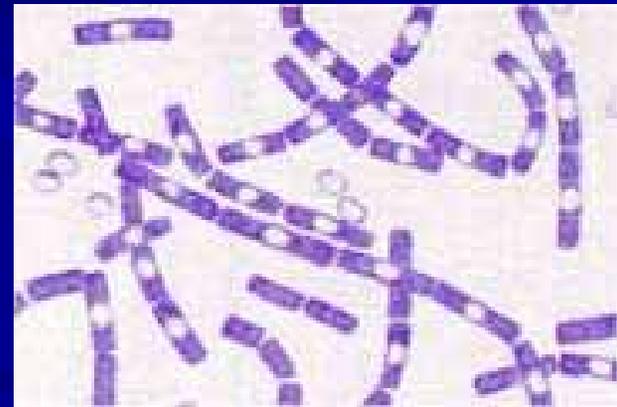


# Agricultural Bioterrorism Protection Act of 2002; Possession, Use, and Transfer of Biological Agents and Toxins

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# Public Health Security and Bioterrorism Preparedness Response Act of 2002

- ❖ Purpose: To improve the ability of the US to prevent, prepare for, and respond to bioterrorism and other public health emergencies



# 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 biological agents and toxins
  - ❑ Notification of Possession
  - ❑ Registration for Possession, Use, and Transfer
  - ❑ Exemptions

# Regulation Citations

- ❖ 9 CFR Part 121

Agricultural Bioterrorism Protection Act of 2002;  
Possession, Use and Transfer of Biological  
Agents and Toxins

- ❖ 7 CFR Part 331

Agricultural Bioterrorism Protection Act of 2002;  
Possession, Use and Transfer of Biological  
Agents and Toxins

- ❖ 42 CFR Part 73

Possession, Use, and Transfer of Select Agents  
and Toxins

# List of biological agents and toxins (Veterinary Services)

## ❖ 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

# List of biological agents and toxins (Veterinary Services)

## ❖ Criteria

- Availability and effectiveness of pharmacotherapies and prophylaxis to treat and prevent any illness caused by the agent or toxin
- Economic Impact
- Inclusion on OIE A and B lists
- Inclusion on Australian Group list

# 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 botulinum
- 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



# List of biological agents and toxins (USDA/VS only)

- 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 (exotic)
- Menangle virus
- Mycoplasma capricolum /M. F38/M. mycoides capri (contagious caprine pleuropneumonia)
- Mycoplasma mycoides mycoides (contagious bovine pleuropneumonia)
- Newcastle disease virus (VVND)
- Peste des petits ruminants virus
- Rinderpest virus
- Sheep pox virus
- Swine vesicular disease virus
- Vesicular stomatitis virus (exotic)



# List of biological agents and toxins (Plant Protection and Quarantine)

## ❖ Criteria

- Effect of exposure to the agent or toxin on plant health, and on the production and marketability of plant products
- Ability to detect and diagnose infection during the early stages of infection
- Non-native / exotic agents
- Economic importance of host

# List of biological agents and toxins (USDA/PPQ only)

- Liberobacter africanus,
- Liberobacter asiaticus
- Peronosclerospora philippinensis
- Phakopsora pachyrhizi
- Plum pox potyvirus
- Ralstonia solanacearum, race 3, biovar 2
- Sclerophthora rayssiae var. zeae
- Synchytrium endobioticum
- Xanthomonas oryzae pv. oryzicola
- Xylella fastidiosa (citrus variegated chlorosis strain)



# List of biological agents and toxins

- ❖ List will be reviewed and republished biennially or more often as needed
- ❖ Requests for attenuated agent strains to be excluded from the agent list
- ❖ APHIS and CDC must concur on the exclusion of attenuated agent strains for overlap agents

# Notification of Possession

- ❖ Notify Secretary of Agriculture of possession of any of the listed agricultural agents by Oct. 11, 2002
- ❖ Notify Secretary of Health and Human Services of possession of any Select Agents, including overlap agents by Sept. 10, 2002
- ❖ All notification forms were sent to a contractor for processing

# Notification of Possession

- ❖ Persons that exclusively possessed products that were, contained, or bore listed agents or toxins and that were cleared, approved, or licensed under FD&C, VST, or FIFRA were exempt
- ❖ Notification of possession is completed
- ❖ Registration applications will be sent to both positive responders and non-responders

# Registration for Possession, Use, and Transfer

- ❖ **Registration** (9 CFR 121)
  - ❖ Possession, use, or transfer of HCLP&T, listed plant agents, or SA
  - ❖ HCLP&T require laboratory inspection
  - ❖ Security Risk assessment required
  - ❖ Security and biosafety plans required
- ❖ **Permit** (9 CFR 122)
  - ❖ Import or interstate movement of any livestock pathogen
  - ❖ HCLP&T and some other agents require laboratory inspection

# Registration for Possession, Use, and Transfer

- ❖ Entities that possess, use, or transfer\* HCLP&T or listed plant agents must register with USDA/APHIS
- ❖ Entities that possess, use, or transfer\* overlap agents 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 for Possession, Use, and Transfer: The Process

- ❖ Entity must designate a Responsible official (RO)
  - ❑ Must have the authority and control to ensure compliance with the regulations
- ❖ An alternate RO may also be designated by an entity
- ❖ RO submits personal information to APHIS
- ❖ RO submits the information required by the Department of Justice (DOJ) for the security risk assessment for both the entity and the RO

# Registration for Possession, Use, and Transfer: The Process

- ❖ RO submits personal information to APHIS for individuals with a legitimate need for access and who have appropriate training
- ❖ RO submits facility and agent information to APHIS
- ❖ RO responsible for development and implementation of the safety and security plans

# Registration for Possession, Use, and Transfer

## ❖ References for Biosafety and Security Plans:

- ❑ “Biosafety in Microbiological and Biomedical Laboratories”

- ❑ “USDA Security Policies and Procedures for Biosafety Level-3 Facilities”

([www.usda.gov/ocio/directives/DM.DM9610-001.htm](http://www.usda.gov/ocio/directives/DM.DM9610-001.htm))

- ❑ Appendix F, “Biosafety in Microbiological and Biomedical Laboratories” ([www.cdc.gov/mmwr](http://www.cdc.gov/mmwr))

# Registration for Possession, Use, and Transfer: Phase In

- ❖ February 11, 2003 effective date for regulations
- ❖ March 12, 2003 Registration applications submitted
- ❖ June 12, 2003 security plans submitted
- ❖ September 12, 2003 security plans implemented
- ❖ November 12, 2003 full compliance upon application

# Transfers

- ❖ CDC form EA-101 for Select agents (including overlap agents) until March 12, 2003
- ❖ APHIS form 2041 “Report of Transfer of Select Biological Agents and Toxins” for USDA only agents
- ❖ March 12, 2003 APHIS form 2041 all transfers

# Exemptions

## ❖ Diagnostic and Clinical Facilities

- Report identification
- Inactivate or transfer agent to registered entity
- 90 days allowed for proficiency testing
- Facilities maintaining viable agents as positive controls must register

# Exemptions

- ❖ Products that are, contain, or bear listed agents or toxins and that are cleared, approved, or licensed under FD&C, VST, or FIFRA are exempt from registration requirements, unless the Administrator determines that additional regulation is required to protect animal health or animal products

# Exemptions

- ❖ Experimental/Investigational Products
  - ❖ Apply for an exemption (APHIS form 2042)
  - ❖ Be authorized under a Federal Act
  - ❖ Determination made within 14 days

# Civil & Criminal Penalties

- ❖ Violation of any provisions of the regulations: up to \$250,000 for an individual and up to \$500,000 for any other person (i.e. an entity)
- ❖ Transfer of an agent or toxin listed in 7 CFR 331, 9 CFR 121, and/or 42 CFR 73 to an unregistered person: civil money penalty listed above and/or imprisonment for up to 5 years

# Civil & Criminal Penalties

- ❖ Unregistered persons possessing an agent or toxin listed in 7 CFR 331, 9 CFR 121, and/or 42 CFR 73: civil money penalty listed on previous slide and/or imprisonment for up to 5 years

# Web Information

- ❖ USDA/VS

[www.aphis.usda.gov/vs/ncie/bta.html](http://www.aphis.usda.gov/vs/ncie/bta.html)

- ❖ USDA/PPQ

[www.aphis.usda.gov/ppq/permits](http://www.aphis.usda.gov/ppq/permits)

- ❖ HHS/CDC

[www.cdc.gov](http://www.cdc.gov)

# Contact Information

- ❖ National Center for Import and Export, VS, APHIS  
4700 River Road Unit 40  
Riverdale, MD 20737-1231

Phone (301) 734-3277

Fax (301)734-3652

- ❖ Biological and Technical Services, PPQ, APHIS  
4700 River Road Unit 133  
Riverdale, MD 20737-1236

Phone (301) 734-5519

Fax (301) 734-8700

# Contact Information

- ❖ Centers for Disease Control and Prevention  
Select Agent Program  
1600 Clifton Rd NE, Mailstop E-79  
Atlanta, GA 30333

Phone (404) 498-2255 Fax (404) 498-2265

**Let's Take A Break!**

# New Forms

- ❖ Application for Laboratory Registration for Possession, Use, and Transfer of Select Agents or High Consequence Livestock Pathogens and Toxins (APHIS Form 2044)
- ❖ Report of Transfer of Select Biological Agents and Toxins (APHIS Form 2041)
- ❖ Report of the Identification of Select Biological Agents and Toxins from Clinical or Diagnostic Laboratories (APHIS Form 2040)

# New Forms

- ❖ Report of Theft, loss, or Release of Select Biological Agents and Toxins (APHIS Form 2041)
- ❖ Request for Exemption of Select Biological Agents and Toxins or High Consequence Livestock Pathogens and Toxins (APHIS Form 2042)

# Registration for Possession, Use, and Transfer Form

- ❖ Purpose: for entities/facilities that want to maintain viable agents (including genetic elements from these) and/or active toxins
- ❖ Completed by the Responsible Official (RO) in two phases
  - ☐ Phase 1
    - Entity information submitted
    - RO information submitted
    - Alternate RO information submitted

# Registration for Possession, Use, and Transfer Form

## □ Phase 2

- RO submits facility information
  - RO submits individual information (PI's & support)
  - RO submits agent information
- 
- ❖ Required information: Facility biosafety information, training information for laboratory personnel, safety plan, security plan, brief description of intended research, etc.

# Transfer of Select Biological Agents and Toxins Form

- ❖ Purpose: for entities/facilities that transfer viable agents (including genetic elements) and/or active toxins
- ❖ Completed by RO
- ❖ Required information: agent information, registration number of both\* facilities, APHIS or CDC approval PRIOR to transfer
- ❖ After the phase in period, the recipient of a transfer must always be a registered facility

# Identification of Select Biological Agents and Toxins Form

- ❖ Purpose: for diagnostic or clinical facilities that identify a select biological agent or toxin in a specimen
- ❖ Completed by Laboratory Director or designee
- ❖ Required information: agent/toxin name, specimen identification (host), final disposition, facility address, source of specimen, etc.

# Report of Theft, Loss, or Release Form

- ❖ Purpose: for entities/facilities that have a theft, loss, or release occur to notify APHIS or CDC
- ❖ Completed by RO within 7 days of the incident
- ❖ Required information: Address, RO information, date of incident, PI, agent information, description of incident, exposures, etc.
- ❖ Immediate notification to APHIS via phone by calling 1-866-994-5678

# Request for Exemption Form

- ❖ Purpose: for entities/facilities that want to have products that they produce exempted from registration requirements (i.e. transfer form)
- ❖ Completed by an entity or individual meeting either of the following criteria:
  - ❑ Have an Investigational New Drug (FDA) or Experimental (CVB) product that containing a select biological agent or toxin and are authorized under a Federal Act

# Request for Exemption Form

- ❑ During an Agricultural or Public Health Emergency exemption from registration requirements may be granted (overlap)
- ❖ Required information: Authorizing act, agent or toxin, product I.D., or description of agricultural emergency, address, applicant information
- ❖ Requests for exemptions products for USDA only agents (non-overlap) may be submitted in writing and must include a justification for the exemption

# Plans for Web Application

- ❖ Web Registration Application
  - ❖ Under development
  - ❖ Estimated launch date: Spring 2003
  - ❖ Other forms to follow

# Comment Period

- ❖ Comments to the Regulation received on or before February 11, 2003 will be considered
  
- ❖ Postal Mail send 4 copies to:  
Docket No. 02-088-1,  
Regulatory Analysis and Development  
PPD, APHIS, Station 3C71,  
4700 River Road Unit 118,  
Riverdale, MD 20737-1238

# Comment Period

- ❖ E-mail comments to:  
[regulations@aphis.usda.gov](mailto:regulations@aphis.usda.gov) include  
“Docket No. 02-088-1” on the subject line

**QUESTIONS?**