

official, who may act for the responsible official when he/she is unavailable. This individual must have the authority and control to ensure compliance with the regulations when acting for the responsible official. This individual will also be subject to a security risk assessment by the Attorney General as part of registration.

§ 331.6 Registration; general provisions.

(a) Unless exempted under this part, an individual or entity shall not possess, use, or transfer any agent or toxin listed in § 331.3 without a certificate of registration issued by APHIS.

(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 controls the entity following a security risk assessment by the Attorney General;⁴ and

(2) Approval of the containment and security of the entity. The entity's containment and security procedures must be commensurate with the risk of the agent or toxin, given its intended use. APHIS will review the Biocontainment and Security Plan, and may inspect and evaluate the premises and records to determine compliance with the regulations and the 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) A certificate of registration will be valid for only the specific agents or toxins listed on 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.

(d) A certificate of registration may be amended to reflect changed circumstances (e.g., replacement of the responsible official, changes in owner-

ship or control of the entity,⁵ changes in the activities involving the agent or toxin). The responsible official must immediately notify APHIS of such changes in circumstances that occur after submission of the application for registration or after receipt of a certificate of registration.

(e) 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 entities in accordance with § 331.12. The responsible official must notify APHIS 5 business days prior to the planned inactivation so that we may have the opportunity to observe the inactivation of the agents or toxins. We will notify the responsible official if we wish to observe the inactivation of the agents or toxins.

(f) A certificate of registration will be valid for a maximum of 3 years.

§ 331.7 Denial, revocation, or suspension of registration.

(a) APHIS may deny an application for registration or revoke registration if:

(1) The Attorney General identifies the responsible official, entity, or the individual who owns or controls the entity as within any of the categories described in 18 U.S.C. 175b; or

(2) The Attorney General identifies the responsible official, entity, or the individual who owns or controls the entity as reasonably suspected by any Federal law enforcement or intelligence agency of:

(i) Committing a crime set forth in 18 U.S.C. 2332b(g)(5); or

(ii) Knowing involvement with an organization that engages in domestic or international terrorism (as defined in 18 U.S.C. 2331) or with any other organization that engages in intentional crimes of violence; or

(iii) Being an agent of a foreign power as defined in 50 U.S.C. 1801; or

(3) The responsible official does not have a lawful purpose to possess, use,

⁴The 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.

⁵Any 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.

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or transfer agents or toxins listed in § 331.3; or

(4) The responsible official is an individual who handles or uses listed agents or toxins and he/she does not have the necessary training or skills to handle such agents or toxins; or

(5) The entity does not meet the containment and security requirements prescribed by the Administrator;⁶ or

(6) There are egregious or repeated violations of the containment or security requirements; or

(7) The Administrator determines that such action is necessary to protect animal or plant health, and animal or plant products.

(b) APHIS may summarily revoke or suspend registration for any of the reasons set forth in paragraph (a) of this section.

(c) APHIS will notify the responsible official in writing if an application for registration is denied or a certificate of registration is revoked or suspended.

(d) Denial of an application for registration, revocation of registration, and suspension of registration may be appealed under § 331.16.

§ 331.8 Registration; how to register.

(a) To apply for a certificate of registration, an individual or entity must submit all of the information and documentation required in the registration application package to APHIS, including the name, source, and characterization data for each agent or toxin to be registered.

(b) The registration application package may be obtained by calling (301) 734-5519 or faxing a request to (301) 734-8700. It is also available on the Internet at <http://www.aphis.usda.gov/ppq/permits>. The completed registration application package may be mailed to APHIS, Plant Protection and Quarantine, Biological and Technical Services, 4700 River Road Unit 133, Riverdale, MD 20737-1236; or faxed to (301) 734-8700. Assistance in completing the registration application may be requested by calling (301) 734-5519.

⁶If registration is denied for this reason, we may provide technical assistance and guidance.

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§ 331.9 Responsibilities of the responsible official.

(a) The responsible official is responsible for ensuring compliance with the regulations, including:

(1) Developing and implementing a Biocontainment and Security Plan in accordance with § 331.11;

(2) Allowing only approved individuals within the entity to have access to any agents or toxins listed in § 331.3 in accordance with § 331.10;

(3) Providing appropriate training in containment and security procedures for all personnel in accordance with § 331.12;

(4) Transferring agents or toxins only to registered individuals or entities in accordance with § 331.13;

(5) Ensuring that all visitors are informed of and follow the entity's security requirements and procedures;

(6) Notifying APHIS of changes in circumstances in accordance with § 331.6;

(7) Providing timely notice of any theft, loss, or release of a biological agent or toxin in accordance with § 331.16;

(8) Maintaining detailed records of information necessary to give a complete accounting of all of the activities related to agents or toxins listed in § 331.3 in accordance with § 331.14.

(b) In addition to the requirements in paragraph (a) of this section, the responsible official for a diagnostic laboratory or other entity possessing, using, or transferring agents or toxins listed in § 331.3 that are contained in specimens presented for diagnosis must immediately report the identification of such agents or toxins to the Administrator and to other appropriate authorities when required by Federal, State, or local law.⁷ During agricultural emergencies or outbreaks, or in endemic areas, the Administrator may require less frequent reporting.

§ 331.10 Restricting access to biological agents and toxins.

(a) An individual may not have access to biological agents or toxins listed in § 331.3 unless approved by APHIS.

⁷A diagnostic laboratory or other person must immediately notify APHIS by calling (301) 734-5519.