

## § 121.1

121.19 Notification of theft, loss, or release.  
121.20 Administrative review.

AUTHORITY: 7 U.S.C. 8401; 7 CFR 2.22, 2.80, and 371.4.

SOURCE: 70 FR 13284, Mar. 18, 2005, unless otherwise noted.

### § 121.1 Definitions.

*Administrator.* The Administrator, Animal and Plant Health Inspection Service, or any person authorized to act for the Administrator.

*Animal and Plant Health Inspection Service (APHIS).* The Animal and Plant Health Inspection Service of the U.S. Department of Agriculture.

*Attorney General.* The Attorney General of the United States or any person authorized to act for the Attorney General.

*Biological agent.* Any microorganism (including, but not limited to, bacteria, viruses, fungi, rickettsiae, or protozoa), or infectious substance, or any naturally occurring, bioengineered, or synthesized component of any such microorganism or infectious substance, capable of causing:

- (1) Death, disease, or other biological malfunction in a human, an animal, a plant, or another living organism;
- (2) Deterioration of food, water, equipment, supplies, or material of any kind; or
- (3) Deleterious alteration of the environment.

*Centers for Disease Control and Prevention (CDC).* The Centers for Disease Control and Prevention of the U.S. Department of Health and Human Services.

*Diagnosis.* The analysis of specimens for the purpose of identifying or confirming the presence or characteristics of a select agent or toxin, provided that such analysis is directly related to protecting the public health or safety, animal health or animal products, or plant health or plant products.

*Entity.* Any government agency (Federal, State, or local), academic institution, corporation, company, partnership, society, association, firm, sole proprietorship, or other legal entity.

*HHS Secretary.* The Secretary of the Department of Health and Human Services or his or her designee, unless otherwise specified.

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*HHS select agent and/or toxin.* A biological agent or toxin listed in 42 CFR 73.3.

*Import.* To move into, or the act of movement into, the territorial limits of the United States.

*Interstate.* From one State into or through any other State, or within the District of Columbia, Guam, the Virgin Islands of the United States, or any other territory or possession of the United States.

*Overlap select agent and/or toxin.* A biological agent or toxin that is listed in § 121.4 and 42 CFR 73.4.

*Permit.* A written authorization by the Administrator to import or move interstate select agents or toxins, under conditions prescribed by the Administrator.

*Proficiency testing.* The process of determining the competency of an individual or laboratory to perform a specified test or procedure.

*Responsible official.* The individual designated by an entity with the authority and control to ensure compliance with the regulations in this part.

*Select agent and/or toxin.* Unless otherwise specified, all of the biological agents or toxins listed in §§ 121.3 and 121.4.

*Specimen.* Samples of material from humans, animals, plants, or the environment, or isolates or cultures from such samples, for diagnosis, verification, or proficiency testing.

*State.* Any of the several States of the United States, the Commonwealth of the Northern Mariana Islands, the Commonwealth of Puerto Rico, the District of Columbia, Guam, the Virgin Islands of the United States, or any other territory or possession of the United States.

*Toxin.* The toxic material or product of plants, animals, microorganisms (including, but not limited to, bacteria, viruses, fungi, rickettsiae, or protozoa), or infectious substances, or a recombinant or synthesized molecule, whatever their origin and method of production, and includes:

- (1) Any poisonous substance or biological product that may be engineered as a result of biotechnology produced by a living organism; or

(2) Any poisonous isomer or biological product, homolog, or derivative of such a substance.

*United States.* All of the States.

*USDA.* The U.S. Department of Agriculture.

*Verification.* The demonstration of obtaining established performance (e.g., accuracy, precision, and the analytical sensitivity and specificity) specifications for any procedure used for diagnosis.

*VS.* The Veterinary Services Programs of the Animal and Plant Health Inspection Service.

*VS select agent and/or toxin.* A biological agent or toxin listed in §121.3.

#### § 121.2 Purpose and scope.

This part implements the provisions of the Agricultural Bioterrorism Protection Act of 2002 setting forth the requirements for possession, use, and transfer of select agents and toxins. The biological agents and toxins listed in this part have the potential to pose a severe threat to public health and safety, to animal health, or to animal products. Overlap select agents and toxins are subject to regulation by both APHIS and CDC.

#### § 121.3 VS select agents and toxins.

(a) Except as provided in paragraphs (d) and (e) of this section, the Administrator has determined that the biological agents and toxins listed in this section have the potential to pose a severe threat to animal health or to animal products.

(b) VS select agents and toxins:

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;  
*Ehrlichia ruminantium* (Heartwater);  
 Foot-and-mouth disease virus;  
 Goat pox virus;  
 Japanese encephalitis virus;  
 Lumpy skin disease virus;  
 Malignant catarrhal fever virus (Alcelaphine herpesvirus type 1);  
 Menangle virus;  
*Mycoplasma capricolum* subspecies  
*capripneumoniae* (contagious caprine  
 pleuropneumonia);

*Mycoplasma mycoides* subspecies *mycoides*  
 small colony (*MmmSC*) (contagious bovine  
 pleuropneumonia);

Peste des petits ruminants virus;

Rinderpest virus;

Sheep pox virus;

Swine vesicular disease virus;

Vesicular stomatitis virus (exotic): Indiana  
 subtypes VSV-IN2, VSV-IN3;

Virulent Newcastle disease virus<sup>1</sup>

(c) Genetic elements, recombinant nucleic acids, and recombinant organisms:

(1) Nucleic acids that can produce infectious forms of any of the select agent viruses listed in paragraph (b) of this section.<sup>2</sup>

(2) Recombinant nucleic acids that encode for the functional forms of any toxin listed in paragraph (b) of this section if the nucleic acids:

(i) Can be expressed *in vivo* or *in vitro*;  
 or

(ii) Are in a vector or recombinant host genome and can be expressed *in vivo* or *in vitro*.

(3) VS select agents and toxins listed in paragraph (b) of this section that have been genetically modified.

(d) VS select agents or toxins that meet any of the following criteria are excluded from the requirements of this part:

(1) Any VS select agent or toxin that is in its naturally occurring environment, provided that the agent or toxin has not been intentionally introduced, cultivated, collected, or otherwise extracted from its natural source.

(2) Nonviable VS select agents or nonfunctional VS toxins.<sup>3</sup>

<sup>1</sup>A virulent Newcastle disease virus (avian paramyxovirus serotype 1) has an intracerebral pathogenicity index in day-old chicks (*Gallus gallus*) of 0.7 or greater or has an amino acid sequence at the fusion (F) protein cleavage site that is consistent with virulent strains of Newcastle disease virus. A failure to detect a cleavage site that is consistent with virulent strains does not confirm the absence of a virulent virus.

<sup>2</sup>The importation and interstate movement of VS select agents or toxins listed in paragraphs (c)(1) through (c)(3) of this section may be subject to the permit requirements under part 122 of this subchapter.

<sup>3</sup>However, the importation and interstate movement of these nonviable select agents may be subject to the permit requirements under part 122 of this subchapter.