

Office of Public Health Preparedness and Response Division of Select Agents and Toxins

Role in Public Health Preparedness and Response

The Division of Select Agents and Toxins (DSAT) administers CDC's Select Agent Program and the Etiologic Agent Import Permit Program. These programs regulate the possession, use, and transfer of certain biological agents and toxins that pose a severe threat to public health and safety, and the importation of etiological agents and vectors of human disease.

CDC Select Agent Program

The CDC Select Agent Program has greatly increased the federal government's oversight of the safety and security of dangerous biological agents and toxins. As a result of the CDC Select Agent Program, many entities registered to possess select agents and toxins have improved and strengthened their biosafety and security practices and procedures. DSAT ensures compliance with safety and security standards by:

- Developing and enforcing select agent regulations
- Inspecting entities that possess, use, or transfer select agents
- Providing guidance to the regulated community

Developing and Enforcing Select Agent Regulations. CDC's Select Agent Program oversees entities that possess, use or transfer select agents and toxins that cause disease in humans. The U.S. Department of Agriculture's (USDA) Animal and Plant Health Inspection Service (APHIS) has a parallel program that oversees entities that possess, use or transfer

select agents that cause disease in animals and plants. Together these two programs regulate 80 select agents and toxins. DSAT regulates 57 agents and toxins including the bacterium that cause bubonic plague, the smallpox virus and toxins such as ricin. DSAT shares responsibility for the regulation of agents that threaten both humans and animals, such as anthrax, with APHIS. The select agent list is reviewed at least every two years to determine if agents need to be added to or deleted from the list.

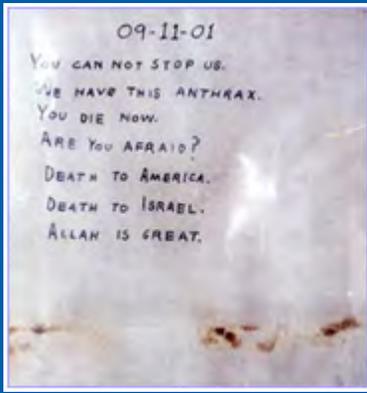
As part of the federal government's decision to implement robust oversight of select agents and toxins, CDC and APHIS issued the Select Agent Regulations. One of the fundamental elements of the Select Agent Regulations is to keep select agents out of the possession of individuals who might intend to misuse them, such as a bioterrorist. DSAT works closely with the Department of Justice's Criminal Justice Information Service (CJIS) to identify those individuals who are prohibited from access to the select agents and toxins regulated by CDC based on the restrictions identified in the USA PATRIOT Act.

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 Department of Justice's Criminal Justice Information Service





Accomplishments

DSAT is continually working to increase laboratory safety and security by inspecting and offering guidance to the regulated community. Recent key accomplishments (fiscal year 2010) to support this effort include:

- Conducted 194 inspections with 90% of the entities inspected on an 18-month inspection cycle and 23% on a 12-month inspection cycle. (The number of inspections has increased by 96% from 2007, the comparable year for a 3-year inspection cycle.) 17 unannounced inspections were also conducted in FY2010, compared to 4 in FY2009, for an 81% increase.
- Established a confidential means for reporting select agent safety and security issues through the Department of Health & Human Services, Office of Inspector General (HHS-OIG) fraud, waste, and abuse hotline.
- Hosted a workshop in Sparks, NV (6/15/10) to educate entities on the select agent regulations.
- Contacted registered entities that were involved in 15 natural disasters to ensure that all select agents and toxins are properly secured to protect them from theft, loss, or release.
- Implemented a tracking system to track packages containing select agents and toxins being shipped by FedEx.
- Submitted a notice of proposed rulemaking to update the current import permit regulations (42 CFR 71.54) and published in the Federal Register an advance notice of proposed rule making that initiated the biennial review of the select agent list.
- Supported international biosecurity efforts regarding select agents by performing five international inspections on the behalf of the National Institutes of Health.



Inspecting Entities that Possess, Use, or Transfer Select Agents. There are currently 411 registered entities that work with select agents, and 323 of these entities are registered with DSAT for the possession, use, or transfer of select agents. All registered entities have been inspected at least once and approximately 11,000 individuals have active approvals to access select agents.

All registered entities must undergo an inspection by DSAT to ensure that entities are following appropriate safety and security measures and complying with all the requirements of the Select Agent Regulations. These in-depth assessments allow inspectors to confirm that registered facilities have the appropriate security and safety measures in place to deter the theft, loss, or release of select agents that laboratorians are adequately trained to work safely with the agents, and that accountability records are maintained.

Providing Guidance to the Regulated Community. The CDC and USDA APHIS Select Agent Programs provide guidance and support to assist the regulated community in meeting the requirements of the select agent regulations. Entities registered with the CDC Select Agent Program are assigned a file manager to assist the entity in maintaining its registration. The file manager is available by phone, FAX, or e-mail to the Responsible Official at the regulated entity during normal business hours to answer questions and provide advice on maintaining the entity's registration. In addition, the National Select Agent Registry website (www.selectagents.gov) is maintained with up-to-date information, including guidance documents, checklists based on regulations and national standards, other resource materials such as inspection videos, and an e-mail link for questions or requests. Since 2008, the CDC and USDA APHIS Select Agent Programs have hosted annual workshops to inform individuals of their legal responsibilities for implementing the select agent regulations.

DSAT also 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.

CDC's Etiologic Agent Import Permit Program

CDC's Etiologic Agent Import Permit Program (EAIPP) regulates the importation of etiologic agents (microorganisms or microbial toxins that cause disease in humans), hosts, and vectors of human disease into the United States. DSAT processes over 2,000 import permits on an annual basis. Prior to issuing an import permit, DSAT reviews all applications to ensure that entities have appropriate safety measures in place for working safely with imported infectious agents. The majority of import permits are issued to laboratories or other entities conducting research or diagnostic activities on these infectious agents or specimens.

DSAT also collaborates with CDC's Division of Global Migration and Quarantine, which is charged with preventing the introduction, transmission, or spread of communicable diseases from foreign countries into the United States and the U.S. Customs and Border Protection.

For more information about CDC's public health preparedness and response activities, go to <http://www.cdc.gov/phpr/>

Office of Public Health Preparedness and Response
Centers for Disease Control and Prevention
1600 Clifton Road NE, Atlanta, GA 30333

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