



Federal Select Agent Program Overview

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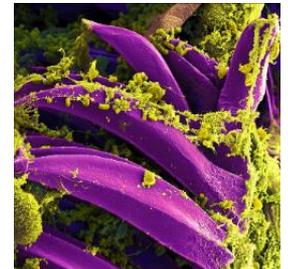
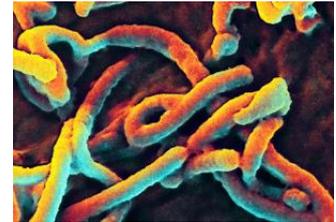
Director, Division of Select Agents and Toxins

Boston Public Health Commission Board Meeting

November 14, 2018

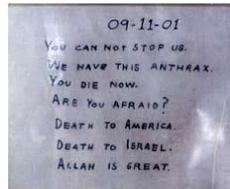
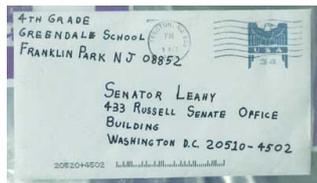
Federal Select Agent Program (FSAP)

- 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



TITLE II—ENHANCING CONTROLS ON DANGEROUS BIOLOGICAL AGENTS AND TOXINS

“SEC. 351A. ENHANCED CONTROL OF DANGEROUS BIOLOGICAL AGENTS AND TOXINS.

“(a) REGULATORY CONTROL OF CERTAIN BIOLOGICAL AGENTS AND TOXINS.—

“(1) LIST OF BIOLOGICAL AGENTS AND TOXINS.—

“(A) IN GENERAL.—The Secretary shall by regulation establish and maintain a list of each biological agent and each toxin that has the potential to pose a severe threat to public health and safety.

“(B) CRITERIA.—In determining whether to include an agent or toxin on the list under subparagraph (A), the Secretary shall—

“(i) consider—

“(I) the effect on human health of exposure to the agent or toxin;

“(II) the degree of contagiousness of the agent or toxin and the methods by which the agent or toxin is transferred to humans;

“(III) the availability and effectiveness of pharmacotherapies and immunizations to treat and prevent any illness resulting from infection by the agent or toxin; and

“(IV) any other criteria, including the needs of children and other vulnerable populations, that the Secretary considers appropriate; and

“(ii) consult with appropriate Federal departments and agencies and with scientific experts representing appropriate professional groups, including groups with pediatric expertise.

“(2) BIENNIAL REVIEW.—The Secretary shall review and republish the list under paragraph (1) biennially, or more often as needed, and shall by regulation revise the list as necessary in accordance with such paragraph.

- 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

HHS SELECT AGENTS AND TOXINS

1. Abrin
 2. *Bacillus cereus* Biovar *anthracis**
 3. Botulinum neurotoxins*
 4. Botulinum neurotoxin producing species of *Clostridium**
 5. Conotoxins (Short, paralytic alpha conotoxins containing the following amino acid sequence X₁CC₂PACGX₃X₄X₅CX₆)¹
 6. *Coxiella burnetii*
 7. Crimean-Congo haemorrhagic fever virus
 8. Diacetoxyscirpenol
 9. Eastern Equine Encephalitis virus³
 10. Ebola virus*
 11. *Francisella tularensis**
 12. Lassa fever virus
 13. Lujo virus
 14. Marburg virus*
 15. Monkeypox virus³
 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)
 17. Ricin
 18. *Rickettsia prowazekii*
 19. SARS-associated coronavirus (SARS-CoV)
 20. Saxitoxin
- South American Haemorrhagic Fever viruses:
21. Chapare
 22. Guanarito
 23. Junin
 24. Machupo
 25. Sabia
26. Staphylococcal enterotoxins A,B,C,D,E subtypes
 27. T-2 toxin
 28. Tetrodotoxin
- Tick-borne encephalitis complex (flavi) viruses:
29. Far Eastern subtype
 30. Siberian subtype
31. Kyasanur Forest disease virus
 32. Omsk hemorrhagic fever virus
 33. Variola major virus (Smallpox virus)*
 34. Variola minor virus (Alastrim)*
 35. *Yersinia pestis**

OVERLAP SELECT AGENTS AND TOXINS

36. *Bacillus anthracis**
37. *Bacillus anthracis* Pasteur strain
38. *Brucella abortus*
39. *Brucella melitensis*
40. *Brucella suis*
41. *Burkholderia mallei**
42. *Burkholderia pseudomallei**
43. Hendra virus
44. Nipah virus
45. Rift Valley fever virus
46. Venezuelan equine encephalitis virus³

USDA SELECT AGENTS AND TOXINS

47. African horse sickness virus
48. African swine fever virus
49. Avian influenza virus³
50. Classical swine fever virus
51. Foot-and-mouth disease virus*
52. Goat pox virus
53. Lumpy skin disease virus
54. *Mycoplasma capricolum*³
55. *Mycoplasma mycoides*³
56. Newcastle disease virus^{2,3}
57. Peste des petits ruminants virus
58. Rinderpest virus*
59. Sheep pox virus
60. Swine vesicular disease virus

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

61. *Coniothyrium glycinis* (formerly *Phoma glycinicola* and *Pyrenochaeta glycinis*)
62. *Peronosclerospora philippinensis* (*Peronosclerospora sacchari*)
63. *Ralstonia solanacearum*
64. *Rathayibacter toxicus*
65. *Sclerophthora rayssiae*
66. *Synchytrium endobioticum*
67. *Xanthomonas oryzae*

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

*Denotes Tier 1 Agent

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*

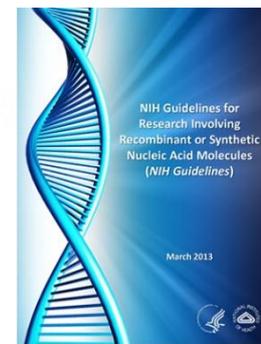
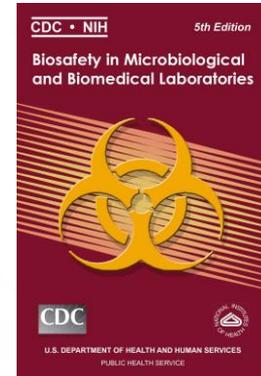
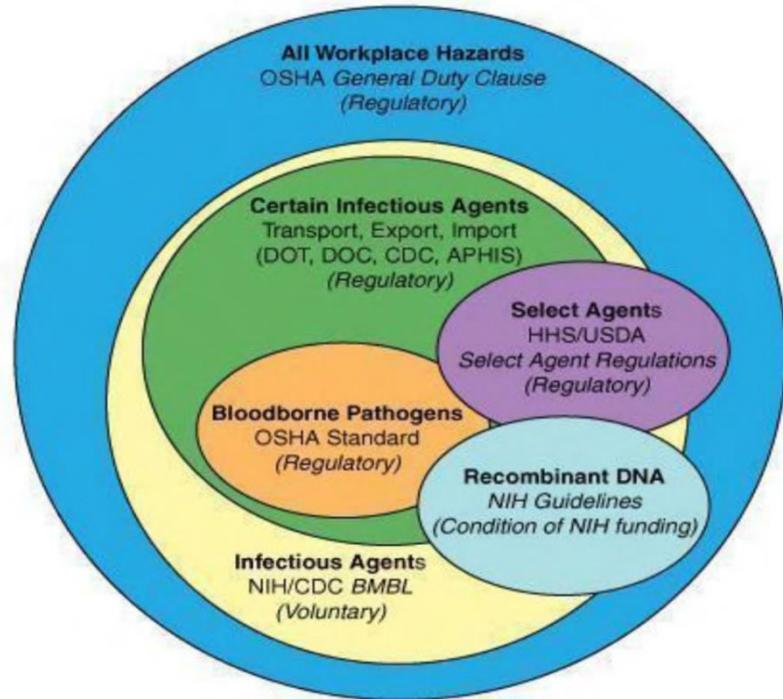
USDA select agents

- (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

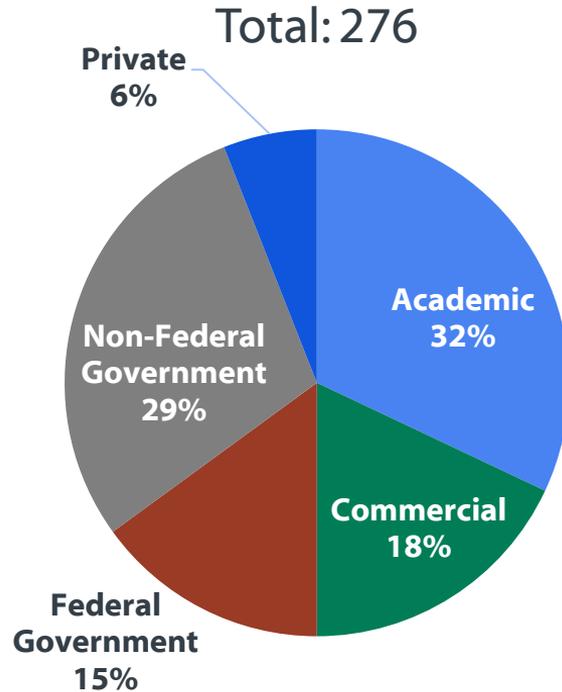


Key Regulatory Functions & Activities

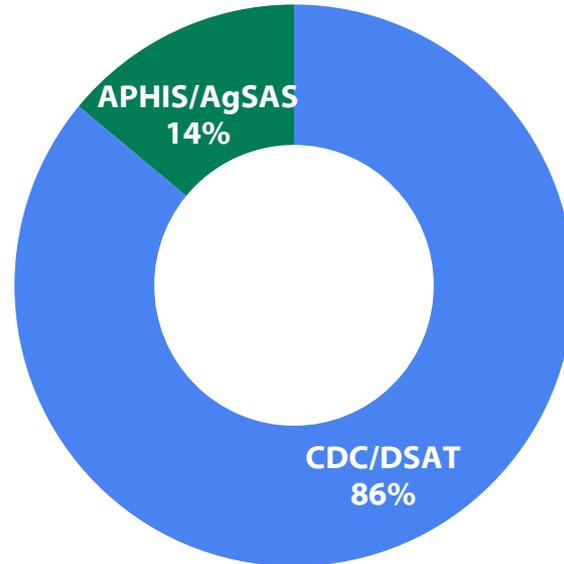
- Promulgate the select agent regulations
- Provide oversight of possession, use, and transfer
- Conduct inspections and approve registrations
- Approve individual access to select agents & toxins
- Receive reports of a theft, loss, or release
- Take appropriate enforcement actions
- Serve as a resource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



Types of Entities Registered with FSAP, 2016



Registered Entities, by Lead Agency (2016)



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



USDA RELEASE FORM TO REPORT ACCIDENTAL THEFT, LOSS, RELEASE, OR OCCUPATIONAL EXPOSURE OF RPPS/SC (FORM 3)

INSTRUCTIONS: Detailed instructions are available at <http://www.aphis.usda.gov/ahis/ahis/ahis3.pdf>. Review all forms completely and type or print in ink. This report must be signed and submitted to either APHIS or CDC.

Approved by: Director, Office of Plant Health and Production, APHIS, USDA, Washington, DC 20250
Printed on: 10/1/2012
Form No.: 3 (10/1/2012)

Approved by: Director, Office of Biotechnology Regulation, CDC, Atlanta, GA 30333
Printed on: 10/1/2012
Form No.: 3 (10/1/2012)

Submit completed form only once by either e-mail, fax, or mail.

SECTION 1 - BASIC INFORMATION AND IDENTIFICATION

1. Name of facility: _____
2. Name of facility (only required if OIG or APHIS): _____
3. Physical address: _____
4. Telephone: _____
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Discussion

www.selectagents.gov

Irsat@cdc.gov or 404-718-2000

For more information, contact CDC
1-800-CDC-INFO (232-4636)
TTY: 1-888-232-6348 www.cdc.gov

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.

