

reporting. A copy of the completed form must be maintained for 3 years.

(b) Diagnostic laboratories and other entities possessing, using, or transferring agents or toxins that are contained in specimens presented for proficiency testing will be exempt from the requirements of this part, provided that:

(1) The identification of such agents or toxins, and their derivatives, is immediately reported to the Administrator, and to other appropriate authorities when required by Federal, State, or local law; and

(2) Within 90 days of receipt, the agent or toxins are transferred or inactivated, and APHIS Form 2040 is submitted to the Administrator. A copy of the completed form must be maintained for 3 years.

(c) An individual or entity receiving diagnostic reagents and vaccines that are, bear, or contain listed agents or toxins, also known as high consequence livestock pathogens or toxins, that are produced at 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, an individual or entity possessing, using, or transferring products that are, bear, or contain listed 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) An individual or entity possessing, using, or transferring experimental products that are, bear, or contain listed agents or toxins may be exempt from the requirements of this

part 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 or plant health, and animal or plant products. An individual or entity possessing, using, or transferring such experimental products may apply for an exemption from the requirements of this part by submitting APHIS Form 2042 to APHIS.

(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 and animal products. An individual or entity that possesses, uses, or transfers agents or toxins 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. If there is a conflict as to any material fact, the individual or entity may request a hearing to resolve the conflict.⁶

§ 121.6 Registration; who must register.

(a) Unless exempted under §§ 121.4 or 121.5, any individual or entity that possesses, uses, or transfers any agent or toxin listed in § 121.3 must register with APHIS or, for overlap agents or toxins, APHIS or CDC.

(b) Each entity must designate an individual to be its responsible official.

www.aphis.usda.gov/vs/ncie.bta.html. The completed form may be mailed to National Center for Import and Export, VS, APHIS, 4700 River Road Unit 40, Riverdale, MD 20737-1231; or faxed to (301) 734-3652.

⁶A request for exemption may be mailed to National Center for Import and Export, VS, APHIS, 4700 River Road Unit 40, Riverdale, MD 20737-1231; or faxed to (301) 734-3652.

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The responsible official must have the authority and control to ensure compliance with the regulations. The responsible official must complete and sign the registration application package, and will be the individual contacted by APHIS or CDC if any questions arise concerning the application or subsequent compliance with the regulations in this part. As part of registration, the responsible official and the entity will be subject to a security risk assessment by the Attorney General. While most registrants are likely to be entities, in the event that an individual applies for and is granted a certificate of registration, APHIS will consider the individual to be the responsible official.

(c) An entity may designate one or more individuals to be an alternate responsible official, who may act for the responsible official when he/she is unavailable. These individuals must have the authority and control to ensure compliance with the regulations when acting as the responsible official. These individuals will also be subject to a security risk assessment by the Attorney General as part of registration.

§ 121.7 Registration; general provisions.

(a) Unless exempted under §§ 121.4 or 121.5, an individual or entity shall not possess, use, or transfer any agent or toxin listed in § 121.3 without a certificate of registration issued by APHIS or CDC.

(b) A certificate of registration may be issued upon:

(1) Approval of the responsible official; the alternate responsible official, where applicable; the entity; and, where applicable, the individual who owns or controls the entity following a security risk assessment by the Attorney General;⁷ and

(2) Approval of the biosafety, containment, and security of the entity. The entity's biosafety, containment, and security procedures must be commensurate with the risk of the agent or toxin, given its intended use. APHIS or

CDC will review the Biosafety and Security Plan, and may inspect and evaluate the premises and records to determine compliance with the regulations and the biosafety, containment, and security requirements; and

(3) A determination by the Administrator that the individual or entity seeking to register has a lawful purpose to possess, use, or transfer such agents or toxins.

(c) For overlap agents, APHIS and CDC will review applications for registration and amendments to a certificate of registration, and a certificate of registration or amendment to a certificate of registration will only be issued if APHIS and CDC concur.

(d) A certificate of registration will be valid for only the specific agents or toxins listed in the certificate and specific activities and locations. A certificate of registration may cover more than one listed agent or toxin, and it may be amended to cover additional listed agents or toxins.

(e) A certificate of registration may be amended to reflect changed circumstances (e.g., replacement of the responsible official, changes in ownership or control of the entity,⁸ changes in the activities involving the agent or toxin). The responsible official must immediately notify the agency that issued the certificate of registration, either APHIS or CDC, of such changes in circumstances that occur after submission of the application for registration or after receipt of a certificate of registration.

(f) If a responsible official wishes to discontinue possessing, using, or transferring a particular agent or toxin, the responsible official may inactivate the agent or toxin or he/she may transfer the agent or toxin to a registered individual or entity in accordance with § 121.13. The responsible official must notify APHIS or, for overlap agents or toxins, APHIS or CDC, 5 business days prior to the planned inactivation so that we may have the opportunity to observe the inactivation of the agents or toxins. APHIS or CDC will notify

⁷The security risk assessment of the entity and the individual who owns or controls such entity may be waived for Federal, State, or local governmental agencies.

⁸Any change in ownership or control of an entity will require a security risk assessment for the new individual(s) who owns or controls the entity.