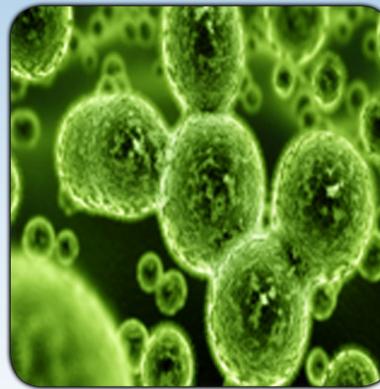


CDC Select Agent Program

Protecting the American public by ensuring the safe and secure possession, use, and transfer of select agents and toxins that pose a threat to public health



Is the nation protected against biological accidents and attacks?

Mail-order plague: The beginnings of bioterrorism awareness

In 1995, a microbiologist was arrested for using fraud to obtain a strain of *Yersinia pestis*, the bacterium that causes plague. How did he get it? By mail order.

At that time, there were no licensing, registration, or safety requirements for laboratories or individuals engaged in transferring disease-causing pathogens or toxins within the United States. There were also no federal requirements to report the transfer of these agents.

Congress acts to deter bioterrorism

CDC Select Agent Program established

A heightened concern about the ease with which disease-causing agents could be obtained led Congress to pass Section 511 of the Antiterrorism and *Effective Death Penalty Act of 1996* (Public Law 104-132).

This Act directed the U.S. Department of Health and Human Services (HHS) to establish a list of biological agents and toxins that could threaten public health and safety, procedures for governing the transfer of those agents, and training requirements for entities working with these "select agents."

HHS delegated the authority to implement this Act to the Centers for Disease Control and Prevention (CDC), which then established the **CDC Select Agent Program**. The Division of Select Agents and Toxins in the CDC Office of Public Health Preparedness and Response oversees this program.

9/11 and increased regulation of select agents

Following the anthrax attacks of 2001, Congress significantly strengthened oversight of select agents by passing the following acts:

- **USA PATRIOT Act** (*Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism Act of 2001; Public Law 107-56*): Restricted access to select agents
- **Bioterrorism Act** (*Public Health Security and Bioterrorism Preparedness and Response Act of 2002; Public Law 107-188*): Increased safeguards and security measures as well as oversight of the possession and use of select agents

Animal and plant agents added to select agent list

Federal Select Agent Program established

In addition to strengthening the regulatory authorities of HHS/CDC, the Bioterrorism Act also granted comparable regulatory authorities to the U.S. Department of Agriculture (USDA) over select agents that pose a severe threat to animal and plant health or products. The USDA's Animal and Plant Health Inspection Service (APHIS), then established the Agricultural Select Agent Program. These two programs constitute the Federal Select Agent Program.

What is a select agent?

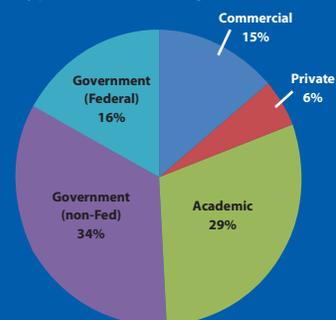
Select agents are biological agents and toxins that could pose a severe threat to public health and plant health, or to animal or plant products.



There are 384 registered entities* in the Federal Select Agent Program:

- HHS/CDC: 320 (86% of total)
- USDA/APHIS: 53 (14% of total)
- Comprised of five different types of entities (see distribution at right)
- Over 11,000 individuals are registered to work with select agents and toxins within these entities

Types of Entities Regulated *



*as of May 2011

CDC and APHIS work together to safeguard select agent research

In March 2005, CDC and APHIS implemented the Bioterrorism Act by issuing the following Select Agent Regulations** for entities possessing, using, or transferring select agents:

- An entity must register with the CDC or APHIS Select Agent Program for each select agent it handles, for each activity it will conduct in association with that agent, and the location where that activity will be conducted.
- Entities must appoint a Responsible Official who must certify that the entities have security measures in place that protect the select agents from theft, loss, and unauthorized access and safety measures in place to prevent the release of agents.
- All individuals who will have access to select agents must undergo a security risk assessment conducted by the Federal Bureau of Investigation's Criminal Justice Information Services Division which evaluates an individual's suitability to access select agents.
- Entities must comply with reporting, training, and incident response requirements.



In addition to strengthening the regulatory authorities of HHS/CDC, the Bioterrorism Act also The Federal Select Agent Program regulates 80 agents (see the complete list of agents in the insert for this brochure). CDC and APHIS share responsibility for some overlap agents because they potentially threaten both humans and animals. The list is reviewed by CDC and APHIS at least every two years to determine if agents need to be added to or deleted from the list.

The establishment of the Select Agent Regulations makes the nation safer from biological threats.

Moving forward: Ensuring safety while supporting research goals

Since 2008, there have been several reviews and reports issued by federal and non-federal experts on how to improve safety and security in biological laboratories, including laboratories that work with select agents. The reports prompted the National Security Staff and the White House Office of Science and Technology Policy to convene experts from across the federal government to synthesize the multiple reports' findings and recommendations to determine how the federal government could best improve security and biosafety of select agents.

This effort led to the issuance of Executive Order 13546, signed by President Obama on July 2, 2010 - *Optimizing the Security of Biological Select Agents and Toxins in the United States*. This executive order will help the United States achieve a crucial balance between two goals that are sometimes seen as being in conflict: increasing the nation's defenses against the threat of biological weapons and reducing the hurdles that legitimate scientists face as they pursue research on potentially dangerous microbes.

Impact of the Select Agent Regulations

As a result of the Select Agent Regulations, the nation now has:

- A registration database containing information on all entities possessing select agents
- Safety and security requirements for all entities working with select agents
- A national system for reporting the theft, loss, or release of select agents
- Security risk assessments performed by the Federal Bureau of Investigation's Criminal Justice Information Service

**Published in the Federal Register on March 18, 2005 (42 CFR Part 73, 7 CFR Part 331 and 9 CFR Part 121)

Impact of the CDC Select Agent Program

The CDC Select Agent Program has greatly enhanced the nation's oversight of the safety and security of dangerous biological agents and toxins. The program promotes laboratory safety and security to minimize the inherent risks that accompany work with select agents by:

Helping secure the nation by developing, implementing, and enforcing the Select Agent Regulations

- Currently, the CDC Select Agent Program works with entities that handle 49 agents, ensuring compliance with requirements for working with select agents such as anthrax, plague, and the smallpox virus.

Strengthening oversight by inspecting entities working with select agents

- 320 entities are registered with and inspected by the CDC Select Agent Program. All aspects of the registration are managed by the program, including amendments to the registration; approval of transfers of select agents; and investigation of reports of theft, loss, or release of select agents. Entities are inspected to ensure compliance with Select Agent Regulations. These assessments allow inspectors to confirm that the appropriate safety and security measures are in place as well as ensure that laboratorians are adequately trained.
- Approximately 11,000 individuals have active approvals to access select agents. CDC works closely with the Criminal Justice Information Services Division to identify those individuals who are prohibited from having access to select agents based on restrictions identified in the USA PATRIOT Act.

Assisting the regulated community by providing guidance and support

- CDC provides technical assistance and guidance to registered entities to promote laboratory safety and APHIS maintain the National Select Agent Registry website (<http://www.selectagents.gov>) that includes applicable regulations, guidance documents, frequently asked questions, links to guidelines, and other helpful information.
- CDC proactively works to provide assistance to registered entities in advance of natural disasters or national events to ensure that all select agents are properly secured to protect them from theft, loss, or release.
- Workshops for registered entities and partners, co-hosted with APHIS, help inform individuals of their legal responsibilities for implementing the Select Agent Regulations.
- An independent whistleblower hotline provides a mechanism for anonymous reporting of safety, security, or other concerns associated with select agents and toxins. For English, call (888) 246-2675; por Español, llame al (888) 246-2857.



Federal and State Partners

The Federal Select Agent Program assists the following government state agencies to ensure laboratories are safe and secure:

- Federal Bureau of Investigation/Weapons of Mass Destruction Unit with criminal investigations regarding potential misuse or illegal acquisition of select agents and toxins.
- Department of Homeland Security/Infrastructure Protection Program with their analysis to determine potential vulnerabilities and threats to registered entities in the United States.
- Department of Transportation (DOT) with their determination whether entities transferring select agents are complying with DOT regulations.
- States with their emergency response planning by providing information to state officials about CDC-registered select agent entities in their states.

For more information:

CDC Select Agent Program
<http://cdc.gov/phpr/dsat>

APHIS Select Agent Program
http://www.aphis.usda.gov/programs/ag_selectagent/

Federal Select Agent Registry
<http://www.selectagents.gov>

Division of Select Agents and Toxins
Office of Public Health Preparedness and Response
Centers for Disease Control and Prevention
1600 Clifton Road NE, Atlanta, GA 30333
<http://cdc.gov/phpr/dsat>

The US Select Agent Program

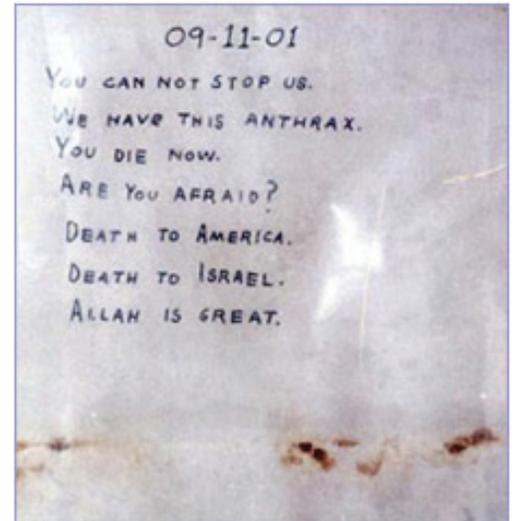
Bioterrorism: A Brief History

Bioterrorism—the deliberate release of disease-causing biological agents (germs) or toxins—poses a significant threat to the health and safety of people, animals, and plants. In the hands of the wrong people, materials intended for legitimate scientific, medical, or commercial use have the potential to harm large numbers of people.

Although the anthrax attacks in the weeks following the 9/11 terrorist attacks focused national attention more acutely on our potential vulnerability, bioterrorism is not a new phenomenon. Throughout history, individuals and groups have used it as a weapon against both military and civilian populations.

- In one of the earliest recorded instances of bioterrorism, Persian armies in the 6th century BC poisoned wells with a fungus that affects rye plants (rye ergot).
- During the American Civil War, a Kentucky physician sold clothing contaminated with smallpox virus to Union troops.

In October 2001, bioterrorism in the US became a reality again when four letters laced with anthrax were sent through the US Postal Service. The attacks resulted in illness in 22 people, the death of 5, and fear and anxiety in millions of others. The cost of decontaminating offices that were exposed totaled over \$23 million.



October 2001 US Anthrax letter

Evolution of the CDC and USDA-APHIS Select Agent Programs

1995-1996

Neo-Nazi extremist illegally obtained bacterium that causes plague (*Yersinia pestis*) by mail order. As a result, Congress passed Section 511 of the Antiterrorism and Effective Death Penalty of 1996 (42 CFR 72.6).

2001-02

US terrorist attacks of 9/11, followed by the Anthrax mailings that resulted in five deaths. As a result, Congress significantly strengthened oversight of select agents by passing the USA PATRIOT Act in 2001 and the Public Health Security and Bioterrorism Preparedness and Response Act of 2002.

2009

On January 9, 2009, President Bush signed Executive Order 13486: Strengthening Laboratory Biosecurity in the United States to review the effectiveness of biosecurity policies regarding select agents and toxins.

2010

President Obama signed an Executive Order giving lead authority to the Department of Health and Human Services (HHS), working with the Department of Agriculture, for inspections of laboratories handling select agents. The Order directs the Secretaries of HHS and USDA to “promulgate final rules and guidance that clearly articulate security actions for registrants who possess, use or transfer” high-risk, or “Tier 1,” pathogens. It also established a Federal Experts Security Advisory Panel within HHS to make recommendations on the security of biological agents and toxins.

Select Agent List

(HHS/CDC regulates agents that pose threats to public health and safety; USDA/APHIS regulates agents that pose a threat to animal and plant health or products.)

HHS Select Agents and Toxins

1. Abrin
 2. Botulinum neurotoxins
 3. Botulinum neurotoxin producing species of *Clostridium*
 4. Cercopithecine herpesvirus 1 (Herpes B virus)
 5. *Clostridium perfringens epsilon toxin*
 6. *Coccidioides posadasii/Coccidioides immitis*
 7. Conotoxins
 8. *Coxiella burnetii*
 9. Crimean-Congo haemorrhagic fever virus
 10. Diacetoxyscirpenol
 11. Eastern Equine Encephalitis virus
 12. Ebola virus
 13. *Francisella tularensis*
 14. Lassa fever virus
 15. Marburg virus
 16. Monkeypox virus
 17. 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)
 18. Ricin
 19. *Rickettsia prowazekii*
 20. *Rickettsia rickettsii*
 21. Saxitoxin
 22. Shiga-like ribosome inactivating proteins
 23. Shigatoxin
- South American Haemorrhagic Fever viruses:
24. Flexal
 25. Guanarito
 26. Junin
 27. Machupo
 28. Sabia
29. Staphylococcal enterotoxins
 30. T-2 toxin
 31. Tetrodotoxin
- Tick-borne encephalitis complex (flavi) viruses:
32. Central European Tick-borne encephalitis
 33. Far Eastern Tick-borne encephalitis
 34. Kyasanur Forest disease
 35. Omsk Hemorrhagic Fever
 36. Russian Spring and Summer encephalitis
37. Variola major virus (Smallpox virus)
 38. Variola minor virus (Alastrim)
 39. *Yersinia pestis*

Overlap Select Agents (on both the CDC and APHIS list)

40. *Bacillus anthracis*
41. *Brucella abortus*
42. *Brucella melitensis*
43. *Brucella suis*
44. *Burkholderia mallei* (formerly *Pseudomonas mallei*)
45. *Burkholderia pseudomallei* (formerly *Pseudomonas pseudomallei*)
46. Hendra virus
47. Nipah virus
48. Rift Valley fever virus
49. Venezuelan Equine Encephalitis virus

USDA Select Agents and Toxins

50. African horse sickness virus
51. African swine fever virus
52. Akabane virus
53. Avian influenza virus (highly pathogenic)
54. Bluetongue virus (exotic)
55. Bovine spongiform encephalopathy agent
56. Camel pox virus
57. Classical swine fever virus
58. *Ehrlichia ruminantium* (Heartwater)
59. Foot-and-mouth disease virus
60. Goat pox virus
61. Japanese encephalitis virus
62. Lumpy skin disease virus
63. Malignant catarrhal fever virus (Alcelaphine herpesvirus type 1)
64. Menangle virus
65. *Mycoplasma capricolum subspecies capripneumoniae* (contagious caprine pleuropneumonia)
66. *Mycoplasma mycoides subspecies mycoides small colony* (Mmm SC) (contagious bovine pleuropneumonia)
67. Peste des petits ruminants virus
68. Rinderpest virus
69. Sheep pox virus
70. Swine vesicular disease virus
71. Vesicular stomatitis virus (exotic): Indiana subtypes VSV-IN2, VSV-IN3
72. Virulent Newcastle disease virus 1

USDA PLANT PROTECTION AND QUARANTINE (PPQ) Select Agents and Toxins

73. *Peronosclerospora philippinensis* (*Peronosclerospora sacchari*)
74. *Phoma glycinicola* (formerly *Pyrenochaeta glycines*)
75. *Ralstonia solanacearum* race 3, biovar 2
76. *Rathayibacter toxicus*
77. *Sclerophthora rayssiae var zaeae*
78. *Synchytrium endobioticum*
79. *Xanthomonas oryzae*
80. *Xylella fastidiosa* (citrus variegated chlorosis strain)

As of 11/17/2008

