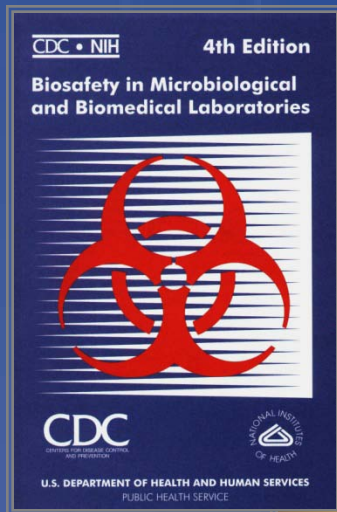


Plant Pathogen Select Agents: Revised Rule Biocontainment Requirements

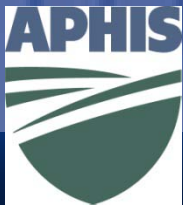
Charles Divan
Assistant Director
Agriculture Select Agent Program
Animal and Plant Health Inspection Service
Plant Protection and Quarantine and Veterinary Services



Federal (APHIS and CDC) Select Agent Program



Protect public, animal, and plant health and deter bioterrorism by ensuring safe and secure possession, use, and transfer of select agents and toxins within the United States.



Federal (APHIS and CDC) Select Agent Program

- Important component of the nation's overall terrorism deterrence strategy.
- Agencies work in cooperation
- Federally mandated and funded.
- Registration and inspection of private, academic, military, and public health research and diagnostic laboratories



Select Agent Program Statutes and Regulations

- Antiterrorism and Effective Death Penalty Act of 1996 (Signed April 24, 1996)
 - 42 C.F.R. 72.6 – Additional Requirements for facilities transferring and receiving Select Agents (Effective April 15, 1997)
- Public Health Security and Bioterrorism Preparedness and Response Act 2002, Title II (Signed June 12, 2002)
 - 42 C.F.R. Part 73 – Possession Use, and Transfer of Select Agents and Toxins, Revised Rule (Published October 4, 2012)



Select Agent Program Statutes and Regulations

- Section 212(a)(2) of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (also known as the Agricultural Bioterrorism Protection Act of 2002) (Signed June 12, 2002)
 - 7 C.F.R. Part 331 - Possession Use, and Transfer of Select Agents and Toxins, Revised Rule (Published October 4, 2012)
 - 9 C.F.R. Part 121 – Possession Use, and Transfer of Select Agents and Toxins, Revised Rule (Published October 4, 2012)



Select Agent Program Statutes and Regulations

- Effective dates for the sections of 7 C.F.R. Part 331, 9 C.F.R. Part 121, and 42 C.F.R. Part 73.
 - December 4, 2012: sections 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 13, 16, 17, 18, 19, 20, and 21
 - April 4, 2013: sections 11, 12, 14, and 15
 - (Security, Biosafety/Biocontainment, Incidence Response, and Training)

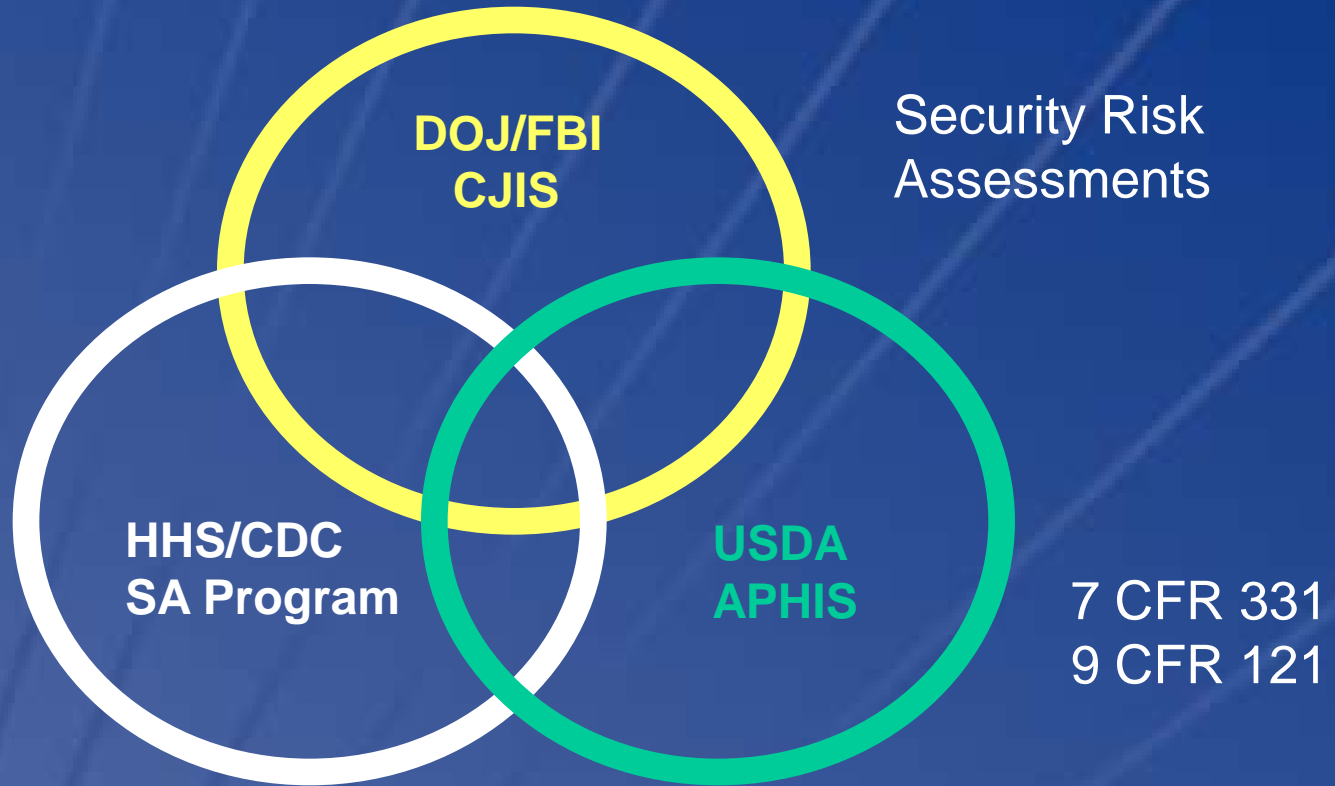


Select Agent Program Statutes and Regulations

- Significant changes to the Federal Select Agent Regulations:
 - Concept of Tier 1 agents and toxins
 - Personnel reliability
 - Physical security
 - Revised definition of genetic elements
 - Revision of the HHS and USDA Select Agent and Toxin lists



Federal Partners



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

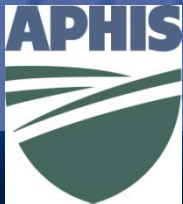
Public Law 107-56 Signed: 10/23/2001

- Sec. 175b. Possession by Restricted Persons
 - No restricted person shall ship, possess, or receive a Select Agent.



USA PATRIOT Act

- Sec. 175b. Restricted Persons
 - Under indictment or convicted of crime > 1 yr or is a fugitive from justice
 - Unlawful user of any controlled substance
 - Alien illegally or unlawfully in U.S.
 - Has been adjudicated as a mental defective or has been committed to any mental institution
 - Dishonorable discharge from Armed Services
 - Is an alien who is a national of a country that Sec. of State has made a determination has provided support for acts of international terrorism



Criteria for Designation of Agriculture Select Agents

The USDA Secretary considered the following criteria for establishing the list as directed in 7 USC 8401:

- The effect of exposure to the agent or toxin; the production and marketability of animal/plant products
- The pathogenicity of the agent or toxin and the methods by which the agent or toxin is transferred to animals or plants;
- The availability and effectiveness of pharmacotherapies and immunizations to treat and prevent any illness resulting from infection by the agent or toxin.
- Other criteria that the Secretary considers appropriate to protect plant/animal health



Criteria for Designation of Public Health Select Agents

The HHS Secretary considered the following criteria for establishing the list as directed in 42 U.S.C. 262a (a)(1)(B):

- The effect on human health of exposure to the agent or toxin;
- The degree of contagiousness of the agent or potency of the toxin and the methods by which the agent or toxin is transferred to humans;
- The availability and effectiveness of pharmacotherapies and immunizations to treat and prevent any illness resulting from infection by the agent or toxin.



Types of Select Agents and Toxins

- **HHS-only Agents** (HHS has sole authority and responsibility to regulate)
 - Select agents and toxins that may affect human health
- **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”** (HHS and USDA)
 - Select agents and toxins that may affect humans and animals.



Types of Select Agents and Toxins

- USDA PLANT PROTECTION AND QUARANTINE (PPQ)
SELECT AGENTS AND TOXINS
- *Peronosclerospora philippinensis* (*Peronosclerospora*
sacchari)
- *Phoma glycinicola* (formerly *Pyrenochaeta glycines*)
- *Ralstonia solanacearum*+
- *Rathayibacter toxicus*
- *Sclerophthora rayssiae*+
- *Synchytrium endobioticum*
- *Xanthomonas oryzae*



Types of Select Agents and Toxins

- USDA PLANT PROTECTION AND QUARANTINE (PPQ)
SELECT AGENTS AND TOXINS
- *Ralstonia solanacearum*+
- *Sclerophthora rayssiae*+
- + ALL subspecies, races and biovars are now considered select agents.
 - *Ralstonia solanacearum*--- all races and biovars are exempt from the regulations EXCEPT race 3 biovar 2.
 - *Sclerophthora rayssiae*--- all subspecies are exempt from the regulations EXCEPT var. *zeae*.
- *Confirmation data must be submitted to AgSAP for exemption.*



Types of Select Agents and Toxins

- USDA VETERINARY SERVICES (VS) SELECT AGENTS AND TOXINS
- African horse sickness virus
- African swine fever virus
- Avian influenza virus
- Classical swine fever virus
- Foot-and-mouth disease virus*
- Goat pox virus
- Lumpy skin disease virus
- Mycoplasma capricolum
- Mycoplasma mycoides
- Newcastle disease virus
- Peste des petits ruminants virus
- Rinderpest virus*
- Sheep pox virus
- Swine vesicular disease virus
- *Denotes Tier 1 agents



Types of Select Agents and Toxins

OVERLAP SELECT AGENTS AND TOXINS

Bacillus anthracis *

Bacillus anthracis Pasteur strain

Brucella abortus

Brucella melitensis

Brucella suis

Burkholderia mallei*

Burkholderia pseudomallei*

Hendra virus

Nipah virus

Rift Valley fever virus

Venezuelan equine encephalitis virus

*Denotes Tier 1 agents



Types of Select Agents and Toxins

HHS SELECT AGENTS AND TOXINS

Abrin

Botulinum neurotoxins*

Botulinum neurotoxin producing species of *Clostridium**

Conotoxins (Short, paralytic alpha conotoxins containing the following amino acid sequence X1CCX2PACGX3X4X5X6CX7)

Coxiella burnetii

Crimean-Congo haemorrhagic fever virus

Diacetoxyscirpenol

Eastern Equine Encephalitis virus

Ebola virus*

*Francisella tularensis**

Lassa fever virus

Lujo virus

Marburg virus*

Monkeypox virus1

Reconstructed replication competent forms of the 1918 pandemic influenza virus containing any portion of the coding regions of all eight gene segments (Reconstructed 1918 Influenza virus)

*Denotes Tier 1 agents



Types of Select Agents and Toxins

HHS SELECT AGENTS AND TOXINS (con't)

Ricin

Rickettsia prowazekii

SARS-associated coronavirus (SARS-CoV)

Saxitoxin

South American Haemorrhagic Fever viruses:

Chapare

Guanarito

Junin

Machupo

Sabia

Staphylococcal enterotoxins A,B,C,D,E subtypes

T-2 toxin

Tetrodotoxin

Tick-borne encephalitis complex (flavi) viruses:

Far Eastern subtype

Siberian subtype

Kyasanur Forest disease virus

Omsk hemorrhagic fever virus

Variola major virus (Smallpox virus)*

Variola minor virus (Alastrim)*

Yersinia pestis*

*Denotes Tier 1 agents



Biocontainment Requirements for Select Agent Plant Pathogens

The biocontainment requirements for plant pathogenic select agents are identical to the biocontainment requirements of any other severe plant pathogen.

These requirements are based on the Plant Protection Act of 2000 and 7 CFR 330, including the requirement for movement and possession permits.



PPQ Plant Pathogen Biocontainment

Plant Pathogen Research Specialty Rooms

Internal Features

- Floors
 - Monolithic, impervious material
 - Drains for water collection and sterilization prior to disposal
- Air Filtration
- Waste Disposal
 - Plant, soil material
 - Water
- Insect/Vector control
- Temperature, light, humidity controls

Greenhouses



PPQ Plant Pathogen Biocontainment

Plant Pathogen Research Specialty Rooms

Growth Chambers



- Plant water collection and sterilization
- Plant material and soil treatment and sterilization
- Access control
- Precise environmental controls
 - Temperature, light, and humidity

PPQ Plant Pathogen Biocontainment

Plant Pathogen Research Specialty Rooms

Greenhouses

External Features

- Location
 - Ground-level vs Rooftop
 - Exterior vegetation
- Translucent Walls and Ceilings
 - Glass Break Detection- Sound, Motion, or Pressure
 - Sealed with caulk internally and externally



Select Agent Requirements

The difference between the Plant Protection Act and the Agriculture Bioterrorism Act is that the latter has requirements for:

- Registration of personnel, agents, facilities
- Security Risk Assessments (SRAs) for personnel with access
- Identification of Responsible official
- Biosafety plans and practices
- Security plans and practices
- Incident Response plans
- Training, safety, security, incident response
- Transfer of agents between entities
- Reporting of identification, theft, lost, or release



For More Information about APHIS Permitting and Select Agents:

- APHIS Select Agent Program
 - Phone 301-851-3300 option 1
 - Fax 301-734-3256
 - E-mail ASAP@aphis.usda.gov
 - Website
http://www.aphis.usda.gov/programs/ag_selectagent/index.shtml
- APHIS Permitting
 - Import website <http://www.aphis.usda.gov/permits/>



For More Information about CDC Select Agent Program:

- CDC Select Agent Program
 - Phone 404-718-2000
 - Fax 404-718-2096
 - E-mail Irsat@cdc.gov
 - Website <http://www.selectagents.gov>
- CDC Import Permit Program
 - Import website <http://www.cdc.gov/od/eaipp>



Federal Select Agent Program

www.selectagents.gov

