

PART 73—SELECT AGENTS AND TOXINS

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AUTHORITY: 42 U.S.C. 262a; sections 201–204, 221 and 231 of Title II of Public Law 107–188, 116 Stat. 637 (42 U.S.C. 262a).

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§ 73.0 Applicability and related requirements.

All individuals and entities that possess SARS-CoV, Lujo virus, or Chapare virus must provide notice to CDC regarding their possession of SARS-CoV, Lujo virus, or Chapare virus on or before December 4, 2012. Currently registered individuals and entities possessing SARS-CoV, Lujo virus, or Chapare virus must meet all the requirements of this part by December 4, 2012. All previously unregistered individuals and entities possessing SARS-CoV, Lujo virus, or Chapare virus must meet all of the requirements of this part by April 3, 2013.

[77 FR 61110, Oct. 5, 2012, as amended at 77 FR 71702, Dec. 4, 2012]

§ 73.1 Definitions.

For purposes of this part:

Administrator means the Administrator, Animal and Plant Health In-

spection Service, or any person authorized to act for the Administrator.

Animal and Plant Health Inspection Service (APHIS) means the Animal and Plant Health Inspection Service of the U.S. Department of Agriculture.

Attorney General means the Attorney General of the United States or any person authorized to act for the Attorney General.

Biological agent means any microorganism (including, but not limited to, bacteria, viruses, fungi, rickettsiae, or protozoa), or infectious substance, or any naturally occurring, bioengineered, or synthesized component of any such microorganism or infectious substance, capable of causing death, disease, or other biological malfunction in a human, an animal, a plant, or another living organism; deterioration of food, water, equipment, supplies, or material of any kind; or deleterious alteration of the environment.

CDC means Centers for Disease Control and Prevention of the Department of Health and Human Services.

Conotoxins means short, paralytic alpha conotoxins containing the following amino acid sequence $X_1CCX_2PACGX_3X_4X_5X_6CX_7$, whereas:

- (1) C = Cysteine residues are all present as disulfides, with the 1st and 3rd Cysteine, and the 2nd and 4th Cysteine forming specific disulfide bridges;
- (2) The consensus sequence includes known toxins α -MI and α -GI (shown above) as well as α -GIA, Ac1.1a, α -CnIA, α -CnIB;
- (3) X_1 = any amino acid(s) or Des-X;
- (4) X_2 = Asparagine or Histidine;
- (5) P = Proline;
- (6) A = Alanine;
- (7) G = Glycine;
- (8) X_3 = Arginine or Lysine;
- (9) X_4 = Asparagine, Histidine, Lysine, Arginine, Tyrosine, Phenylalanine or Tryptophan;
- (10) X_5 = Tyrosine, Phenylalanine, or Tryptophan;
- (11) X_6 = Serine, Threonine, Glutamate, Aspartate, Glutamine, or Asparagine;
- (12) X_7 = Any amino acid(s) or Des X; and
- (13) “Des X” = “an amino acid does not have to be present at this position.” For example if a peptide sequence were XCCHPA then the related peptide CCHPA would be designated as Des-X.

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

HHS means the Department of Health and Human Services.

HHS Secretary means the Secretary of the Department of Health and Human Services or his or her designee, unless otherwise specified.

HHS select agent and/or toxin means a biological agent or toxin included in § 73.3.

Information security means 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.

Occupational exposure means any reasonably anticipated skin, eye, mucous 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 means a biological agent or toxin listed in § 73.4 and 9 CFR part 121.4.

Principal investigator means the one individual who is designated by the entity to direct a project or program and who is responsible to the entity for the scientific and technical direction of that project or program.

Proficiency testing means the process of determining the competency of an individual or laboratory to perform a specified test or procedure.

Recombinant nucleic acids means:

(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 means the individual designated by an entity with the authority and control to ensure compliance with the regulations in this part.

Security barrier means a physical structure that is designed to prevent entry by unauthorized persons.

Select agent and/or toxin means unless otherwise specified, all of the biological agents or toxins listed in §§ 73.3 and 73.4.

Specimen means samples of material from humans, animals, plants or the environment or isolates or cultures from such samples for the diagnosis, verification, or proficiency testing.

State means 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 means:

(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 means 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 any poisonous substance or biological product that may be engineered as a result of biotechnology, produced by a living organism; or any poisonous isomer or biological product, homolog, or derivative of such a substance.

United States means all of the States.

USDA means the United States Department of Agriculture.

Verification means the demonstration of obtaining established performance

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(e.g., accuracy, precision, and the analytical sensitivity and specificity) specifications for any procedure used for diagnosis.

[70 FR 13316, Mar. 18, 2005, as amended at 77 FR 61110, Oct. 5, 2012]

§ 73.2 Purpose and scope.

This part implements the provisions of the Public Health Security and Bio-terrorism Preparedness and Response 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 CDC and APHIS.

§ 73.3 HHS select agents and toxins.

(a) Except for exclusions under paragraphs (d) and (e) of this section, the HHS Secretary 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. 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) HHS select agents and toxins:

Abrin
Botulinum neurotoxins*
Botulinum neurotoxin producing species of *Clostridium**
Conotoxins (Short, paralytic alpha conotoxins containing the following amino acid sequence X₁CCX₂PACGX₃X₄X₅X₆CX₇)
Coxiella burnetii
Crimean-Congo haemorrhagic fever virus
Diacetoxyscirpenol
Eastern Equine Encephalitis virus
Ebola virus*
*Francisella tularensis**
Lassa fever virus
Lujo virus
Marburg virus*
Monkeypox virus
Reconstructed replication competent forms of the 1918 pandemic influenza virus containing any portion of the coding regions of all eight gene segments (Reconstructed 1918 Influenza virus)
Ricin
Rickettsia prowazekii
SARS-associated coronavirus (SARS-CoV)
Saxitoxin

South American Haemorrhagic Fever viruses:
Chapare
Guanarito
Junin
Machupo
Sabia
Staphylococcal enterotoxins (subtypes A–E)
T-2 toxin
Tetrodotoxin
Tick-borne encephalitis virus
Far Eastern subtype
Siberian subtype
Kyasanur Forest disease virus
Omsk haemorrhagic fever virus
Variola major virus (Smallpox virus)*
Variola minor virus (Alastrim)*
*Yersinia pestis**

(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.

(2) Recombinant and/or Synthetic nucleic acids that encode for the functional form(s) of any of the toxins 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) HHS select agents and toxins listed in paragraph (b) of this section that have been genetically modified.

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

(1) Any HHS select agent or toxin that is in its naturally occurring environment provided the select agent or toxin has not been intentionally introduced, cultivated, collected, or otherwise extracted from its natural source.

(2) Non-viable HHS select agents or nonfunctional HHS toxins.

(3) Except as required in § 73.16(1), the aggregate amount of the toxin under the control of a principal investigator, treating physician or veterinarian, or commercial manufacturer or distributor does not, at any time, exceed the following amounts: 100 mg of Abrin; 0.5 mg of Botulinum neurotoxins; 100 mg of Conotoxins