

§ 121.6

9 CFR Ch. I (1–1–12 Edition)

USDA diagnostic facilities will be exempt from the requirements of this part.

(d) Unless the Administrator by order determines that additional regulation is necessary to protect animal health or animal products, products that are, bear, or contain VS select agents or toxins will be exempt from the requirements of this part if the products have been cleared, approved, licensed, or registered pursuant to:

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

(2) Section 351 of Public Health Service Act (42 U.S.C. 262);

(3) The Virus-Serum-Toxin Act (21 U.S.C. 151–159); or

(4) The Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 131 *et seq.*).

(e) The Administrator may exempt from the requirements of this part an experimental product that is, bears, or contains a VS select agent or toxin if such product is being used in an investigation authorized by any Federal law and the Administrator determines that additional regulation under this part is not necessary to protect animal health or animal products. To apply for an exemption, an individual or entity must submit APHIS/CDC Form 5. A written decision granting or denying the exemption will be issued. The applicant must notify APHIS when an authorization for an investigation no longer exists. This exemption automatically terminates when such authorization is no longer in effect.

(f) In addition to the exemptions provided in paragraphs (a) through (e) of this section, the Administrator may grant a specific exemption upon a showing of good cause and upon his or her determination that such exemption is consistent with protecting animal health or animal products. An individual or entity may request in writing an exemption from the requirements of this part. If granted, such exemptions are valid for a maximum of 3 years; thereafter, an individual or entity must request a new exemption. If a request for exemption is denied, an individual or entity may request reconsideration in writing to the Administrator. The request for reconsideration must state all of the facts and reasons

upon which the individual or entity relies to show that the exemption was wrongfully denied. The Administrator will grant or deny the request for reconsideration as promptly as circumstances allow and will state, in writing, the reasons for the decision.

[70 FR 13284, Mar. 18, 2005, as amended at 73 FR 61331, Oct. 16, 2008]

§ 121.6 Exemptions for overlap select agents and toxins.

(a) Clinical or diagnostic laboratories and other entities that possess, use, or transfer an overlap select agent or toxin that is contained in a specimen presented for diagnosis or verification will be exempt from the requirements of this part for such agent or toxin contained in the specimen, provided that:

(1) Unless directed otherwise by the Administrator or the HHS Secretary, within 7 calendar days after identification, the agent or toxin is transferred in accordance with § 121.16 or 42 CFR 73.16 or destroyed on-site by a recognized sterilization or inactivation process;

(2) The agent or toxin is secured against theft, loss, or release during the period between identification of the agent or toxin and transfer or destruction of such agent or toxin, and any theft, loss, or release of such agent or toxin is reported; and

(3) The identification of the agent or toxin is reported to APHIS or CDC.

(i) The identification of any of the following overlap select agents and toxins must be immediately reported by telephone, facsimile, or e-mail: *Bacillus anthracis*, *Brucella melitensis*, Hendra virus, Nipah virus, Rift Valley fever virus, and Venezuelan equine encephalitis virus. This report must be followed by submission of APHIS/CDC Form 4 within 7 calendar days after identification.

(ii) For all other overlap select agents or toxins, APHIS/CDC Form 4 must be submitted within 7 calendar days after identification.

(iii) Less stringent reporting may be required during agricultural emergencies or outbreaks, or in endemic areas.

(iv) A copy of APHIS/CDC Form 4 must be maintained for 3 years.

(b) Clinical or diagnostic laboratories and other entities that possess, use, or transfer an overlap select agent or toxin that is contained in a specimen presented for proficiency testing will be exempt from the requirements of this part for such agent or toxin contained in the specimen, provided that:

(1) Unless directed otherwise by the Administrator or the HHS Secretary, within 90 days of receipt, the agent or toxin is transferred in accordance with § 121.16 or 42 CFR 73.16 or destroyed on-site by a recognized sterilization or inactivation process;

(2) The agent or toxin is secured against theft, loss, or release during the period between identification of the agent or toxin and transfer or destruction of such agent or toxin, and any theft, loss, or release of such agent or toxin is reported; and

(3) The identification of the agent or toxin, and its derivative, is reported to APHIS or CDC. To report the identification of an overlap select agent or toxin, APHIS/CDC Form 4 must be submitted within 90 calendar days of receipt of the agent or toxin. A copy of the completed form must be maintained for 3 years.

(c) Unless the Administrator by order determines that additional regulation of a specific product is necessary to protect animal health or animal products, products that are, bear, or contain overlap select agents or toxins will be exempt from the requirements of this part if the products have been cleared, approved, licensed, or registered pursuant to:

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

(2) Section 351 of Public Health Service Act (42 U.S.C. 262);

(3) The Virus-Serum-Toxin Act (21 U.S.C. 151–159); or

(4) The Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 131 *et seq.*).

(d) After consultation with the HHS Secretary, the Administrator may exempt from the requirements of this part an investigational product that is, bears, or contains an overlap select agent or toxin if such product is being used in an investigation authorized by any Federal law and the Administrator determines that additional regulation

under this part is not necessary to protect animal health or animal products.

(1) To apply for an exemption, an individual or entity must submit APHIS/CDC Form 5.

(2) The Administrator will make a determination regarding an exemption within 14 calendar days after receipt of the application and notification that the investigation has been authorized under a Federal law. A written decision granting or denying the exemption will be issued.

(3) The applicant must notify APHIS or CDC when an authorization for an investigation no longer exists. This exemption automatically terminates when such authorization is no longer in effect.

(e) The Administrator may exempt an individual or entity from the requirements of this part for 30 calendar days if it is necessary to respond to a domestic or foreign agricultural emergency involving an overlap select agent or toxin. The Administrator may extend the exemption once for an additional 30 days. An individual or entity may apply for this exemption by submitting APHIS/CDC Form 5. A written decision granting or denying the exemption will be issued.

(f) Upon request of the Secretary of Health and Human Services, the Administrator may exempt an individual or entity from the requirements of this part for 30 calendar days if the Secretary of Health and Human Services has granted an exemption for a public health emergency involving an overlap select agent or toxin. The Administrator may extend the exemption once for an additional 30 days.

[70 FR 13284, Mar. 18, 2005, as amended at 73 FR 61331, Oct. 16, 2008]

§ 121.7 Registration and related security risk assessments.

(a) Unless exempted under § 121.5, an individual or entity shall not possess, use, or transfer any VS select agent or toxin without a certificate of registration issued by the Administrator. Unless exempted under § 121.6 or 42 CFR 73.6, an individual or entity shall not possess, use, or transfer any overlap select agent or toxin without a certificate of registration issued by the Administrator and the HHS Secretary.