

specimens for processing or shipping to another laboratory.

Diagnostic laboratory. A laboratory facility that receives specimens for the purpose of determining the identities of pests, pathogens, contaminants, or causes of disease.

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

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 agent or toxin. Any microorganism (including, but not limited to, bacteria, viruses, fungi, rickettsiae, or protozoa) or toxin that poses a risk to both human and animal health and that is listed in §121.3(b).

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

Proficiency testing. A sponsored, time-limited analytical trial whereby one or more analytes, previously confirmed by the sponsor, are submitted to the testing laboratory for analysis and where final results are graded, scores are recorded and provided to participants, and scores for participants are evaluated for acceptance.

Responsible official. The individual designated by an entity to act on its behalf. This individual must have the authority and control to ensure compliance with the regulations in this part.

Specimen. A sample of material collected for use in testing, such as tissues, gastrointestinal contents, feces, bodily fluids (blood, serum, etc.), soil, water, feed or feed ingredients, swabs, cultures, and suspensions.

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 United States Department of Agriculture.

§ 121.2 Purpose and scope.

(a) This part sets forth the requirements for possession, use, and transfer of biological agents or toxins that have been determined to have the potential to pose a severe threat to both human and animal health, to animal health, or to animal products. The purpose of this part is to ensure the safe handling of such agents or toxins, and to protect against the use of such agents or toxins in domestic or international terrorism or for any other criminal purpose.

(b) Accordingly, this part provides that any individual or entity that possesses, uses, or transfers any agent or toxin listed in §121.3 must register in accordance with §121.7. To register, each entity must designate an individual who has the authority and control to ensure compliance with the regulations to be the responsible official. The responsible official must complete and submit the registration application package to APHIS or, for overlap agents or toxins, to APHIS or CDC. As part of registration, the responsible official, the entity, and, where applicable, the individual who owns or controls such entity will be subject to a security risk assessment by the Attorney General.

(c) The responsible official is responsible for ensuring compliance with the safety procedures in this part, including implementing the Biosafety and Security Plan in accordance with §121.12, providing the proper training

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to individuals who handle or use agents or toxins listed in §121.3, and providing proper laboratory facilities to contain and dispose of such agents or toxins. In addition, the responsible official is responsible for ensuring compliance with the safeguard and security measures in this part, including restricting access to only those individuals who have a legitimate need to handle or use agents or toxins and who have been approved in accordance with §121.11, and transferring such agents or toxins only to registered individuals or entities in accordance with §121.13.

§ 121.3 List of biological agents and toxins.

(a) Except as provided in paragraphs (f) and (g) 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 both human and animal health, to animal health, or to animal products.

(b) Overlap agents and toxins.

- Bacillus anthracis
Botulinum neurotoxins
Botulinum neurotoxin producing species of Clostridium
Brucella abortus
Brucella melitensis
Brucella suis
Burkholderia mallei
Burkholderia pseudomallei
Clostridium botulinum
Clostridium perfringens epsilon toxin
Coccidioides immitis
Coxiella burnetii
Eastern equine encephalitis virus
Francisella tularensis
Hendra virus
Nipah virus
Rift Valley fever virus
Shigatoxin
Staphylococcal enterotoxins
T-2 toxin
Venezuelan equine encephalitis virus

(c) Genetic elements, recombinant nucleic acids, and recombinant organisms of overlap agents or toxins:

(1) Biological agent viral nucleic acids (synthetic or naturally derived, contiguous or fragmented, in host chromosomes or in expression vectors) that can encode infectious and/or replication competent forms of any of the biological agent viruses.

(2) Nucleic acids (synthetic or naturally derived) that encode for the func-

tional form(s) of any of the toxins listed in paragraph (b) of this section, if the nucleic acids:

- (i) Are in a vector or host chromosome;
(ii) Can be expressed in vivo or in vitro; or
(iii) Are in a vector or host chromosome and can be expressed in vivo or in vitro.

(3) Viruses, bacteria, fungi, and toxins listed in paragraph (b) of this section that have been genetically modified.

(d) Animal 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 (exotic)
Menangle virus
Mycoplasma capricolum/M. F38/M. mycoides capri (contagious caprine pleuropneumonia)
Mycoplasma mycoides mycoides (contagious bovine pleuropneumonia)
Newcastle disease virus (VVD)
Peste des petits ruminants virus
Rinderpest virus
Sheep pox virus
Swine vesicular disease virus
Vesicular stomatitis virus (exotic)

(e) The Administrator has determined that it would be impractical to regulate a biological agent or toxin that is in its naturally occurring environment. Therefore, any biological agent or toxin listed in this section that is in its naturally occurring environment will not be subject to the requirements of this part, provided that the biological agent or toxin has not been intentionally introduced, cultivated, collected, or otherwise extracted from its natural source.

(f) The Administrator has determined that biological agents or toxins that meet any of the following criteria do not have the potential to pose a severe threat to both human and animal health, or to animal health or animal products. Therefore, an individual or