Federal Select Agent Program (FSAP) Multi-Agency Informational Meeting

FSAP Reporting Requirements for Entities with Shipping and Laboratory Practices information
Agenda and Times

- **11:00 - 11:05** – Moderator
  - Housekeeping
  - Introduction of Speakers
- **11:05 - 11:20** – Federal Select Agent Program (FSAP) Directors
  - Opening Remarks
  - Overview of the Program
- **11:20 - 11:45** – Department of Transportation (DOT)
  - Shipping of Category B Diagnostic Samples
- **11:45 - 12:10** – APHIS/CDC Form 2 - Request To Transfer Select Agents and Toxins
Agenda and Times

- **12:10 - 12:40** – APHIS/CDC Form 3 – Incident Notification and Reporting (Theft, Loss, Release)
- **12:40 - 1:10** – 30-minute Break
- **1:10 - 1:40** – APHIS/CDC Form 4 – Reporting the Identification of a Select Agent or Toxin from a Clinical/Diagnostic Specimen
- **1:40 - 2:10** – Minnesota Department of Health
  - Laboratory Practices
- **2:10 - 2:40** – Open for Additional Questions
- **2:40 - 2:45** – Closing Remarks
Overview of the Federal Select Agent Program

Directors, Federal Select Agent Program

Multi-Agency Informational Meeting to Discuss Select Agent and Toxin Reporting Requirements

September 23, 2020
Overview & History

- 2001 anthrax attacks led to strengthening of program
- Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Title II
  - Legal authority for the current Federal Select Agent Program (FSAP)
  - Required security measures in addition to biosafety measures
  - Strengthened the regulatory authorities of the U.S. Department of Health and Human Services (HHS)
  - Granted comparable regulatory authorities to the U.S. Department of Agriculture (USDA)
Federal Select Agent Program (FSAP)

- Regulates the possession, use, and transfer of biological select agents and toxins (BSAT) with the potential to pose a severe threat to public, animal or plant health, or to animal or plant products

- Began in its current regulatory form in 2003

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

- Relevant regulations include:
  - 7 C.F.R. Part 331 (plants and plant products)
  - 9 C.F.R. Part 121 (animals and animal products)
  - 42 C.F.R. Part 73 (public health)

- List-based regulatory program (currently 67 agents)

- Requires review and republication of agent list every two years
Types of Select Agents and Toxins

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

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

- **“Overlap” agents** (HHS and USDA have authority and responsibility to regulate)
  - Subject to regulation by both agencies because they have potential to affect both humans and animals (requires interagency coordination)
  - *Bacillus anthracis*, *Brucella abortus*, Rift Valley fever virus
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.

<table>
<thead>
<tr>
<th>HHS select agents and toxins</th>
<th>USDA select agents</th>
<th>Overlap select agents</th>
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<tbody>
<tr>
<td>(1) <em>Bacillus cereus</em> Biovar <em>anthracis</em></td>
<td>(1) Foot-and-Mouth Disease virus</td>
<td>(1) <em>Bacillus anthracis</em> (excluding Pasteur strain)</td>
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<td>(2) Botulinum neurotoxin</td>
<td>(2) Rinderpest virus</td>
<td>(2) <em>Burkholderia mallei</em></td>
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<td>(3) Botulinum neurotoxin producing species of Clostridium</td>
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<td>(3) <em>Burkholderia pseudomallei</em></td>
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<td>(4) Ebola virus</td>
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<td>(5) <em>Francisella tularensis</em></td>
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<td>(6) Marburg virus</td>
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<td>(7) Variola major virus</td>
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<td>(8) Variola minor virus</td>
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<td>(9) <em>Yersinia pestis</em></td>
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# Current Select Agents and Toxins List

## HHS SELECT AGENTS AND TOXINS

1. Abrin
2. Bacillus cereus (Bacillus anthracis)
3. Botulimum neurotoxin
4. Botulimum neurotoxin producing species of Clostridium
5. Contaminus (short, palytic; alpha contains the following amino acid sequence HlyCysGlyAclyGlyCys)
6. Coxiella burnetii
7. Crimean-Congo haemorrhagic fever virus
8. Dieckmannsthriale
9. Eastern Equine Encephalitis virus
10. Ebola virus
11. Francisella tularensis
12. Lassa fever virus
13. Lujo virus
14. Marburg virus
15. Monkeypox virus
16. Reconstructed replication competent forms of the 1918 pandemic influenza virus containing any portion of the coding region of all eight gene segments (Reconstructed 1918 Influenza virus)
17. Rift
18. Rockfeller pneumovirus
19. SARS-associated coronavirus (SARS-CoV)
20. Senecavirus

### South American Hemorrhagic Fever viruses:
- Chapare
- Guasaito
- Machupo
- Sabin
- Staphylococcal enterotoxins A, B, C, D, E subtypes
- Y 2 toxin
- Tetrodotoxin

### Tick-borne encephalitis complex (flavir) viruses:
- Far Eastern subtype
- Siberian subtype
- Kyasanur Forest disease virus
- Crimean haemorrhagic fever virus
- Varlak major virus (Smallpox virus)
- Varlak minor virus (Alkhimov)
- Vesicular exanthem

*Denotes Tier 1 Agent

## USDA SELECT AGENTS AND TOXINS

1. Anthrax
2. Bacillus anthracis Pasteur strain
3. Brucellosis abortus
4. Brucellosis melitensis
5. Brucellosis suis
6. Burkholderia mallei
7. Burkholderia pseudomallei
8. Hendra virus
9. Nipah virus
10. Rift Valley fever virus
11. Venezuelan equine encephalitis virus

### USDA SELECT AGENTS AND TOXINS

12. African horse sickness virus
13. African swine fever virus
14. Avian influenza virus
15. Classical swine fever virus
16. Foot-and-mouth disease virus
17. Goat pox virus
18. Lumpy skin disease virus
19. Mycoplasma capricolum
20. Mycoplasma mycoides
21. Newcastle disease virus
22. Pest des petits ruminants virus
23. Rabies virus
24. Sheep pox virus
25. Swine vesicular disease virus

## USDA PLANT PROTECTION AND QUARANTINE (PPQ) SELECT AGENTS AND TOXINS

1. Coniothyrium minitans (formerly Phoma glutinosa and Phytophthora glycines)
2. Puccinia chrysanthemi
3. Ralstonia solanacearum
4. Rodhainia boliviensis
5. Scirrhopthora graminearum
6. Synchytium endobioticum
7. Xanthomonas arvense

## 67 agents and toxins on the HHS and USDA list:
- 35 HHS only
- 21 USDA only
- 11 Overlap

Including 14 Tier 1 agents

[https://www.selectagents.gov/SelectAgentsandToxinsList.html](https://www.selectagents.gov/SelectAgentsandToxinsList.html)
Types of Entities Registered with FSAP, 2019

Total: 247

- Academic: 34%
- Non-Federal Government: 28%
- Federal Government: 16%
- Commercial: 17%
- Private: 6%

Key Regulatory Functions and Activities

- Promulgate the select agent regulations
- Provide oversight of possession, use, and transfer
- Conduct inspections and approve registrations
- Approve individual access to select agents and toxins
Key Regulatory Functions and Activities (Cont.)

- Receive reports of a theft, loss, or release
- Take appropriate enforcement actions
- Serve as a resource on compliance with the regulations
Select Agent Enforcement

- **Voluntary action**
  - Corrective Action Plan (CAP)

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

- **Civil monetary 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
Key FSAP Reporting Forms

- Application for Registration for Possession, Use, and Transfer of Select Agents and Toxins (APHIS/CDC Form 1)
- Request to Transfer Select Agents or Toxins (APHIS/CDC Form 2)
- Incident Notification and Reporting (Theft, Loss, or Release) (APHIS/CDC Form 3)
- Reporting the Identification of a Select Agent or Toxin (APHIS/CDC Form 4)
- Request for Exemption of Select Agents and Toxins for an Investigational Product (APHIS/CDC Form 5)
Electronic FSAP (eFSAP) Information System

- Secure, web-based information system used to submit and share select agent program information with registered entities

- Searchable; provides FSAP immediate, real-time information on **who** has **what** select agents, **how** they are being used, and **where** they are located

- Increased efficiency; FSAP can be timelier and more effective

- Information available at [https://www.selectagents.gov/efsap.html](https://www.selectagents.gov/efsap.html)
Includes a variety of program information and resources, including:

- Regulations
- Frequently asked questions
- Policies
- Guidance documents
- Forms
- Publications
- Reports

www.selectagents.gov
Discussion

www.selectagents.gov

CDC: lrsat@cdc.gov or 404-718-2000

APHIS: AgSAS@usda.gov or 301-851-3300 option 3 (voice only)