

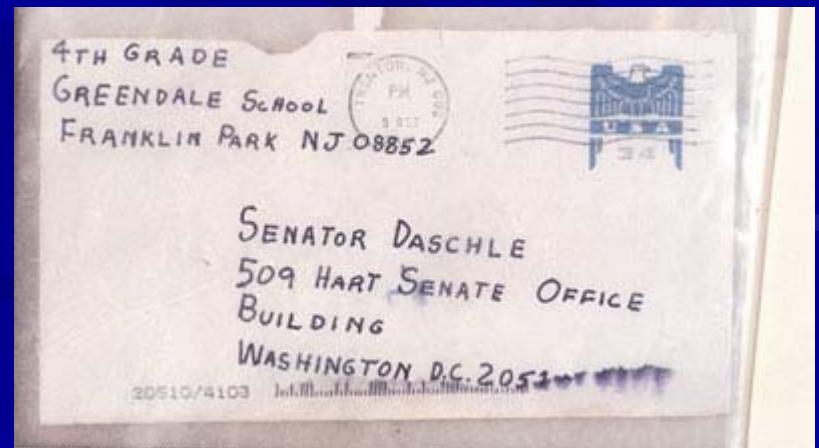
Agricultural Bioterrorism Protection Act of 2002; Possession, Use, and Transfer of Biological Agents and Toxins (7 CFR 331; 9 CFR 121)



Lee Ann Thomas, D.V.M., M. S.
Director, Select Agent, Organisms and Vectors, and Animals
National Center for Import and Export
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Public Health Security and Bioterrorism Preparedness Response Act of 2002

- Signed into law June 12, 2002
- Subtitle B cited as the “**Agricultural Bioterrorism Protection Act of 2002**”
- Requirements:
 - List of select agents and toxins
 - Notification of Possession
 - Registration for Possession, Use, and Transfer
 - Exemptions



USA Patriot Act

(Uniting and Strengthening America by Providing
Appropriate Tools Required to Intercept and Obstruct
Terrorism
Act of 2001)

- Public Law 107-56 Signed: 10/23/2001
- Sec. 175b. Possession by Restricted Persons
 - No restricted person shall ship, possess, or receive a select agent.

Types of Select Agents and Toxins

- HHS-only Agents (HHS has sole authority and responsibility to regulate)
 - Select agents and toxins that may affect public health and safety
- USDA-only Agents (USDA has sole authority and responsibility to regulate)
 - Select agents and toxins that may affect animal and plant health and animal and plant products
- “Overlap Agents”
 - Select agents and toxins subject to regulation by both agencies

The Act provides for interagency coordination between the two departments regarding overlap select agents and toxins

List of Biological Agents and Toxins (VS)

Criteria:

- Effect of exposure to the agent or toxin on animal health, and on the production and marketability of animal products
- Pathogenicity of the agent or the toxicity of the toxin
- Methods of transmission
- Availability/effectiveness of pharmacotherapies and prophylaxis
- Economic impact
- Inclusion on OIE A and B or Australian Group lists

List of Biological Agents and Toxins (VS)

African horse sickness virus

African swine fever virus

Akabane virus

Avian influenza virus (highly pathogenic)

Bluetongue virus (exotic)

Bovine spongiform encephalopathy agent

Camel pox virus

Classical swine fever virus

Cowdria ruminantium (Heartwater)

Foot-and-mouth disease virus

Goat pox virus

Japanese encephalitis virus

Lumpy skin disease virus

Malignant catarrhal fever virus
(Alcelaphine Herpes virus)

Menangle virus

Mycoplasma capricolum /*M.* F38/*M.*
mycoides capri (contagious caprine
pleuropneumonia)

Mycoplasma mycoides mycoides
(contagious bovine pleuropneumonia)

Newcastle disease virus (velogenic)

Peste des petits ruminants virus

Rinderpest virus

Sheep pox virus

Swine vesicular disease virus

Vesicular stomatitis virus (exotic)



List of Biological Agents and Toxins (Overlap USDA/HHS)

Bacillus anthracis

Botulinum neurotoxins

Botulinum neurotoxin producing
species of *Clostridium*

Brucella abortus

Brucella melitensis

Brucella suis

Burkholderia mallei

Burkholderia pseudomallei

Clostridium perfringens epsilon
toxin

Coccidioides immitis

Coxiella burnetii

Eastern equine encephalitis virus

Francisella tularensis

Hendra virus

Nipah virus

Rift Valley fever virus

Shigatoxin

Staphylococcal enterotoxins

T-2 toxin

Venezuelan equine encephalitis
virus



Exemptions from Registration

- Clinical or diagnostic laboratories (agents or toxins contained in diagnostic specimens or for verification):
 - Identification immediately reported
 - Within 7 days of identification agents or toxins transferred or inactivated
- Clinical and diagnostic laboratories (agents or toxins contained in proficiency test samples):
 - Identification immediately reported
 - Within 90 days of receipt, agents/toxins transferred or inactivated

Exemptions from Registration

- Possession, use, or transfer of products that are, bear, contain select agents or toxins licensed under:
 - Federal Food, Drug, and Cosmetic Act
 - The Virus Serum Toxin Act
 - The Federal Insecticide, Fungicide, and Rodenticide Act
 - Public Health Service Act pertaining to biological products (42 U.S.C. 262)
 - Investigational products authorized any Federal laws above
 - Administrator determines no additional regulation is required
 - Requires exemption request

Exemptions from Registration

- Toxins (aggregate per principal investigator):
 - 0.5 mg of Botulinum neurotoxin
 - 5 mg of Staphylococcal enterotoxin
 - 100 mg of *Clostridium perfringens* epsilon toxin
 - 100 mg of Shigatoxin
 - 1,000 mg of T-2 toxin
- Exclusions for attenuated agents
 - *B. abortus* RB5, Strain 19
 - <http://www.aphis.usda.gov/vs/ncie/bta.html>
(Notification of exclusion of attenuated strains)

Registration for Possession, Use, and Transfer

- Entities that possess, use, or transfer* VS or PPQ only select agents must register with USDA/APHIS.
- Entities that possess, use, or transfer* overlap agents or toxins must register with either USDA/APHIS or HHS/CDC, but not both.
- Registrations will be valid for a maximum of 3 years and may be renewed.
- Registration package and other forms are the same for both agencies

Possession, Use, and Transfer of Select Agent or Toxin

Registration:

1. Application (APHIS/CDC Form 1)
 - Responsible Official and Alternate Responsible Official
 - List of Agents/Toxins
 - Biosafety and Laboratory Information
 - Personnel to be authorized access
 - Specific laboratory information
2. Security Risk Assessment (SRA) individuals, entity, and corporate officers
3. Security and Biosafety Plans
4. Laboratory Inspection

SECURITY RISK ASSESSMENT (SRA)

- All individuals needing access to select agents or toxins and owners of entities seeking to register must have a security risk assessment (database and fingerprint check) conducted by the Attorney General.
- The Attorney General has designated the Federal Bureau of Investigation (FBI), Criminal Justice Information Services Division (CJIS), to conduct the security risk assessments.
- CJIS sends results to lead agency (CDC or APHIS)

SECURITY RISK ASSESSMENT (SRA) – Restricted Individuals

- Under indictment for a crime punishable by imprisonment for a term exceeding 1 year
- Convicted of any crime punishable by imprisonment for a term exceeding 1 year
- A fugitive from justice
- Unlawful user of any controlled substance
- Alien illegally or unlawfully in the US
- Adjudicated as a mental defective or committed to a mental institution
- Alien who is a national of a country to which the Secretary of State has determined that that country has repeatedly provided support for acts of international terrorism
- Discharged under dishonorable conditions

Security Plans

Sufficient to safeguard against unauthorized access, theft, loss or release.

- Must be based on a site-specific risk assessment and provide graded protection in accordance with the risk.
 - Describe procedures for physical security, inventory control, and information systems control
 - Provisions for controlling access
 - Provision for routine cleaning and maintenance
 - Procedures for removing unauthorized individuals
 - Procedures for addressing loss or compromise of keys, passwords, etc
 - Procedures for reporting unauthorized or suspicious persons or activities; theft, loss and release; or alteration of inventory records
 - Provisions for ensuring all personnel with SRA approval understand and comply with the security procedures in place

Security

The entity must adhere to the following or implement measures to achieve an equivalent or greater level of security:

- Allow access to only to individuals with an SRA-approval
- Allow individuals without SRA-approval to conduct routine cleaning, maintenance, or repairs only when continuously escorted by an approved individual
- Provide for control of agents by requiring freezers, refrigerators, cabinets, or other areas where agents are stored to be secured against access
- Inspect all suspicious packages before they are brought into or removed from an area where agents are stored or used
- Establish a procedure for intra-entity transfer, including chain of custody
- Require that SRA-approved individuals refrain from sharing unique means of accessing agents (ie passwords, keys....)
- Require immediate reporting of: 1) loss of keys, passwords; 2) Suspicious persons or packages; 3) theft or loss of agent; 4) Evidence of alteration of inventory/use records
- Separate areas where agents are used/stored are separate from public areas of the building

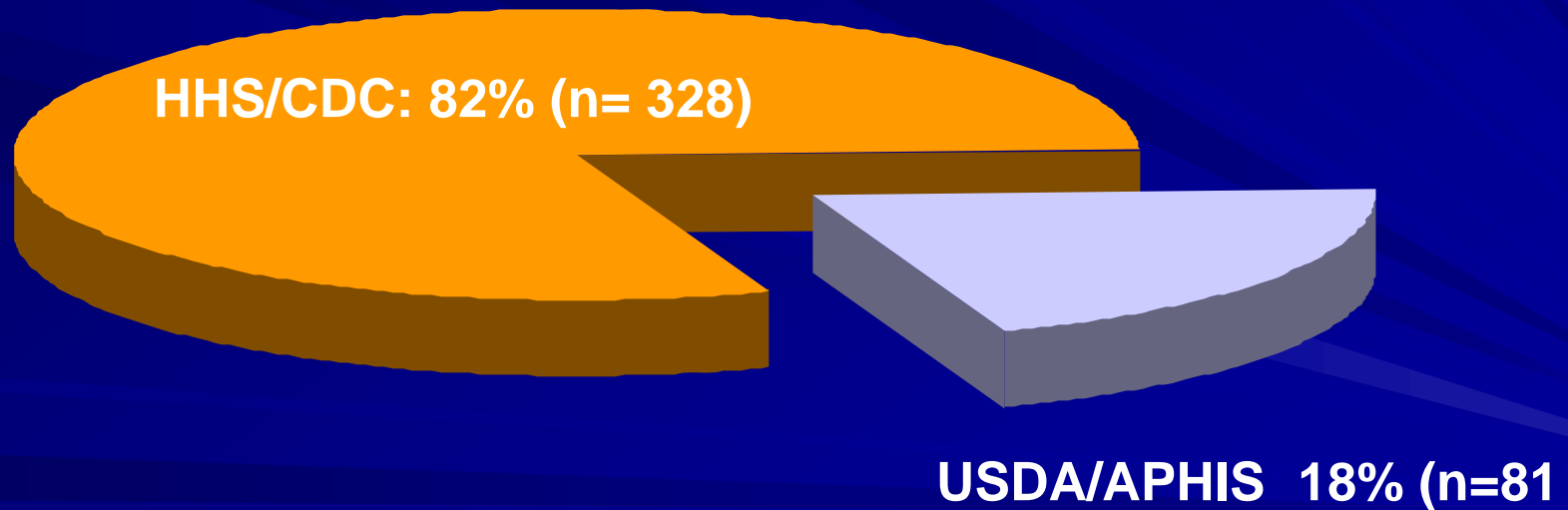
<http://www.selectagents.gov/securitydoc.htm>

Laboratory Inspection

- Coordination efforts between CDC and USDA (**one inspection**)
- Inspection covers:
 - Biosafety (laboratory and animal)
 - Security
 - Records
 - Training
 - Incident Response

Number of Entities Registering a Select Agent or Toxin with HHS/CDC or USDA/APHIS

(n = 409 registered entities; 7/25/07)



Additional requirements

■ Notification:

1. Transfer (APHIS/CDC Form 2)
2. Theft, Loss, Release (APHIS/CDC Form 3)
3. Identification (APHIS/CDC Form 4)
4. Request for Exemption of Select Biological Agents and Toxins – Investigational products, public health or agricultural emergency (APHIS/CDC Form 5)

• Web Sites:

http://www.aphis.usda.gov/programs/ag_selectagent/index.shtml

- <http://www.selectagents.gov/>

The Sunshine Project
News Release
12 April 2007

Texas A&M University Violates Federal Law in Biodefense Lab Infection

- Student climbs into dirty bioaerosol chamber and contracts brucellosis*
- A&M failed to report the incident to federal authorities*
- May lose federal funding and owe \$750,000 or more in fines.*

Inquiry leaves Boston tularemia mystery unsolved

April 14, 2005 (CIDRAP News) – Despite 4 months of investigation, the source of bacteria that caused tularemia in three laboratory workers at Boston University remains a mystery, the Boston Public Health Commission (BPHC) has reported.



Plague-Infected Mice Missing From N.J. Lab

Officials Concerned, but Say Public Health Risk Is Low



Sept. 15, 2005 — Authorities are investigating the disappearance from a New Jersey bioterror research lab of at least three mice carrying a deadly strain of plague.

Sources say FBI agents and bioterrorism experts have interviewed and polygraphed employees at the University of Medicine and Dentistry in Newark, N.J., the location of the lab run by the Public Health Research Institute, a leading center for research on infectious diseases.

Questions?

