

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.

Diagnosis means the analysis of specimens for the purpose of identifying or confirming the presence of a listed select agent or toxin provided that such analysis is directly related to protecting the public health or safety.

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 Department of Health and Human Services or his or her designee, unless otherwise specified.

HHS select agent or toxin means a biological agent or toxin included in § 73.4.

Overlap select agent or toxin means a biological agent or toxin included in § 73.5.

Proficiency testing means 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.

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.

Select agent or toxin or select agent and toxin without identification as HHS or overlap means all of those biological agents or toxins included in §§ 73.4 and 73.5 of this part.

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 the United States of America, the District of Columbia, Puerto Rico, and the territories and possessions of the United States.

USDA means the United States Department of Agriculture.

USDA Secretary means the Department of Agriculture or his or her designee, unless otherwise specified.

Verification means the processes required to assure the accuracy, precision, and the analytical sensitivity and specificity of any procedure used for diagnosis.

§ 73.2 Purpose and scope.

(a) This part sets forth requirements regarding the possession or use in the United States, receipt from outside the United States, or transfer within the United States, of select agents and toxins. The requirements are designed to implement provisions of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Public Law 107-188). The Act was designed to provide protection against the effects of misuse of select agents and toxins whether inadvertent or the result of terrorist acts against the United States homeland or other criminal acts. The agents and toxins subject to requirements under this part are those that have the potential to pose a severe threat to public health and safety. They are further identified as either HHS select agents and toxins or overlap select agents and toxins. The term HHS select agents and toxins refers to those select agents and toxins subject to these regulations but not subject to USDA requirements at 9 CFR part 121. The overlap group consists of those select agents and toxins subject to requirements promulgated by the HHS Secretary under this part

§ 73.3

42 CFR Ch. I (10–1–04 Edition)

and also subject to corresponding requirements promulgated by USDA at 9 CFR part 121.

(b) This part does not set requirements for the exportation of select agents or toxins. The Department of Commerce has primary responsibility for regulating the exportation of microorganisms and toxins in Title 15 of the Code of Federal Regulations.

(c) This part does not set requirements for the transportation in commerce of select agents or toxins. The Department of Transportation has primary responsibility for regulating the transportation of such select agents and toxins as hazardous materials under 49 CFR parts 171 through 180.

§ 73.3 General prohibition.

An entity or individual may not possess or use in the United States, receive from outside the United States, or transfer within the United States, a select agent or toxin unless such activities are conducted for a lawful purpose and in accordance with the provisions of this part. Registration, exclusions, and exemptions are automatically revoked when any event occurs that results in an entity or individual no longer being eligible.

§ 73.4 HHS select agents and toxins.

Except for exclusions under paragraph (f) of this section, the viruses, bacteria, fungi, toxins, genetic elements, recombinant nucleic acids, and recombinant organisms specified in paragraphs (a) through (e) of this part are HHS select agents and toxins.

(a) Viruses:

- (1) Crimean-Congo haemorrhagic fever virus.
- (2) Ebola viruses.
- (3) Cercarial dermatitis (Swimmer's itch).
- (4) Lassa fever virus.
- (5) Marburg virus.
- (6) Monkeypox virus.
- (7) South American Haemorrhagic Fever viruses (Junin, Machupo, Sabia, Flexal, Guanarito).
- (8) Tick-borne encephalitis complex (flavi) viruses (Central European Tick-borne encephalitis, Far Eastern Tick-borne encephalitis [Russian Spring and Summer encephalitis, Kyasanur Forest disease, Omsk Hemorrhagic Fever]).

(9) Variola major virus (Smallpox virus) and Variola minor virus (Alastrim).

(b) Bacteria:

- (1) *Rickettsia prowazekii*.
- (2) *Rickettsia rickettsii*.
- (3) *Yersinia pestis*.

(c) Fungi: *Coccidioides posadasii*.

(d) Toxins:

- (1) Abrin.
- (2) Conotoxins.
- (3) Diacetoxyscirpenol.
- (4) Ricin.
- (5) Saxitoxin.
- (6) Tetrodotoxin.
- (7) Shiga-like ribosome inactivating proteins.

(e) Genetic Elements, Recombinant Nucleic Acids, and Recombinant Organisms:

(1) Select 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 select agent viruses.

(2) Nucleic acids (synthetic or naturally derived) that encode for the functional form(s) of any of the toxins listed in paragraph (d) 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 paragraphs (a) through (d) of this section that have been genetically modified.

(f) Exclusions:

(1) This section does not include any select agent or toxin that is in its naturally occurring environment provided it has not been intentionally introduced, cultivated, collected, or otherwise extracted from its natural source.

(2) This section does not include non-viable select agent organisms or non-functional toxins.

(3) Paragraph (a) of this section does not include the vaccine strain of Junin virus (Candid #1).

(4) Paragraph (d) of this section does not include the following toxins (in the purified form or in combinations of