PART 121—POSSESSION, USE, AND TRANSFER OF SELECT AGENTS AND TOXINS

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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.


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.


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.

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.
§ 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 virus1

(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.2

(2) Recombinant nucleic acids that encode for the functional forms of any

1A 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.

2The 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.