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 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 infectious agents and vectors of human disease.

CDC Select Agent Program

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 (USDA) Animal and Plant Health Inspection Service's Agriculture Select Agent Services (AgSAS) has a parallel program that oversees entities that possess, use or transfer select agents that cause disease in animals and plants. These two programs constitute the Federal Select Agent Program (FSAP) and regulate 65 select agents and toxins. DSAT shares responsibility for the regulation of agents that threaten both humans and animals, such as anthrax, with AgSAS. 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, FSAP issued the Select Agent Regulations. One of the fundamental elements of the Select Agent Regulations is to keep select agents and toxins out of the possession of individuals who might intend to misuse them, such as a bioterrorist. FSAP works closely with the Department of Justice's Criminal Justice Information Services Division (CJIS) to identify those individuals who are prohibited from access to the select agents and toxins regulated by the FSAP based on the restrictions identified in the USA PATRIOT Act.

Inspecting Entities that Possess, Use, or Transfer Select Agents. There are currently 324 entities registered with the FSAP that work with select agents and toxins, and 284 of these entities are registered with DSAT. All registered entities have been inspected at least once and approximately 9,500 individuals have active approvals to access select agents and toxins.

All registered entities must undergo an inspection by the FSAP 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 and toxins; to verify that laboratorians are adequately trained to work safely with the agents, and ensure accountability of records are maintained.

Benefits of the Select Agent Regulations

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

- A comprehensive real time database containing information on all entities possessing select agents and toxins
- Reporting systems to track the identification, theft, loss, release, safety or security concerns related to select agents and toxins
- A tracking mechanism to monitor shipments
- Security risk assessments performed by the Department of Justice's Criminal Justice Information Service

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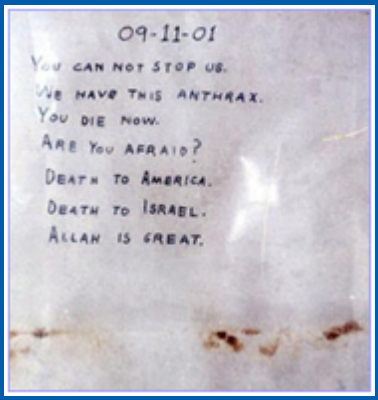

Accomplishments

DSAT is continually working to increase laboratory safety and security by inspecting and offering guidance to the regulated community. Recent key accomplishments (calendar year 2013) to support this effort include:

- Regulated the safe and secure possession, use, and transfer of biological select agents and toxins (167 inspections) and permitted the importation of infectious biological agents, infectious substances, and vectors (1610 Import Permits). Efforts resulted in the low incidence of confirmed thefts (0), confirmed losses (2), and confirmed releases (2) that an exposure occurred that resulted in occupational illness.
- Contacted 83 entities to verify the security of their select agents and toxins contemporaneously with 8 natural disasters and the Boston Marathon bombing.
- Published "Biosafety Recommendations for Working with Influenza Viruses Containing a Hemagglutinin from the A/goose/Guangdong/1/96 Lineage" in the June issue of the Morbidity and Mortality Weekly Report.
- In coordination with USDA, dev eloped and published on the CDC Influenza Division website, guidelines for safely working with the emerging pathogen influenza A H7N9.
- DSAT hosted an international biosecurity meeting for representatives from 11 countries in March to promote the safe and secure use of dangerous biological agents and toxins.
- Supported international biosecurity efforts regarding select agents and toxins by performing three international inspections.

Providing Guidance to the Regulated Community. The FSAP provides guidance and support to assist the regulated community in meeting the requirements of the select agent regulations. The FSAP 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 FSAP has hosted annual workshops to inform individuals of their legal responsibilities for implementing the select agent regulations.

Federal Partners. The FSAP assists the following partners 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
- Departments of Defense, Energy, Homeland Security, Veterans Affairs and Environmen-tal Protection Agency to better coordinate the inspections of entities that are federally owned or federally funded

CDC's Import Permit Program

CDC's Import Permit Program (IPP) regulates the importation of infectious biological agents, infectious substances, and vectors of human disease into the United States. Prior to issuing an import permit, IPP reviews all applications to ensure that entities have appropriate safety measures in place for working safely with imported infectious agents.

Inspecting Permittees. IPP may inspect applicants to ensure that the facilities have implemented the appropriate biosafety measures for the infectious agent or vector to be imported.

Providing Guidance to the Regulated Community. IPP provides guidance and support to assist the regulated community in meeting the requirements of the import permit regulations. IPP website (www.cdc.gov/od/eaipp/) is maintained with up-to-date information including guidance documents, resource materials, and an e-mail link for questions or requests.

Federal Partners. IPP 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/.

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