

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

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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, 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.

*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.

*Information security.* Protecting information and information systems from unauthorized access, use, disclosure, disruption, modification, or destruction in order to provide:

- (1) *Integrity*, which means guarding against improper information modification or destruction, and includes ensuring information authenticity;

- (2) *Confidentiality*, which means preserving authorized restrictions on access and disclosure, including means for protecting personal privacy and proprietary information; and

- (3) *Availability*, which means ensuring timely and reliable access to and use of information.

*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.

*Occupational exposure.* Any reasonably anticipated skin, eye, mucous

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membrane, parenteral contact, or respiratory aerosol exposure to select agents or toxins that may result from the performance of an employee's duties.

*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.

*Recombinant nucleic acids.* (1) Molecules that are constructed by joining nucleic acid molecules and that can replicate in a living cell; or

(2) Molecules that result from the replication of those described in paragraph (1) of this definition.

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

*Security barrier.* A physical structure that is designed to prevent entry by unauthorized persons.

*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.

*Synthetic nucleic acids.* (1) Molecules that are chemically or by other means synthesized or amplified, including those that are chemically or otherwise modified but can base pair with naturally occurring nucleic acid molecules (*i.e.*, synthetic nucleic acids); or

(2) Molecules that result from the replication of those described in paragraph (1) of this definition.

*Toxin.* The toxic material or product of plants, animals, microorganisms (including, but not limited to, bacteria, viruses, fungi, 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.

[70 FR 13284, Mar. 18, 2005, as amended at 77 FR 61077, Oct. 5, 2012]

### § 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. The select agents and toxins marked with an asterisk (\*) are designated as Tier 1 select agents and toxins and are subject to additional requirements as listed in this part.