

CDC Select Agent Program: Ensuring the Safe and Secure Possession, Use, and Transfer of Select Agents in the U.S. 2008

1

2

3

4

5

6

An important component of the nation's overall terrorism deterrence strategy



DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR DISEASE CONTROL AND PREVENTION

SAFER • HEALTHIER • PEOPLE™



Background

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 events of September 11, 2001, 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 the toxin, 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 present-day United States became a reality when four letters laced with anthrax were sent through the United States 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 climbed to over 23 million dollars.

Congress Acts to Deter Bioterrorism

Establishment of Oversight of Select Agents

In 1995, a neo-Nazi extremist and microbiologist was arrested for illegally obtaining *Yersinia pestis*, the bacteria that causes plague, by mail order in the United States. 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 and no federal requirements to report the transfer of these agents.

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*. This law directed the U.S. Department of Health and Human Services (HHS) to establish a list of biological agents and toxins that potentially threaten public health and safety, procedures governing the transfer of those agents, and training requirements for entities working with these “select agents.” This Act led to the establishment of the Select Agent Program at the Centers for Disease Control and Prevention (CDC).

Following the events of 2001, Congress significantly strengthened oversight of select agents with the passage of the *Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism Act of 2001* (USA PATRIOT Act) and the *Public Health Security and Bioterrorism Preparedness and Response Act of 2002* (Bioterrorism Act). The USA PATRIOT Act restricted who could have access to select agents. The Bioterrorism Act created increased safeguards and security measures for select agents. The Bioterrorism Act strengthened the regulatory authorities of HHS and granted comparable regulatory authorities to the United States Department of Agriculture (USDA) over biological agents and toxins that pose a severe threat to animal health, plant health, animal products, or plant products. USDA delegated its authority to the Animal and Plant Health Inspection Service (APHIS). CDC and APHIS share responsibility for some agents because they potentially threaten both humans and animals (overlap agents).

The Select Agent Regulations

CDC and APHIS implemented the Bioterrorism Act through a series of regulations. These regulations culminated with the publication of the final Select Agent Regulations (42 CFR Part 73, 7 CFR Part 331, 9 CFR Part 121) in the *Federal Register* on March 18, 2005.

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 that handle these agents must appoint a Responsible Official who must certify that the entity meets the requirements described in the Select Agent Regulations. All individuals who will have access to select agents must undergo a security risk assessment conducted by the Department of Justice. For example, entities must 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. Entities must comply with reporting, training, and incident response requirements.

The Select Agent List

In determining whether to include an agent in the list, the Bioterrorism Act requires that HHS considers the following criteria:

- the effect on human health after exposure to the agent or toxin;
- the infectivity and means of transmission of the agent or toxin to humans;
- the availability and effectiveness of pharmacotherapies and immunizations to treat and prevent any illness resulting from infection by the agent or toxin.
- any other criteria that the Secretary deems appropriate

CDC regulates 41 agents which include Ebola virus, monkey pox virus, anthrax bacteria, and ricin. CDC and APHIS review the select agent list at least every two years to determine if agents need to be added to or deleted from the list. A complete list of the select agents is available at www.selectagents.gov.

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 Select Agent Program promotes laboratory safety and security by

- developing, implementing, and enforcing the select agent regulations,
- providing guidance to the regulated community and
- inspecting facilities working with select agents.

The Select Agent Program oversees entities that possess, use, or transfer HHS or overlap select agents to ensure that entities are in compliance with all the requirements of the Select Agent Regulations. As of May 2, 2008, 324 entities are registered with the CDC Select Agent Program. The program manages all aspects of the entity registration, including amendments to the registration, approval of transfers of select agents, and investigation of reports of theft, loss, or release of select agents. Since 2003, the program has conducted over 700 inspections to ensure that entities are following appropriate safety and security measures and complying with all other requirements of the Select Agent Regulations. Inspections consist of an extensive review of laboratory safety and security. Verification site visits may be conducted to ensure that the registered entities have corrected inspection findings.

Select Agent Program Highlights

Emergency Response

CDC proactively works with registered entities in advance of imminent natural disasters to ensure that all select agents are properly secured. For example, prior to the landfall of Hurricane Katrina in 2005, CDC contacted all registered entities located in Louisiana, Mississippi, and Alabama. CDC collected information regarding the entities' plans to safeguard select agents during and after the storm and informed the entities that CDC stood ready to expedite the emergency transfer of select agents should the need arise. After the storm subsided, CDC followed-up with these entities and confirmed that no agents were compromised.

Response to Old Threats That are New Again

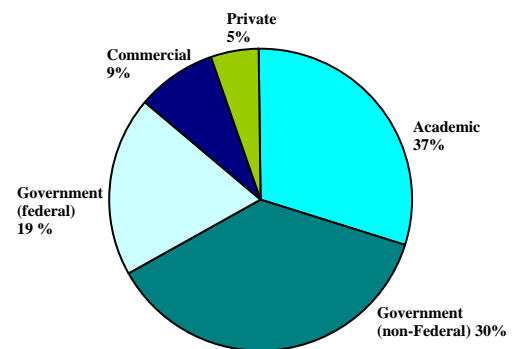
After the complete coding sequence for the 1918 Pandemic Influenza A H1N1 virus, which killed over 5 million worldwide, was reconstructed in 2005, CDC acted quickly to determine if it should be placed on the select agent list. Based on a study that demonstrated the high virulence of the virus and historical mortality data, CDC determined the reconstructed virus posed a severe threat to public health and published an interim final rule adding the reconstructed virus to the HHS select agent list. This action was taken within two months of the virus being reconstructed. By designating the 1918 strain as a select agent, the CDC Select Agent Program has placed strict regulatory controls on the possession, use, and transfer of this strain and has been proactive in protecting the public from the consequences of a release of the 1918 strain.

In fiscal year 2007, CDC:

- conducted 110 inspections to ensure that appropriate security and safety measures are in place to deter the theft, loss, or release of select agents; all registered entities have been inspected at least once.
- authorized 489 requests to transfer select agents.
- granted approval to access select agents to 3,609 individuals and denied access to 21 individuals based on a security risk assessments conducted by the Department of Justice.

Regulating the possession, use, and transfer of select agents is an important component of the nation's deterrence strategy.

Types of Institutions Registered with the CDC Select Agent Program
(As of 05/02/2008)



Guidance

While enforcing the Select Agent Regulations is the CDC Select Agent Program's primary responsibility, the program also promotes laboratory safety and security by providing technical assistance and guidance to registered entities. The CDC and APHIS Select Agent Programs maintain a Web site (www.selectagents.gov) that includes applicable regulations, guidance documents, frequently asked questions, links to guidelines, and other helpful information. Guidance that CDC and APHIS have developed collaboratively includes a security plan template, inspection checklists, theft, loss, and release guidance, and videos describing the facility inspection process.

“The creation of the CDC Select Agent Program has given our nation an important tool to help minimize the inherent risks that accompany work with select agents.”

Dr. Richard Besser, Director of CDC's Coordinating Office for Terrorism Preparedness and Emergency Response

Future Directions

Web-based Submission of Forms

The addition of a new capability to the joint CDC-APHIS information management system, the National Select Agent Registry (NSAR), will enhance operations. This new Web-based interface will allow entities to complete and submit all forms to the program electronically. This will help to improve customer service, decrease response time for entity requests, and improve data reliability.



Expanding Guidance

CDC plans to continue to expand the guidance that it provides to entities on the Select Agent Regulations. Additional outreach and training will be provided to the regulated community through presentations at professional conferences, development of a video with an overview of the Select Agent Regulations, and creation of additional guidance documents related to biosafety, incident response, and record-keeping.

Monitoring Emerging Technologies

The CDC Select Agent Program must address the challenge of how the Select Agent Regulations apply to emerging technologies, such as synthetic genomics and nanotechnology. With technology advancing at a rapid pace, CDC and its federal partners are committed to ensuring that the Select Agent Regulations can respond to new threats and vulnerabilities.

Sharing Information with States

CDC recognizes that sharing the identity and location of entities registered for possession of select agents with State officials will assist those officials with emergency preparedness planning. CDC will be contacting state preparedness officials to inform them that this information is available and describe the requirements that they must meet to receive this information.

¹ Transmission Electron Micrograph of the Ebola Virus. Courtesy of the CDC Public Health Images Library

² Arthroconidia of *Coccidioides immitis*. Courtesy of the CDC Public Health Images Library

³ Negative stained transmission electron micrograph (TEM) of recreated 1918 influenza virions collected from the supernatant of a 1918-infected Madin-Darby Canine Kidney (MDCK) cell culture 18 hours after infection. Courtesy of the CDC Public Health Images Library

⁴ Laboratorian examining reconstructed 1918 Pandemic Influenza Virus inside a specimen vial containing an orange-colored supernatant culture medium.. Courtesy of the CDC Public Health Images Library

⁵ The international biological hazard symbol

⁶ Transmission electron micrograph of *Bacillus anthracis*. Courtesy of the CDC Public Health Images Library

⁷ Upper right: One of the letters laced with anthrax bacteria. Lower right: U.S. government personnel working to identify contaminated mail after the anthrax attacks of 2001. Courtesy of the Federal Bureau of Investigation

⁸ Image of homepage of the National Select Agent Registry website: www.selectagents.gov

For more information, please contact
Centers for Disease Control and Prevention
Select Agent Program
1600 Clifton Rd. MS A-46
Atlanta, GA 30333

Telephone: 404-718-2000 • E-mail: Irsat@cdc.gov • Website: www.selectagents.gov