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

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Animals, Organisms and Vectors, and Select Agents
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Agricultural Bioterrorism Protection Act of 2002; Possession, Use, and Transfer of Biological Agents and Toxins

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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

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