§ 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.

(b) As a condition of registration, each entity must designate an individual to be its responsible official. While most registrants are likely to be entities, in the event that an individual applies for and is granted a certificate of registration, the individual will be considered the responsible official.

(c)(1) As a condition of registration, the following must be approved by the Administrator or the HHS Secretary based on a security risk assessment by the Attorney General:
   (i) The individual or entity;
   (ii) The responsible official; and
   (iii) Unless otherwise exempted under this section, any individual who owns or controls the entity.

(2) Federal, State, or local governmental agencies, including public accredited academic institutions, are exempt from the security risk assessments for the entity and the individual who owns or controls such entity.
(3) An individual will be deemed to own or control an entity under the following conditions: 6

(i) For a private institution of higher education, an individual will be deemed to own or control the entity if the individual is in a managerial or executive capacity with regard to the entity’s select agents or toxins or with regard to the individuals with access to the select agents or toxins possessed, used, or transferred by the entity.

(ii) For entities other than institutions of higher education, an individual will be deemed to own or control the entity if the individual:

(A) Owns 50 percent or more of the entity, or is a holder or owner of 50 percent or more of its voting stock; or

(B) Is in a managerial or executive capacity with regard to the entity’s select agents or toxins or with regard to the individuals with access to the select agents or toxins possessed, used, or transferred by the entity.

(4) An entity will be considered to be an institution of higher education if it is an institution of higher education as defined in section 101(a) of the Higher Education Act of 1965 (20 U.S.C. 1001(a)), or is an organization described in 501(c)(3) of the Internal Revenue Code of 1986, as amended (26 U.S.C. 501(c)(3)).

(5) To obtain a security risk assessment, an individual or entity must submit the information necessary to conduct a security risk assessment to the Attorney General.

(d) To apply for a certificate of registration for only VS select agents or toxins, or for VS and PPQ select agents or toxins, an individual or entity must submit the information requested in the registration application package (APHIS/CDC Form 1) to APHIS. To apply for a certificate of registration for overlap select agents or toxins and any combination of PPQ or VS select agents or toxins and any combination of PPQ or VS select agents or toxins, or HHS select agents or toxins and any combination of PPQ or VS select agents or toxins, an individual or entity must submit the information requested in the registration application package (APHIS/CDC Form 1) to APHIS or CDC, but not both.

(e) Prior to the issuance of a certificate of registration, the responsible official must promptly provide notification of any changes to the application for registration by submitting the relevant page(s) of the registration application.

(f) The issuance of a certificate of registration may be contingent upon 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.

(g) A certificate of registration will be valid for one physical location (a 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. 7

(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

6These conditions may apply to more than one individual.

7Depending 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; 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.

§ 121.9 Responsible official.

(a) An individual or entity required to register under this part must designate an individual to be the responsible official. The responsible official must:

(1) Be approved by the Administrator or the HHS Secretary following a security risk assessment by the Attorney General;

(2) Be familiar with the requirements of this part;

(3) Have authority and responsibility to act on behalf of the entity;

(4) Ensure compliance with the requirements of this part; and

(5) Ensure that annual inspections are conducted for each laboratory where select agents or toxins are stored or used in order to determine compliance with the requirements of this part. The results of each inspection must be documented, and any deficiencies identified during an inspection must be corrected.

(b) An entity may designate one or more individuals to be an alternate responsible official, who may act for the responsible official in his/her absence. These individuals must have the authority and control to ensure compliance with the regulations when acting as the responsible official.

(c) The responsible official must report the identification and final disposition of any select agent or toxin.