

§ 121.20

- (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.¹⁴ The appeal must be in writing, state the factual basis for the ap-

¹⁴An entity may not appeal the denial or limitation of an individual's access to select agents or toxins.

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peal, 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.

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, or which are diseased or infected with any contagious, infectious, or communicable disease of animals or poultry or which have been exposed to any such disease.

(f) *Permittee*. A person who resides in the United States or operates a business establishment within the United