

§ 121.8

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room, a building, or a group of buildings) where the responsible official will be able to perform the responsibilities required in this part, for specific select agents or toxins, and for specific activities.

(h) A certificate of registration may be amended to reflect changes in circumstances (e.g., replacement of the responsible official or other personnel changes, changes in ownership or control of the entity, changes in the activities involving any select agents or toxins, or the addition or removal of select agents or toxins).

(1) Prior to any change, the responsible official must apply for an amendment to a certificate of registration by submitting the relevant page(s) of the registration application.⁶

(2) The responsible official will be notified in writing if an application to amend a certificate of registration has been approved. Approval of an amendment may be contingent upon an inspection or submission of additional information, such as the security plan, biosafety plan, incident response plan, or any other documents required to be prepared under this part.

(3) No change may be made without such approval.

(i) An entity must immediately notify APHIS or CDC if it loses the services of its responsible official. In the event that an entity loses the services of its responsible official, an entity may continue to possess or use select agents or toxins only if it appoints as the responsible official another individual who has been approved by the Administrator or the HHS Secretary following a security risk assessment by the Attorney General and who meets the requirements of this part.

(j) A certificate of registration will be terminated upon the written request of the entity if the entity no longer possesses or uses any select agents or toxins and no longer wishes to be registered.

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

⁶Depending on the change, a security risk assessment by the Attorney General may also be required (e.g., replacement of the responsible official, changes in ownership or control of the entity, new researchers or graduate students, etc.)

§ 121.8 Denial, revocation, or suspension of registration.

(a) An application may be denied or a certificate of registration revoked or suspended if:

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

(2) The individual or entity, the responsible official, or an individual who owns or controls the entity is 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;

(3) The individual or entity does not meet the requirements of this part;⁷ or

(4) It is determined that such action is necessary to protect animal health or animal products.

(b) Upon revocation or suspension of a certificate of registration, the individual or entity must:

(1) Immediately stop all use of each select agent or toxin covered by the revocation or suspension order;

(2) Immediately safeguard and secure each select agent or toxin covered by the revocation or suspension order from theft, loss, or release; and

(3) Comply with all disposition instructions issued by the Administrator for each select agent or toxin covered by the revocation or suspension.

(c) Denial of an application for registration and revocation of registration may be appealed under § 121.20. However, any denial of an application for registration or revocation of a certificate of registration will remain in effect until a final agency decision has been rendered.

⁷If registration is denied for this reason, we may provide technical assistance and guidance.