Commercial: 18%
- Federal Government: 15%
- Non-Federal Government: 29%
- Private: 6%

Total: 276

Registered Entities, by Lead Agency (2016)

- CDC/DSAT: 86%
- APHIS/AgSAS: 14%

Total: 276

FSAP Inspection Basics

- **Biosafety**
  - Entity-specific biosafety plan
  - Standards described in *Biosafety in Microbiological and Biomedical Laboratories* (BMBL, 5th edition) or equivalent
  - NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules
  - Notification of select agent release
  - Select agent inactivation

- **Biosecurity**
  - Entity-specific security plan
  - Registration and related security risk assessments
  - Access controls
  - Inventory and accountability – long-term select agents and toxins
  - Notification of theft or loss
  - Tier 1: 3 security barriers, suitability

*Training; drills or exercises*
FSAP Inspection Statistics, 2016

- Total inspections conducted: 181
  - 103 by DSAT
  - 29 by AgSAS
  - 49 joint DSAT/AgSAS

- Average duration for an inspection: 3 days
  - Range of 1-8 days

Select Agent Enforcement

- Voluntary action
  - Corrective Action Plan (CAP)

- Administrative actions
  - Denial of application
  - Revocation or suspension of registration

- Civil money penalties
  - Up to $250k for an individual for each violation
  - Up to $500k for an entity for each violation

- Criminal
  - Imprisonment for up to 5 years, a fine, or both
Program Metrics

Since 2003, there have been:

- **No** reported thefts of a select agent or toxin from a registered entity
- **No** deaths among laboratory workers
- **No** reported cases of illness or death in the general public due to work with these agents in regulated laboratories
Discussion

www.selectagents.gov

lrsat@cdc.gov or 404-718-2000

For more information, contact CDC
1-800-CDC-INFO (232-4636)

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.