

§ 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 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, exclu-

sions, 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) Cercopithecine herpesvirus 1 (Herpes B virus).

(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 pure and impure forms) if the aggregate amount under the control of a principal investigator does not, at any time, exceed the amount specified: 100 mg of Abrin; 100 mg of Conotoxins; 1,000 mg of Diacetoxyscirpenol; 100 mg of Ricin; 100 mg of Saxitoxin; 100 mg of Shiga-like ribosome inactivating proteins; or 100 mg of Tetrodotoxin.

(5) The HHS Secretary may exclude from this section attenuated strains of HHS select agents or toxins upon a determination that they do not pose a severe threat to the public health and safety. To apply for an exclusion an applicant must submit a request in writing in accordance with § 73.21 to the HHS Secretary establishing that the attenuated strain or toxin is eligible for exclusion. The HHS Secretary will provide a written decision granting the request, in whole or in part, or denying the request. An exclusion will be effective upon notification to the applicant. Exclusions will be published in the notice section of the FEDERAL REGISTER and will be listed on the CDC Web site

at <http://www.cdc.gov>. Exclusions also will be referenced in this section when changes are made based on periodic reviews.

§ 73.5 Overlap 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 overlap select agents and toxins.

(a) Viruses:

(1) Eastern Equine Encephalitis virus.

(2) Nipah and Hendra Complex viruses.

(3) Rift Valley fever virus.

(4) Venezuelan Equine Encephalitis virus.

(b) Bacteria:

(1) *Bacillus anthracis*.

(2) *Brucella abortus*.

(3) *Brucella melitensis*.

(4) *Brucella suis*.

(5) *Burkholderia mallei* (formerly *Pseudomonas mallei*).

(6) *Burkholderia pseudomallei* (formerly *Pseudomonas pseudomallei*).

(7) Botulinum neurotoxin producing species of *Clostridium*.

(8) *Coxiella burnetii*.

(9) *Francisella tularensis*.

(c) Fungi: *Coccidioides immitis*.

(d) Toxins:

(1) Botulinum neurotoxins.

(2) *Clostridium perfringens* epsilon toxin.

(3) Shigatoxin.

(4) Staphylococcal enterotoxins.

(5) T-2 toxin.

(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;