

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 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*

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*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 functional 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 entity that only possesses, uses, or transfers an agent or toxin that meets any of the following criteria will not be subject to the requirements of this part:

(1) Nonviable agents or fixed tissues that are, bear, or contain agents or toxins listed in this section.<sup>1</sup>

(2) Genetic elements or subunits of agents or toxins listed in paragraph (d) of this section, if the genetic elements or subunits are not capable of causing disease.<sup>2</sup>

(3) Overlap toxins under the control of a principal investigator (or equivalent), if the total aggregate amount does not, at any time, exceed the following amounts: 0.5 mg of Botulinum neurotoxins (types A–G), 100 mg of *Clostridium perfringens* epsilon toxin, 100 mg of Shigatoxin, 5 mg of Staphylococcal enterotoxins, and 1,000 mg of T-2 toxin.

(g) *Attenuated strains.* Attenuated strains of biological agents listed in this section may not have the potential to pose a severe threat to both human and animal health, to animal health, or

<sup>1</sup>However, the importation and interstate movement of these genetic elements or subunits of listed agents or toxins are still subject to the permit requirements under part 122 of this subchapter.

<sup>2</sup>See footnote 1.

to animal products. Thus, an individual or entity may request review by the Administrator to determine whether a specific attenuated strain poses a severe threat to both human and animal health, or to animal health or animal products. For overlap agents, an individual or entity may request review by APHIS or CDC.

(1) If APHIS or CDC determines that a specific attenuated strain does not pose a severe threat to human and animal health, or to animal health or animal products, an individual or entity will not be subject to the requirements of this part. This determination will be limited to the specific attenuated strain and to the specific activities involving that attenuated strain.

(2) An individual or entity may request a review by writing to the Administrator or, for overlap agents, by writing to the Administrator or CDC.<sup>3</sup>

(3) If it is determined that a specific attenuated strain does not pose a severe threat, APHIS or CDC will notify the applicant and publish a notice in the FEDERAL REGISTER.

(4) An individual or entity may request reconsideration of an adverse decision in writing to the Administrator. The request for reconsideration must state all of the facts and reasons upon which the individual or entity relies upon to show the decision was incorrect. The Administrator will grant or deny the request for reconsideration as promptly as circumstances allow and will state, in writing, the reasons for the decision. If there is a conflict as to any material fact, the individual or entity may request a hearing to resolve the conflict.

#### § 121.4 Exemptions for overlap agents or toxins.

(a) Clinical or diagnostic laboratories and other entities possessing, using, or transferring overlap agents or toxins

that are contained in specimens presented for diagnosis or verification will be exempt from the requirements of this part, provided that:

(1) The identification of such agents or toxins is immediately reported to APHIS or CDC, and to other appropriate authorities when required by Federal, State, or local law; and

(2) Within 7 days after identification, the agents or toxins are transferred or inactivated, and APHIS Form 2040 is submitted to APHIS or CDC.<sup>4</sup> During agricultural emergencies or outbreaks, or in endemic areas, the Administrator may require less frequent reporting. A copy of the completed form must be maintained for 3 years.

(b) Clinical or diagnostic laboratories and other entities possessing, using, or transferring overlap agents or toxins that are contained in specimens presented for proficiency testing will be exempt from the requirements of this part, provided that:

(1) The identification of such agents or toxins, and their derivatives, is immediately reported to the APHIS or CDC, and to other appropriate authorities when required by Federal, State, or local law; and

(2) Within 90 days of receipt, the agents or toxins are transferred or inactivated, and APHIS Form 2040 is submitted to APHIS or CDC. A copy of the completed form must be maintained for 3 years.

(c) Unless the Administrator by order determines that additional regulation of a specific product is necessary to protect animal or plant health, or animal or plant products, an individual or entity possessing, using, or transferring products that are, bear, or contain overlap agents or toxins will be exempt from the requirements of this part if the products have been cleared, approved, licensed, or registered pursuant to:

<sup>3</sup>A request to review an attenuated strain may be mailed to National Center for Import and Export, VS, APHIS, 4700 River Road Unit 40, Riverdale, MD 20737-1231; or faxed to (301) 734-3652. For overlap agents, a request for review may be mailed to the above address or to Select Agent Program, Centers for Disease Control and Prevention, 1600 Clifton Road, NE, Mail Stop E 79, Atlanta, GA 30333; or faxed to (404) 498-2265.

<sup>4</sup>A clinical or diagnostic laboratory, or other entity, may immediately notify APHIS by faxing (301) 734-3652. APHIS Form 2040 may be obtained by calling APHIS at (301) 734-3277 or by calling CDC at (404) 498-2265. The form is also available on the Internet at <http://www.aphis.usda.gov/vs/ncie.bta.html> or <http://www.cdc.gov/od/ohs/lrsat.htm>. The completed form may be mailed or faxed to APHIS or CDC, as provided in footnote 3.