

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

(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.¹
- (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

¹The 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.