

§ 73.6

(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 that 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) does not include the vaccine strain of Rift Valley fever virus (MP-12) or Venezuelan Equine encephalitis virus vaccine strain TC-83.

(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: 0.5 mg of Botulinum neurotoxins; 5 mg of Staphylococcal enterotoxins; 100 mg of *Clostridium perfringens* epsilon toxin; 100 mg of Shigatoxin; or 1,000 mg of T-2 toxin.

(5) The HHS Secretary, after consultation with the USDA Secretary, may exclude from this section attenuated strains of overlap select agents or toxins upon a determination that they do not pose a severe threat to the public health and safety and do not meet the criteria in 9 CFR part 121 for inclusion. To apply for an exclusion, an applicant must submit a request in writing in accordance with § 73.21 to the HHS Secretary or the USDA Secretary in accordance with 9 CFR part 121, establishing that the attenuated strain is eligible for exclusion. In response to an application submitted to the HHS Secretary, 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

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and will be listed on the CDC Web site at <http://www.cdc.gov>. Also, they will be referenced in this section when changes are made based on periodic reviews.

§ 73.6 Exemptions from requirements under this part.

(a) An entity is exempt from the provisions of this part, other than § 73.14 (transfer), provided that all of the following apply:

(1) The only activities conducted by the entity that are subject to this part concern select agents or toxins that are contained in specimens or in isolates from specimens presented for diagnosis, verification, or proficiency testing;

(2) Upon identification of a select agent or toxin as the result of diagnosis or verification, the entity immediately reports to the HHS Secretary by telephone, facsimile, or e-mail in accordance with § 73.21 any of the following: Variola major virus (Smallpox virus) and Variola minor (Alastrim), *Bacillus anthracis*, *Yersinia pestis*, Botulinum neurotoxins, *Francisella tularensis*, Ebola viruses, Marburg virus, Lassa fever virus, and South American Haemorrhagic Fever viruses (Junin, Machupo, Sabia, Flexal, Guanarito);

(3) The entity reports as required under Federal, State, or local law, to appropriate authorities;

(4) After the diagnosis, verification, or proficiency testing, the entity either transfers the specimens or isolates containing a select agent or toxin from the specimens to a facility eligible for receiving them under this part, or destroys them on-site by autoclaving, incineration, or by a sterilization or neutralization process sufficient to cause inactivation;

(5) The entity transfers or destroys those select agents or toxins used for diagnosis or testing within seven days after identification, unless directed otherwise by the Federal Bureau of Investigation or other law enforcement entity after consultation with the HHS Secretary; and

(6) The entity transfers or destroys those select agents or toxins used for proficiency testing within 90 days after receipt; and

(7) The entity prepares a record of the identification and transfer or destruction on CDC Form 0.1318, submits the completed form to the HHS Secretary in accordance with § 73.21 within seven days after identification, and maintains a copy of the record for a period of three years.

(b) Unless the HHS Secretary issues an order to an entity making specific provisions of this part applicable to protect the public health and safety, products that are, bear, or contain listed select agents or toxins that are cleared, approved, licensed, or registered under any of the following laws, are exempt from the provisions of this part insofar as their use is only for the approved purpose and meets the requirements of such laws:

(1) The Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 *et seq.*);

(2) Section 351 of the Public Health Service Act pertaining to biological products (42 U.S.C. 262);

(3) The Act commonly known as the Virus-Serum-Toxin Act (21 U.S.C. 151-159); or

(4) The Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136 *et seq.*).

(c) The HHS Secretary may exempt from the requirements of this part on a case-by-case basis an investigational product that is, bears, or contains a select agent or toxin, when such product is being used in an investigation authorized under a Federal Act referred to in paragraph (b) of this section and additional regulation under this part is not necessary to protect public health and safety. To apply for an exemption an applicant must submit to the HHS Secretary in accordance with § 73.21 a completed CDC Form 0.1317 certifying that the product is being used in an investigation authorized under a Federal Act referred to in paragraph (b) of this section, and that additional regulation under this part is not necessary to protect public health and safety. The HHS Secretary shall make a determination regarding the application within 14 calendar days after receipt, provided the application meets all of the requirements of this section and the application establishes that the investigation has been authorized under the cited Act. The HHS Secretary will provide a

written decision granting the request, in whole or in part, or denying the request. The applicant must notify the HHS Secretary when an authorization for an investigation no longer exists. This exemption automatically ceases when such authorization is no longer in effect.

(d) The HHS Secretary may temporarily exempt an entity from the requirements of this part, in whole or in part, based on a determination that the exemption is necessary to provide for the timely participation of the entity in response to a domestic or foreign public health emergency. With respect to the emergency involved, the exemption may not exceed 30 days, except that the HHS Secretary may grant one extension of an additional 30 days. To apply for an exemption or an extension of an exemption, an applicant must submit to the HHS Secretary in accordance with § 73.21 a completed CDC Form 0.1317 establishing the need to provide for the timely participation of the entity in a response to a domestic or foreign public health emergency. The HHS Secretary will provide a written decision granting the request, in whole or in part, or denying the request.

(e) Upon request of the USDA Secretary, after the USDA Secretary has granted an exemption under section 212(g)(1)(D) of the Agricultural Bioterrorism Protection Act of 2002 based on a finding that there is an agricultural emergency, the HHS Secretary may temporarily exempt an entity from the applicability of the requirements of this part, in whole or in part, to provide for the timely participation of the entity in response to the agricultural emergency. With respect to the emergency, the exemption under this part may not exceed 30 days, except that upon the request of the USDA Secretary, the HHS Secretary may grant one extension of an additional 30 days.

§ 73.7 Registration.

(a) An entity may not possess or use in the United States, receive from outside the United States, or transfer within the United States, any select agent or toxin unless the entity has