

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

FSAP Reporting Requirements for Entities with Shipping and Laboratory Practices information

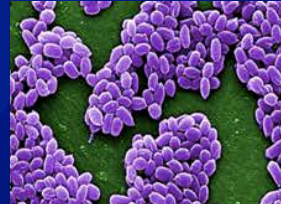


Agenda and Times

- ❑ **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

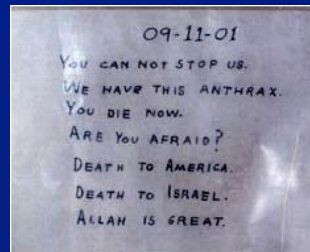
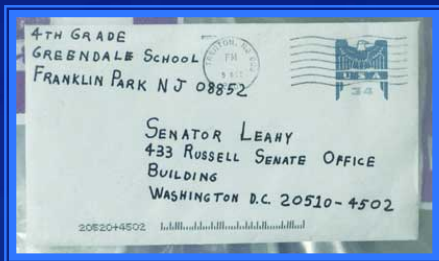


September 23, 2020



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

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*

Current Select Agents and Toxins List

HHS and USDA Select Agents and Toxins
7CFR Part 331, 9 CFR Part 121, and 42 CFR Part 73

HHS SELECT AGENTS AND TOXINS	OVERLAP SELECT AGENTS AND TOXINS
1. Abrin	36. <i>Bacillus anthracis</i> *
2. <i>Bacillus cereus</i> Biovar <i>anthracis</i> *	37. <i>Bacillus anthracis</i> Pasteur strain
3. Botulinum neurotoxins*	38. <i>Brucella abortus</i>
4. Botulinum neurotoxin producing species of <i>Clostridium</i> *	39. <i>Brucella melitensis</i>
5. Conotoxins (Short, paralytic alpha conotoxins containing the following amino acid sequence X ₁ (CCX) ₂ PACGX ₃ X ₄ (S) ₆ (CX) ₇) ¹	40. <i>Brucella suis</i>
6. <i>Coxiella burnetii</i>	41. <i>Burkholderia mallei</i> *
7. Crimean-Congo haemorrhagic fever virus	42. <i>Burkholderia pseudomallei</i> *
8. Diacetoxyscirpenol	43. Hendra virus
9. Eastern Equine Encephalitis virus ³	44. Nipah virus
10. Ebola virus*	45. Rift Valley fever virus
11. <i>Francisella tularensis</i> *	46. Venezuelan equine encephalitis virus ³
12. Lassa fever virus	USDA SELECT AGENTS AND TOXINS
13. Lujo virus	47. African horse sickness virus
14. Marburg virus*	48. African swine fever virus
15. Monkeypox virus ³	49. Avian influenza virus ³
16. Reconstructed replication competent forms of the 1918 pandemic influenza virus containing any portion of the coding regions of all eight gene segments (Reconstructed 1918 Influenza virus)	50. Classical swine fever virus
17. Ricin	51. Foot-and-mouth disease virus*
18. <i>Rickettsia prowazekii</i>	52. Goat pox virus
19. SARS-associated coronavirus (SARS-CoV)	53. Lumpy skin disease virus
20. Saxitoxin	54. <i>Mycoplasma capricolum</i> ³
South American Haemorrhagic Fever viruses:	55. <i>Mycoplasma mycoides</i> ³
21. Chapare	56. Newcastle disease virus ^{2,3}
22. Guanarito	57. Peste des petits ruminants virus
23. Junin	58. Rinderpest virus*
24. Machupo	59. Sheep pox virus
25. Sabia	60. Swine vesicular disease virus
26. Staphylococcal enterotoxins A,B,C,D,E subtypes	USDA PLANT PROTECTION AND QUARANTINE (PPQ) SELECT AGENTS AND TOXINS
27. T-2 toxin	61. <i>Caniothyrium glycinis</i> (formerly <i>Phoma glycinicola</i> and <i>Pyrenochaeta glycinis</i>)
28. Tetrodotoxin	62. <i>Peronosclerospora philippinensis</i> (<i>Peronosclerospora sacchari</i>)
Tick-borne encephalitis complex (flavi) viruses:	63. <i>Ralstonia solanacearum</i>
29. Far Eastern subtype	64. <i>Rathayibacter toxicus</i>
30. Siberian subtype	65. <i>Sclerophthora rayssiae</i>
31. Kyasanur Forest disease virus	66. <i>Synchytrium endobioticum</i>
32. Omsk hemorrhagic fever virus	67. <i>Xanthomonas oryzae</i>
33. Variola major virus (Smallpox virus)*	
34. Variola minor virus (Alastrim)*	
35. <i>Yersinia pestis</i> *	

¹Denotes Tier 1 Agent

67 agents and toxins on the HHS and USDA list:

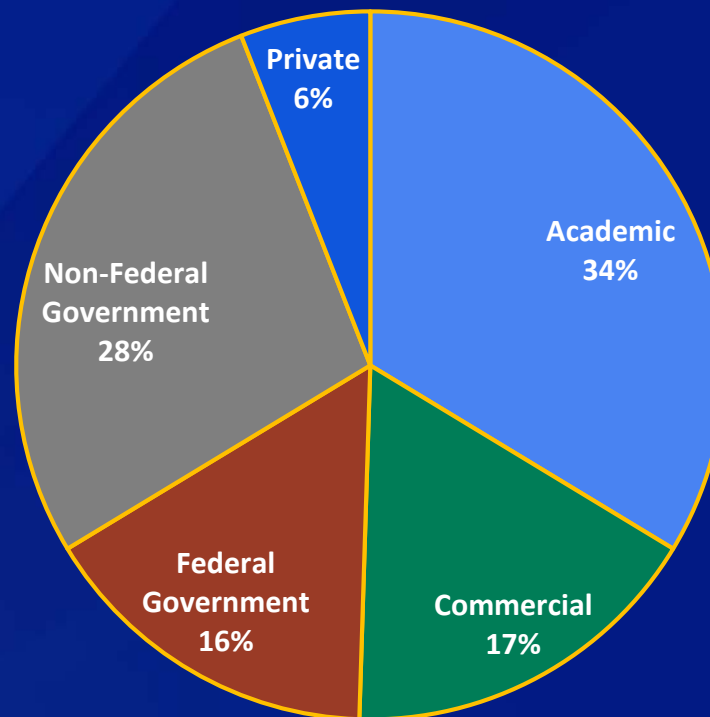
- 35 HHS only
- 21 USDA only
- 11 Overlap

Including 14 Tier 1 agents

<https://www.selectagents.gov/SelectAgentsandToxinsList.html>

Types of Entities Registered with FSAP, 2019

Total: 247



Source: 2019 Annual Report of the Federal Select Agent Program, <https://www.selectagents.gov/annualreport2019.html>

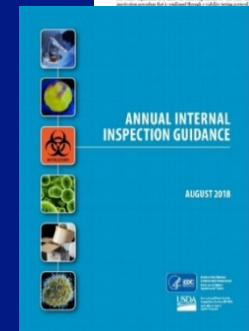
Key Regulatory Functions and Activities

- ❑ 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

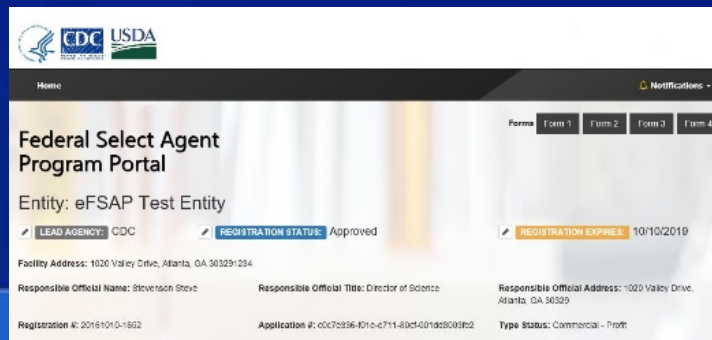


Key FSAP Reporting Forms

- ❑ **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>



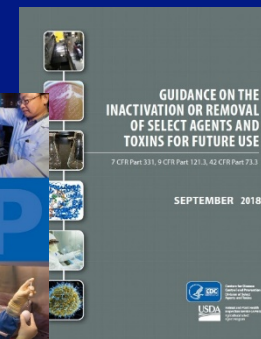
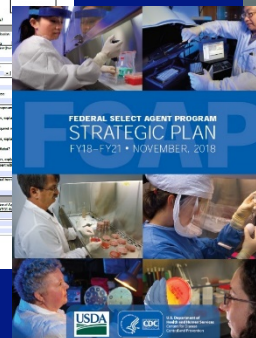
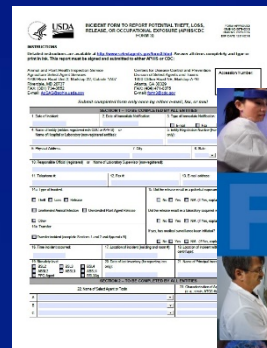
The screenshot displays the Federal Select Agent Program Portal interface. At the top, there are logos for CDC and USDA. The main heading is "Federal Select Agent Program Portal". Below this, the entity is identified as "Entity: eFSAP Test Entity". Key registration details are shown in a row: "LEAD AGENCY: CDC", "REGISTRATION STATUS: Approved", and "REGISTRATION EXPIRES: 10/10/2019". A "Forms" section contains buttons for Form 1, Form 2, Form 3, and Form 4. The bottom of the page lists contact information: "Facility Address: 1020 Valley Drive, Atlanta, GA 30329-294", "Responsible Official Name: Stevenon Shev", "Responsible Official Title: Director of Science", "Responsible Official Address: 1020 Valley Drive, Atlanta, GA 30329", "Registration #: 20161010-1802", "Application #: 00c72836-851e-e711-81c1-019019098e2", and "Type Status: Commercial - Profit".

FSAP Website

□ 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: Irsat@cdc.gov or 404-718-2000

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

