

## § 121.2

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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.

(b) VS select agents and toxins: African horse sickness virus; African swine fever virus; Avian influenza virus; Classical swine fever virus; \*Foot-and-mouth disease virus; Goat pox virus; Lumpy skin disease virus; *Mycoplasma capricolum*; *Mycoplasma mycoides*; Newcastle disease virus;<sup>1</sup> Peste des petits ruminants virus; \*Rinderpest virus; Sheep pox virus; Swine vesicular disease virus.

(c) Genetic elements, recombinant and/or synthetic nucleic acids, and recombinant and/or synthetic 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 and/or synthetic 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

(3) Any low pathogenic strains of avian influenza virus, any strain of Newcastle disease virus which does not meet the criteria for virulent Newcastle disease virus, all subspecies *Mycoplasma capricolum* except subspecies *capripneumoniae* (contagious caprine pleuropneumonia), and all subspecies *Mycoplasma mycoides* except subspecies *mycoides* small colony (*Mmm* SC) (contagious bovine pleuropneumonia), provided that the individual or entity can verify that the agent is within the exclusion category.

(e) An attenuated strain of a select agent or an inactive form of a select toxin may be excluded from the requirements of this part based upon a determination by the Administrator that the attenuated strain or inactivated toxin does not pose a severe threat to animal health or to animal products.

(1) To apply for exclusion, an individual or entity must submit a written request and supporting scientific information. A written decision granting or denying the request will be issued. An exclusion will be effective upon notification to the applicant. Exclusions will be listed on the National Select Agent Registry Web site at <http://www.selectagents.gov/>.

(2) If an excluded attenuated strain or inactivated toxin is subjected to any manipulation that restores or enhances its virulence or toxic activity, the resulting select agent or toxin will be subject to the requirements of this part.

(f) Any VS select agent or toxin seized by a Federal law enforcement agency will be excluded from the requirements of this part during the period between seizure of the agent or toxin and the transfer or destruction of such agent or toxin provided that:

(1) As soon as practicable, the Federal law enforcement agency transfers the seized agent or toxin to an entity eligible to receive such agent or toxin or destroys the agent or toxin by a recognized sterilization or inactivation process.

(2) The Federal law enforcement agency safeguards and secures the

may be subject to the permit requirements under part 122 of this subchapter.

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seized agent or toxin against theft, loss, or release, and reports any theft, loss, or release of such agent or toxin.

(3) The Federal law enforcement agency reports the seizure of the select agent or toxin to APHIS or CDC.

(i) The seizure of any of the following VS select agents and toxins must be reported within 24 hours by telephone, facsimile, or e-mail: African horse sickness virus, African swine fever virus, avian influenza virus (highly pathogenic), bovine spongiform encephalopathy agent, classical swine fever virus, foot-and-mouth disease virus, virulent Newcastle disease virus, rinderpest virus, and swine vesicular disease virus. This report must be followed by submission of APHIS/CDC Form 4 within 7 calendar days after seizure of the select agent or toxin.

(ii) For all other VS select agents or toxins, APHIS/CDC Form 4 must be submitted within 7 calendar days after seizure of the agent or toxin.

(iii) A copy of APHIS/CDC Form 4 must be maintained for 3 years.

(4) The Federal law enforcement agency reports the final disposition of the select agent or toxin by submission of APHIS/CDC Form 4. A copy of the completed form must be maintained for 3 years.

[70 FR 13284, Mar. 18, 2005, as amended at 73 FR 61331, Oct. 16, 2008; 77 FR 61077, Oct. 5, 2012]

### § 121.4 Overlap 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 public health and safety, 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.

(b) Overlap select agents and toxins: *\*Bacillus anthracis*; *Bacillus anthracis* (Pasteur strain); *Brucella abortus*; *Brucella melitensis*; *Brucella suis*; *\*Burkholderia mallei*; *\*Burkholderia pseudomallei*; Hendra virus; Nipah virus; Rift Valley fever virus; Venezuelan equine encephalitis virus.

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

(1) Nucleic acids that can produce infectious forms of any of the overlap select agent viruses listed in paragraph (b) of this section.<sup>4</sup>

(2) Recombinant and/or synthetic nucleic acids that encode for the functional forms of any overlap 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) Overlap select agents and toxins listed in paragraph (b) of this section that have been genetically modified.

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

(1) Any overlap 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 overlap select agents or nonfunctional overlap toxins.<sup>5</sup>

(3) Any subtypes of Venezuelan equine encephalitis virus except for Subtypes IAB or IC, provided that the individual or entity can verify that the agent is within the exclusion category.

(e) An attenuated strain of a select agent or an inactive form of a select toxin may be excluded from the requirements of this part based upon a determination by the HHS Secretary or Administrator that the attenuated strain or inactivated toxin does not pose a severe threat to public health and safety, to animal health or to animal products.

(1) To apply for exclusion, an individual or entity must submit a written

<sup>4</sup>The importation and interstate movement of overlap 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>5</sup>However, the importation and interstate movement of these nonviable overlap select agents may be subject to the permit requirements under part 122 of this subchapter.