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AGRICULTURAL BIOTERRORISM PROTECTION ACT OF 2002;
POSSESSION, USE, AND TRANSFER OF BIOLOGICAL AGENTS AND
TOXINS

Lee Ann Thomas
Director
Animals, Organisms and Vectors, and Select Agents
Veterinary Services
Agricultural Bioterrorism Protection Act of 2002; Possession, Use, and Transfer of Biological Agents and Toxins

Lee Ann Thomas
Director
Animals, Organisms and Vectors, and Select Agents
Veterinary Services
Agricultural Bioterrorism Protection Act of 2002 Requirements

- List of biological agents and toxins
- Notification of Possession
- Registration for Possession, Use, and Transfer
- Exemptions
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
  - 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 Australia 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

- 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
Registration for Possession, Use, and Transfer

- Entities that possess, use, or transfer select agents and toxins 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
- Interfacility transfers of select agents and toxins must be approved by USDA/APHIS or HHS/CDC prior to the transfer
Registration for Possession, Use, and Transfer

- **Registration (9 CFR 121)**
  - Possession, use, or transfer of select agents and toxins
  - Require laboratory inspection
  - Security Risk assessment required
  - Security and biosafety plan implementation

- **Permitting (9 CFR 122)**
  - Import or interstate movement of any livestock pathogen
  - Select agents and some other pathogens require laboratory inspection
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

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

- USDA/VS
  - www.aphis.usda.gov/vs/ncie/bta.html
    - Select agent registration application
    - Transfer forms
    - General information

- www.aphis.usda.gov/vs/ncie
  - USDA/VS permit application
  - On-line permit application
  - General information
Contact Information

National Center for Import and Export, VS, APHIS
4700 River Road Unit 2
Mailstop 22, Cub 1A07
Riverdale, MD 20737

Phone (301) 734-5960 Fax (301) 734-3652