

§ 121.18

future use, such as in a freezer or lyophilized materials), including:

(i) The name and characteristics (e.g., strain designation, GenBank Accession number, etc.);

(ii) The quantity acquired from another individual or entity (e.g., containers, vials, tubes, etc.), date of acquisition, and the source;

(iii) Where stored (e.g., building, room, and freezer);

(iv) When moved from storage and by whom and when returned to storage and by whom;

(v) The select agent used and purpose of use;

(vi) Records created under § 121.16 or 42 CFR 73.16 (Transfers);

(vii) For intra-entity transfers (sender and the recipient are covered by the same certificate of registration), the select agent, the quantity transferred, the date of transfer, the sender, and the recipient; and

(viii) Records created under § 121.19 or 42 CFR 73.19 (Notification of theft, loss, or release);

(2) An accurate, current inventory for each toxin held, including:

(i) The name and characteristics;

(ii) The quantity acquired from another individual or entity (e.g., containers, vials, tubes, etc.), date of acquisition, and the source;

(iii) The initial and current quantity amount (e.g., milligrams, milliliters, grams, etc.);

(iv) The toxin used and purpose of use, quantity, date(s) of the use and by whom;

(v) Where stored (e.g., building, room, and freezer);

(vi) When moved from storage and by whom and when returned to storage and by whom, including quantity amount;

(vii) Records created under § 121.16 or 42 CFR 73.16 (Transfers);

(viii) For intra-entity transfers (sender and the recipient are covered by the same certificate of registration), the toxin, the quantity transferred, the date of transfer, the sender, and the recipient;

(ix) Records created under § 121.19 or 42 CFR 73.19 (Notification of theft, loss, or release);

9 CFR Ch. I (1–1–11 Edition)

(x) If destroyed, the quantity of toxin destroyed, the date of such action, and by whom.

(3) A current list of all individuals that have been granted access approval by the Administrator or the HHS Secretary;

(4) Information about all entries into areas containing select agents or toxins, including the name of the individual, name of the escort (if applicable), and the date and time of entry;

(5) Accurate, current records created under § 121.9 or 42 CFR 73.9 (Responsible official), § 121.11 or 42 CFR 73.11 (Security), § 121.12 or 42 CFR 73.12 (Biosafety), § 121.14 or 42 CFR 73.14 (Incident response), and § 121.15 or 42 CFR 73.15 (Training); and

(6) A written explanation of any discrepancies.

(b) The individual or entity must implement a system to ensure that all records and databases created under this part are accurate, have controlled access, and that their authenticity may be verified.

(c) All records created under this part must be maintained for 3 years and promptly produced upon request.

§ 121.18 Inspections.

(a) Without prior notification, APHIS must be allowed to inspect any site at which activities regulated under this part are conducted and must be allowed to inspect and copy any records relating to the activities covered by this part.

(b) Prior to issuing a certificate of registration to an individual or entity, APHIS may inspect and evaluate the premises and records to ensure compliance with this part.

§ 121.19 Notification of theft, loss, or release.

(a) An individual or entity must immediately notify APHIS or CDC upon discovery of the theft or loss of a select agent or toxin. Thefts or losses must be reported even if the select agent or toxin is subsequently recovered or the responsible parties are identified.

(1) The theft or loss of a select agent or toxin must be reported by telephone, facsimile, or e-mail. The following information must be provided:

(i) The name of the select agent or toxin and any identifying information (e.g., strain or other characterization information);

(ii) An estimate of the quantity stolen or lost;

(iii) An estimate of the time during which the theft or loss occurred;

(iv) The location (building, room) from which the theft or loss occurred; and

(v) The list of Federal, State, or local law enforcement agencies to which the individual or entity reported, or intends to report, the theft or loss.

(2) A completed APHIS/CDC Form 3 must be submitted within 7 calendar days.

(b) An individual or entity must immediately notify APHIS or CDC upon discovery of a release of a select agent or toxin causing occupational exposure or a release of a select agent or toxin outside of the primary barriers of the biocontainment area.

(1) The release of a select agent or toxin must be reported by telephone, facsimile, or e-mail. The following information must be provided:

(i) The name of the select agent or toxin and any identifying information (e.g., strain or other characterization information);

(ii) An estimate of the quantity released;

(iii) The time and duration of the release;

(iv) The environment into which the release occurred (e.g., in building or outside of building, waste system);

(v) The location (building, room) from which the release occurred; and

(vi) The number of individuals potentially exposed at the entity;

(vii) Actions taken to respond to the release; and

(viii) Hazards posed by the release.

(2) A completed APHIS/CDC Form 3 must be submitted within 7 calendar days.

§ 121.20 Administrative review.

An individual or entity may appeal a denial, revocation, or suspension of registration under this part. An individual may appeal a denial, limitation, or revocation of access approval under

this part.¹⁵ The appeal must be in writing, state the factual basis for the appeal, and be submitted to the Administrator within 30 calendar days of the decision. Where the denial, revocation, or suspension of registration or the denial, limitation, or revocation of an individual's access approval is based upon an identification by the Attorney General, the request for review will be forwarded to the Attorney General. The Administrator's decision constitutes final agency action.

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

PART 122—ORGANISMS AND VECTORS

Sec.

122.1 Definitions.

122.2 Permits required.

122.3 Application for permits.

122.4 Suspension or revocation of permits.

AUTHORITY: 7 U.S.C. 8301–8317; 21 U.S.C. 151–158; 7 CFR 2.22, 2.80, and 371.4.

§ 122.1 Definitions.

The following words, when used in the regulations in this part 122, shall be construed, respectively, to mean:

(a) *Department*. The U.S. Department of Agriculture.

(b) *Secretary*. “Secretary” means the Secretary of Agriculture of the United States, or any officer or employee of the Department to whom authority has heretofore been delegated, or to whom authority may hereafter be delegated, to act in his stead.

(c) *Administrator*. The Administrator, Animal and Plant Health Inspection Service, United States Department of Agriculture, or any person authorized to act for the Administrator.

(d) *Organisms*. All cultures or collections of organisms or their derivatives, which may introduce or disseminate any contagious or infectious disease of animals (including poultry).

(e) *Vectors*. All animals (including poultry) such as mice, pigeons, guinea pigs, rats, ferrets, rabbits, chickens, dogs, and the like, which have been treated or inoculated with organisms,

¹⁵ An entity may not appeal the denial or limitation of an individual's access to select agents or toxins.