

§ 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