

Regulation of Select Agents and Toxins in the U.S.



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City of Frederick Containment Lab Community Advisory Committee

March 13, 2012



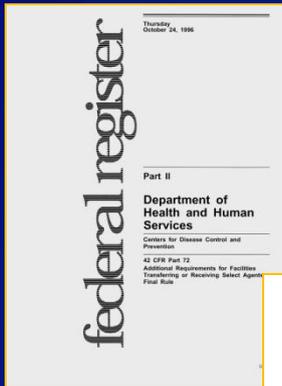
Centers for Disease Control and Prevention

Office of Public Health Preparedness and Response

Select Agent Program Legislative Mandates

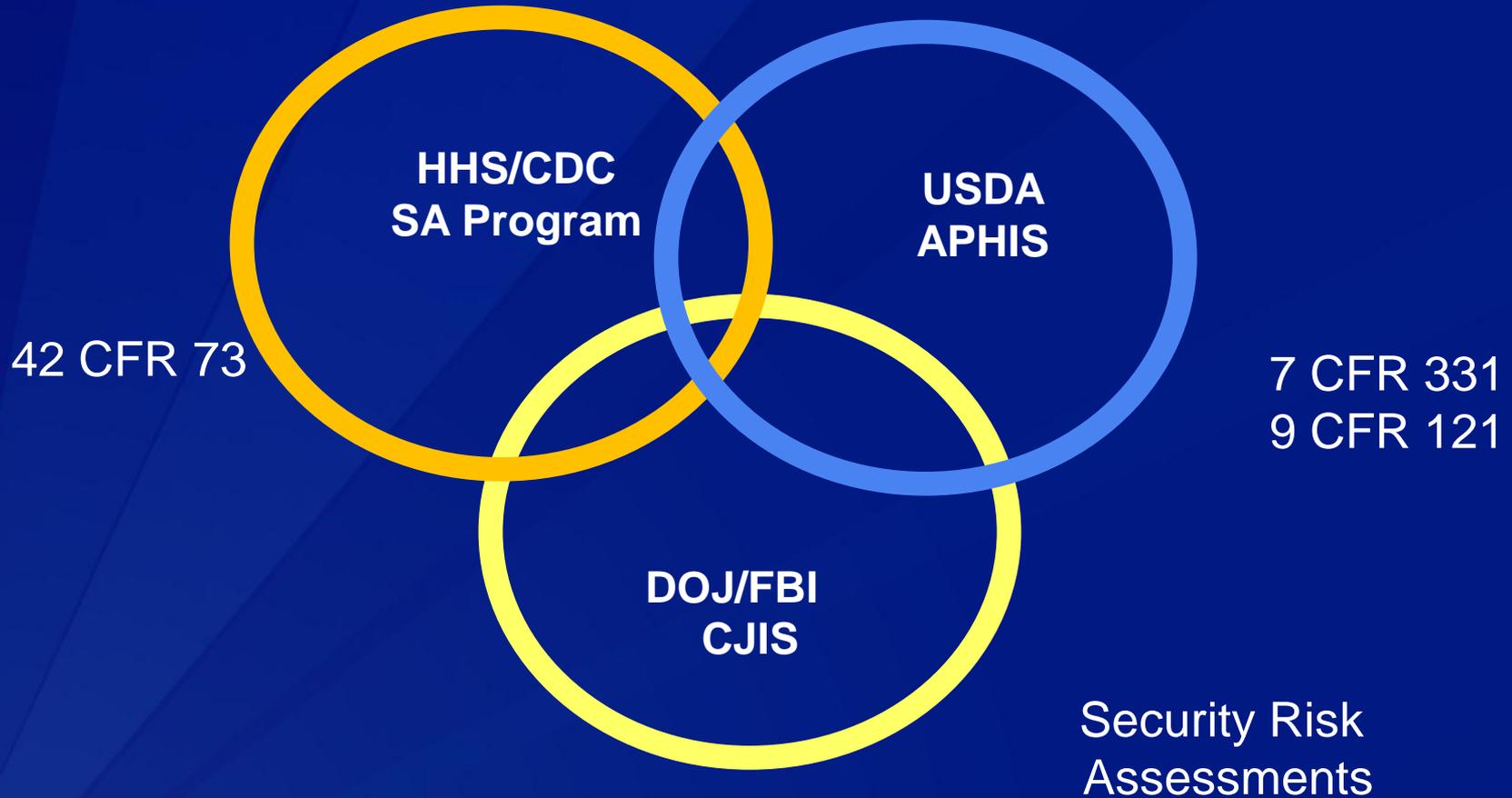
- Antiterrorism and Effective Death Penalty Act of 1996 (signed April 24, 1996)
 - Authorized 42 CFR Part 72.6 “Additional Requirements for Facilities Transferring or Receiving Select Agent”
- USA PATRIOT Act (Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism Act of 2001, signed October 23, 2001)
- Public Health Security and Bioterrorism Preparedness and Response Act 2002, Title II (signed June 12, 2002)

What are the Select Agent Regulations?



- **Interim Final Rule: “Possession Use, and Transfer of Select Agents and Toxins” (42 C.F.R. 73, 9 C.F.R. 121, and 7 C.F.R. 331)**
 - **Effective February 7, 2003**
- **Final Rule: “Possession, Use, and Transfer of Select Agents and Toxins” (42 C.F.R. 73, 9 C.F.R. 121, and 7 C.F.R. 331)**
 - **Effective April 18, 2005**
- **Interim Final Rule: “Reconstructed Replication Competent Forms of the 1918 Pandemic Influenza Virus Containing Any Portion of the Coding Regions of All Eight Gene Segments” (42 C.F.R. 73)**
 - **Effective October 20, 2005**

Primary Federal Partners



Examples of Select Agents and Toxins

- **HHS-only Agents**

- Ebola virus, Lassa fever virus, Smallpox virus
- *Yersinia pestis*, *Francisella tularensis*, ricin

- **USDA-only Agents**

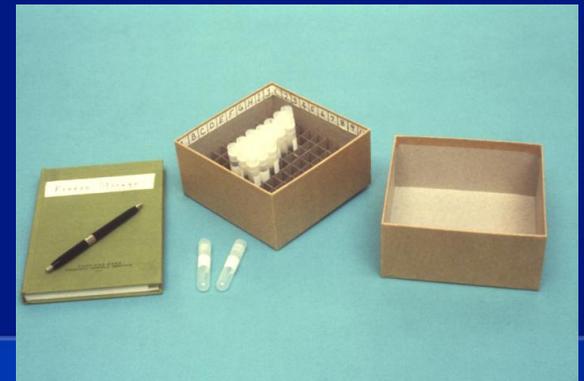
- Highly Pathogenic Avian Influenza virus, Blue Tongue virus, Bovine Spongiform Encephalopathy prion
- Newcastle virus, Sheep Pox virus, Foot and Mouth virus

- **Overlap Agents**

- *Bacillus anthracis*, *Brucella abortus*, *Coccidioides immitis*, *Francisella tularensis*, Botulinum toxin, VEE, EEE

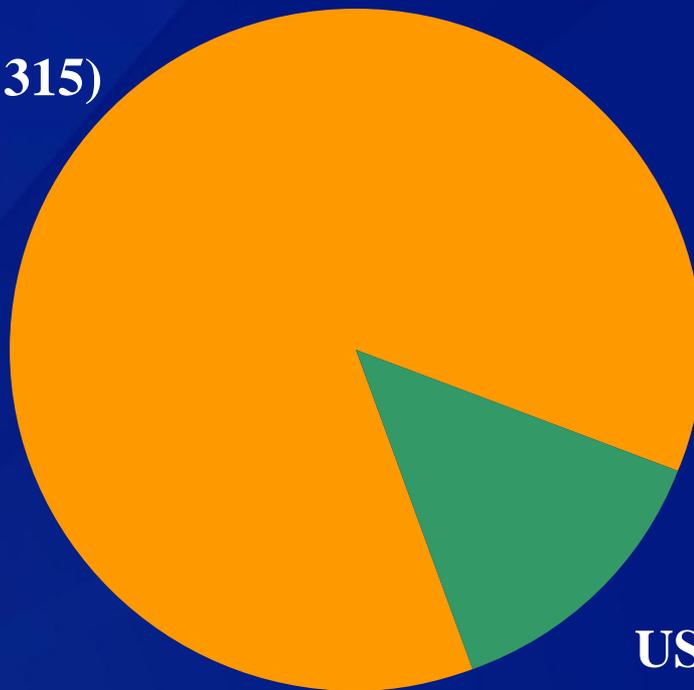
Entity Requirements

- Register for each select agent or toxin it intends to possess, use, or transfer
- Designate a Responsible Official (RO)
- Receive APHIS or CDC approval of the entity (owners), RO, & individuals who need access to select agents
 - Based on FBI/CJIS check of electronic databases - Security Risk Assessment (SRA)
- Maintain records:
- Receive prior approval of all transfers
- Develop safety, security, and incident response plans
- Conduct drills or exercises at least annually
- Conduct safety and security training
- Provide notification of theft, loss, or release
- Allow for inspections by CDC or APHIS



Number of Entities Registering a Select Agent or Toxin with HHS/CDC or USDA/APHIS (as of 03/01/2012)

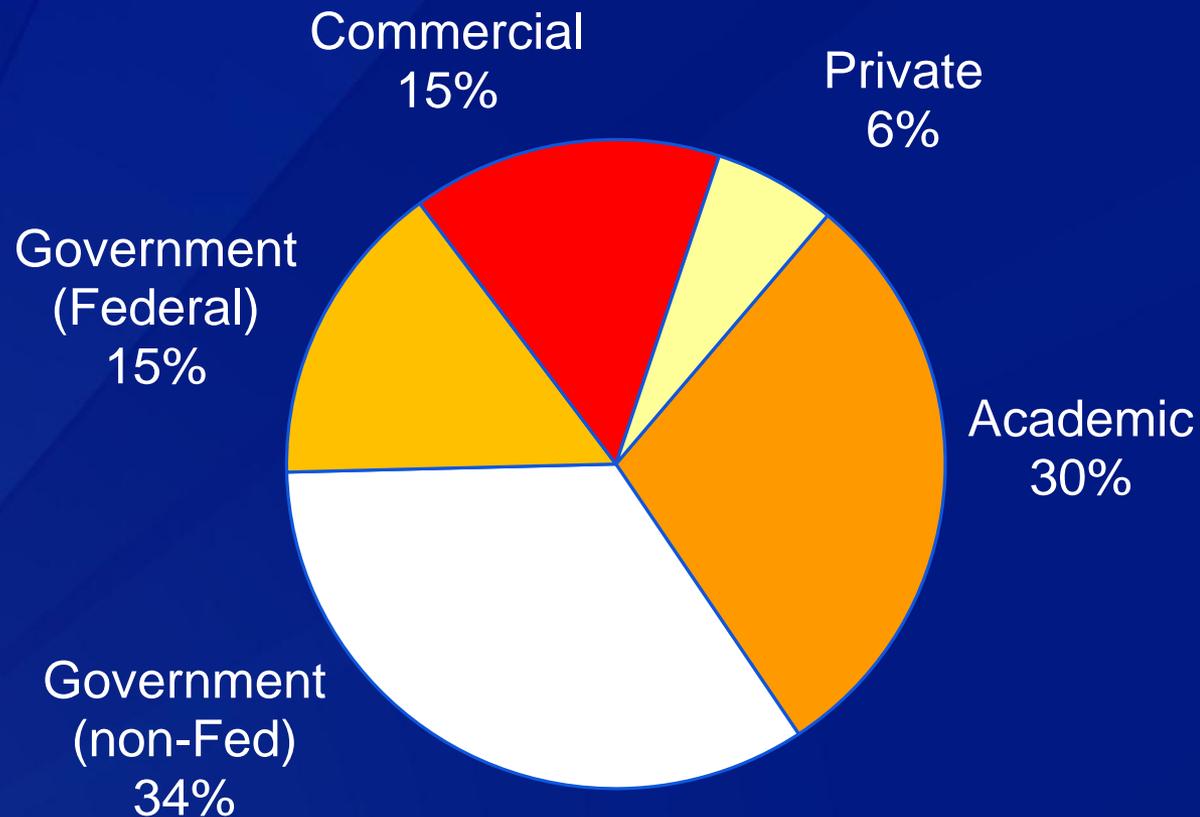
HHS/CDC: 86% (n= 315)



USDA/APHIS: 14% (n=50)

Types of CDC-Lead Entities Registered

(Total = 315 as of March 1, 2012)



Inspection Process

- **Registered laboratories**
 - Follow entity entry and exit requirements (Personal protective equipment (PPE))
 - Biosafety (Medical surveillance program/plan)
 - Inventory audit/review of inventory records
 - Interviews of RO, ARO, PI, laboratorians
- **Shipping/Receiving**
- **Document Review**
 - Plans (biosafety, incident response, security)
 - Training
 - Access records (manual and electronic, if applicable)
 - Institutional Biosafety Committee Minutes/Approvals
 - Institutional Animal Care and Use Committee Minutes/Approvals
 - APHIS/CDC Form 2, 3, and 4; intra-entity transfers
 - Incident Reports
- **Security**
 - Record observations from time on campus
 - Visit camera monitoring stations, etc., if applicable

Select Agent Enforcement

- HHS - Office of Inspector General
- USDA - Investigative and Enforcement Services
- DOJ - FBI

Select Agent Enforcement

- **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

HHS Non-Compliance Statistics

- 9 cases of administrative actions
 - 5 Applications denied
 - 2 Registrations suspended
 - 2 Registrations revoked
- 19 entities have participated in Performance Improvement Plan (PIP)
 - 18 entities successfully completed PIP
 - 1 entity continuing on PIP
- 15 entities that failed to comply with the select agent regulations resulted in over two million dollars in civil monetary penalties (http://oig.hhs.gov/fraud/enforcement/cmp/agents_toxins.asp)

Reporting Incidents

Notification of Releases:

“Upon discovery of a release of an agent or toxin causing **occupational exposure** or **release of a select agent or toxin outside of the primary barriers of the biocontainment area**, an individual or entity must immediately notify CDC or APHIS.”

42 CFR 73.19(b)



Reporting Incidents

“**Occupational exposure** means reasonably anticipated skin, eye, mucous membrane, or parenteral contact with blood or other potentially infectious materials that may result from performance of an employee’s duties”

29 CFR 1910.1030



Reporting Incidents

Event Discovery

- By entity, law enforcement, inspection



Notification to CDC

- Immediately by email, fax, phone
- Submit Form 3 within 7 calendar days



CDC Contacts

- Federal Bureau of Investigation
- CDC response groups
- Animal and Plant Health Inspection Service (APHIS)
- Other Federal agencies
- Local and state health departments
- Local and state law enforcement



Reporting Incidents

- **Event data collection and processing**
 - Agent
 - Dates (event, discovery, report)
 - Contact information
 - Circumstances
 - Number of persons potentially exposed
 - Actions taken to mitigate release
 - Specific hazards of release
- **Risk assessments**
 - Public health risk
 - Occupational health risk
 - Environmental risk
- **Incident Investigations**
- **Event follow – up and closure**
- **Data analysis**

Statutory Protections for Federal Agencies Possessing NSAR Information [42 USCS § 262a(h)]

- Protection from disclosure through the Freedom Of Information Act.
- Congressional exemption

System of Records Notice

- Report of a New Privacy Act System of Records
- In accordance with Appendix I of OMB Circular A-130, Management of Federal Information Resources
- Published July 2, 2007

Federal Register / Vol. 72, No. 126 / Monday, July 2, 2007 / Notices 35993

Federal Communications Commission
Markus H. Burk,
Secretary.
[FR Doc. 07-1254 Filed 6-30-07; 2:56 pm]
BILLING CODE 6730-01-9

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Disease Control and Prevention
Privacy Act of 1974; New System of Records

AGENCY: Department of Health and Human Services (HHS), Centers for Disease Control and Prevention (CDC).
ACTION: Notice of a New System of Records.

SUMMARY: In accordance with the requirements of the Privacy Act, the Centers for Disease Control and Prevention (CDC) is proposing to establish a new system of records (SCR), 09-20-0170, "National Select Agent Registry (NSAR)/Select Agent Transfer and Entry Registration Information System (SATERIS), HHS/CDC/CCTFEE". The purpose of the system is to limit access to those biological agents and toxins listed in 42 CFR Part 73.9 CFR Part 121, and 7 CFR Part 391, to those individuals who have a legitimate need to handle or use such agents or toxins, and who are not identified as restricted persons by the U.S. Attorney General. NSAR is a single web-based information management system shared by CDC and the U.S. Department of Agriculture (USDA)/Animal and Plant Health Inspection Service (APHIS) that tracks the possession, use and transfer of select agents and toxins that could pose a severe threat to public health and safety, to the health and safety of animals, and to the safety of plants or animal and plant products. We have provided background information about the new system in the **SUPPLEMENTARY INFORMATION** section below.

DATES: Effective Date: CDC filed a new

was submitted to OMB and the Congress, whichever is later, unless CDC receives comments that persuade us to defer implementation.
ADDRESS: Comments should be addressed to the CDC Privacy Act Officer at the address listed below. Comments received will be available for review at this location by appointment during regular business hours from 8 a.m. to 4:30 p.m., Monday through Friday in the CDC Royal Facility, Building 23, Room 8125, Atlanta, Georgia.

FOR FURTHER INFORMATION CONTACT: Jeffrey S. Dushinsky, Privacy Act Officer, Office of the Chief Science Officer, Centers for Disease Control and Prevention, 1600 Clifton Road, NE, Building 23, Room 8125, Mailstop 33-74, Atlanta, Georgia 30333, (404) 639-4642.

SUPPLEMENTARY INFORMATION: CDC proposes to establish a new system of records within its Coordinating Office for Terrorism Preparedness and Emergency Response (CTFER), 09-20-0170, "National Select Agent Registry (NSAR)/ Select Agent Transfer and Entry Registration Information System (SATERIS), HHS/CDC/CCTFEE." An important component of the nation's overall terrorism deterrence policy, the Division of Select Agents and Toxins (DSAT) in the Coordinating Office for Terrorism Preparedness and Emergency Response (CTFER) within the CDC regulates the possession, use, and transfer of biological agents and toxins (select agents) that could pose a severe threat to public health and safety. A select agent is defined as a virus, bacterium, fungus or toxin that could pose a severe threat to public health and safety, to animal or plant health, or animal or plant products.

Description of the Proposed System of Records
A. Statutory and Regulatory Basis for DSAT. The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 requires entities to register with the U.S. Department

within the USDA, APHIS has a strict responsibility for registering entities and personnel handling agents that pose a severe threat to animal or plant health, or animal or plant products.
The Acts require safeguards and security measures that will adequately protect these agents. This includes controlling access and screening of entities and personnel through security risk assessments conducted by the U.S. Attorney General. The Acts also require the establishment of a national database of registered entities. While some entities register for select agents regulated only by HHS, others the select agents regulated only by USDA, there are a number of entities registering for select agents that can pose a severe threat to public health and safety, to animal health, or to animal products ("overlap" select agents). Since DSAT and APHIS coordinate regulatory activities for those overlap select agents that would be regulated by both agencies, the Acts require that a single national database be established. This new Privacy Act system of records notice (SCR/N) describes the records and processes that enable DSAT to fulfill HHS requirements. APHIS will be publishing a similar SCR/N to address how USDA will fulfill theirs.

B. Collection or Maintenance of Data in the System
CDC will only collect the minimum amount of personal data necessary to achieve the purpose of this system, which is to limit access to the select agents listed in 42 CFR Part 73.9 CFR Part 121, and 7 CFR Part 391, to those individuals who have a legitimate need to handle or use such agents, and who are not identified as a restricted person by the U.S. Attorney General. The data elements required are name, address, date of birth, job title, and the name of the institution that would be housing the select agent(s).
Entity handling select agents must

System of Records Notice: Disclosure of Records

- To deal more effectively with outbreaks and conditions of public health significance
- To assist in making a determination concerning an individual's trustworthiness to access select agents and toxins
- To prevent domestic or international terrorism or for any criminal purpose
- To ensure that the transfer of select agents and toxins is done safely and in compliance with Department of Transportation regulations
- To respond to a congressional inquiry
- To defend the government in the event of a litigation

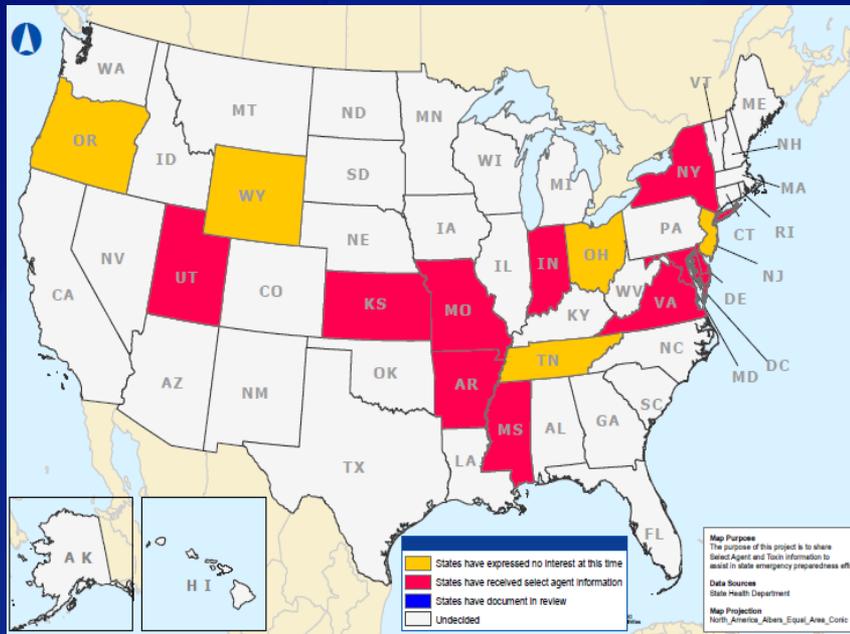
Memorandum of Understanding with Other Federal Partners

- Department of Homeland Security's Infrastructure Protection Program to assist program with their analysis to determine potential vulnerabilities and threats to registered entities in the United States.
- Department of Transportation (DOT) to determine whether entities transferring select agents are complying with DOT regulations.
- Department of Health and Human Services' Food and Drug Administration (FDA) to confirm that the FDA has accepted or approved Investigational New Drug application
- Federal Bureau of Investigation to assist them with on-going criminal investigations regarding potential misuse or illegal acquisition of select agents and toxins

Sharing Select Agent Information with the States

- Having information about the location of the facilities that possess select agents and toxins will assist the states with emergency preparedness efforts.
- Must meet the following requirements prior to receiving select agent information:
 - The state must provide the state's plan for using the information for public health preparedness planning.
 - The state must provide the state's policies and procedures for safeguarding the information from unauthorized access or release.
 - The proposed custodian of the information must sign an agreement limiting the sharing of information.
 - The state must provide a written legal opinion from their state's legal counsel stating that the information provided can be protected from further release under the applicable state open records laws.

Sharing Select Agent Information with the States



- Information Provided:
 - Registered entities in State
 - Name of a contact person for each registered entity
- As of March 1, 2012,
 - Ten states have received select agent information including one city (New York).
 - Five states have expressed that they are not interested in receiving this information.
 - All other states are undecided.

Sharing Select Agent Information with Maryland

- Agreement signed in June 2010
- Information provided as part of the agreement:
 - Name and location of registered entities within state
 - Name and contact information for Responsible Officials of registered entities within state

Executive Order 13546

- Tiered/Reduced Select Agent List
- Federal Expert Security Advisory Panel
 - Recommendations on strengthening personal reliability of BSAT workers
 - Recommendations on strengthening physical security at BSAT facilities
- Streamlined Agency/Department BSAT Policies
- Coordinated Inspections

Inspection Roles

- Army, Navy, and Air Force conduct general, compliance-oriented, technical inspections of chemical, biological, radiological, nuclear, and other technical operations as required by their regulations and directing authorities.
- APHIS/CDC Federal Select Program inspects laboratories and areas where select agents and toxins are possessed, used, or stored.
- DHS conducts compliance support and oversight for registered DHS entities and select agent activities conducted or sponsored by DHS
- DOT/PHMSA inspects shipping areas where hazardous materials are packaged, shipped, and received.

Executive Order 13546

- CDC and APHIS have convened an Interagency Working Group to execute Sections 6(a) and 8 of the Executive Order 13546 on Optimizing the Security of Biological Select Agents and Toxins in the United States.
 - **Joint inspections:** A joint inspection program has been initiated between the Select Agent Programs and other federal agencies that fund or own entities where select agent work is conducted to minimize the number of select agent inspections that these entities undergo per year.
 - **Information sharing:** Memoranda of understanding are being developed among Select Agent Programs and other federal agencies (i.e., EPA, Veterans Health Administration (VHA), DOE, DHS and DOD) to share information, primarily inspection data.

www.selectagents.gov



For more information please contact Centers for Disease Control and Prevention

1600 Clifton Road NE, Atlanta, GA 30333

Telephone, 1-800-CDC-INFO (232-4636)/TTY: 1-888-232-6348

E-mail: cdcinfo@cdc.gov Web: 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.



**Centers for Disease Control and Prevention
Office of Public Health Preparedness and Response**