committee minutes and approved protocols, and records associated with occupational health and suitability programs. All records created under this part must be maintained for 3 years.

[70 FR 13284, Mar. 18, 2005, as amended at 77 FR 61081, Oct. 5, 2012; 82 FR 6210, Jan. 19, 2017]

§ 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.

(a) An individual or entity may appeal a denial, revocation, or suspension of registration under this part. 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.

(b) An individual may appeal a denial, limitation, or revocation of access approval under this part. The appeal must be in writing, state the factual basis for the appeal, and be submitted to the Administrator within 180 calendar days of the decision.

(c) The Administrator's decision constitutes final agency action.

[77 FR 61081, Oct. 5, 2012]

PART 122—ORGANISMS AND VECTORS

Sec.

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 States, to whom a permit to import or transport organisms or vectors has been issued under the regulations.

(g) *Person.* Any individual, firm, partnership, corporation, company, society, association, or other organized group of any of the foregoing, or any agent, officer, or employee of any thereof.

[31 FR 81, Jan. 5, 1966, as amended at 57 FR 30899, July 13, 1992]

§ 122.2 Permits required.

No organisms or vectors shall be imported into the United States or transported from one State or Territory or the District of Columbia to another State or Territory or the District of Columbia without a permit issued by the Secretary and in compliance with the terms thereof: *Provided,* That no permit shall be required under this section for importation of organisms for which an import permit has been issued pursuant to part 102 of this subchapter or for transportation of organisms produced at establishments licensed under part 102 of this subchapter. As a condition of issuance of permits under this section, the permittee shall agree in writing to observe the safeguards prescribed by the Administrator for public protection with respect to the particular importation or transportation.

(Approved by the Office of Management and Budget under control number 0579–0015)

[28 FR 7896, Aug. 2, 1963. Redesignated at 31 FR 81, Jan. 5, 1966 and amended at 48 FR 57473, Dec. 30, 1983; 57 FR 30899, July 13, 1992; 59 FR 67134, Dec. 29, 1994]

§ 122.3 Application for permits.

The Secretary may issue, at his discretion, a permit as specified in § 122.2 when proper safeguards are set up as provided in § 122.2 to protect the public. Application for such a permit shall be made in advance of shipment, and each permit shall specify the name and address of the consignee, the true name and character of each of the organisms or vectors involved, and the use to which each will be put.

(Approved by the Office of Management and Budget under control number 0579–0015)

[23 FR 10065, Dec. 23, 1958. Redesignated at 31 FR 81, Jan. 5, 1966 and amended at 48 FR 57473, Dec. 30, 1983; 59 FR 67134, Dec. 29, 1994]

§ 122.4 Suspension or revocation of permits.

(a) Any permit for the importation or transportation of organisms or vectors issued under this part may be formally suspended or revoked after opportunity for hearing has been accorded the permittee, as provided in part 123 of this subchapter, if the Secretary finds that the permittee has failed to observe the safeguards and instructions prescribed by the Administrator with respect to the particular importation or transportation or that such importation or transportation for any other reason may result in the introduction or dissemination from a foreign country into the United States, or from one State, Territory or the District of Columbia to another, of the contagion of any

contagious, infectious or communicable disease of animals (including poultry).

(b) In cases of wilfulness or where the public health, interest or safety so requires, however, the Secretary may without hearing informally suspend such a permit upon the grounds set forth in paragraph (a) of this section, pending determination of formal proceedings under part 123 of this subchapter for suspension or revocation of the permit.

[23 FR 10065, Dec. 23, 1958. Redesignated at 31 FR 81, Jan. 5, 1966, and amended at 57 FR 30899, July 13, 1992]

PART 123—RULES OF PRACTICE GOVERNING PROCEEDINGS UNDER THE VIRUS-SERUM-TOXIN ACT

AUTHORITY: 7 U.S.C. 8301–8317; 21 U.S.C. 151–159; 7 CFR 2.22, 2.80, and 371.4.

§ 123.1 Scope and applicability of rules of practice.

The Uniform Rules of Practice for the Department of Agriculture promulgated in subpart H of part 1, subtitle A, title 7, Code of Federal Regulations, are the Rules of Practice applicable to adjudicatory, administrative proceedings under the Virus-Serum-Toxin Act.

[42 FR 10960, Feb. 25, 1977]

PART 124—PATENT TERM RESTORATION

Subpart A—General Provisions

Sec.
124.1 Scope.
124.2 Definitions.

Subpart B—Eligibility Assistance

124.10 APHIS liaison with PTO.

Subpart C—Regulatory Review Period

124.20 Patent term extension calculation.
124.21 Regulatory review period determination.
124.22 Revision of regulatory review period determination.
124.23 Final action on regulatory review period determination.

Subpart D—Due Diligence Petitions

124.30 Filing, format, and content of petitions.
124.31 Applicant response to petition.
124.32 APHIS action on petition.
124.33 Standard of due diligence.

Subpart E—Due Diligence Hearing

124.40 Request for hearing.
124.41 Notice of hearing.
124.42 Hearing procedure.
124.43 Administrative decision.

AUTHORITY: 35 U.S.C. 156; 7 CFR 2.22, 2.80, and 371.4.

SOURCE: 58 FR 11369, Feb. 25, 1993, unless otherwise noted.

Subpart A—General Provisions

§ 124.1 Scope.

(a) This parts sets forth procedures and requirements for APHIS review of applications for the extension of the term of certain patents for veterinary biological products pursuant to 35 U.S.C. 156—Extension of patent term. Responsibilities of APHIS include:

(1) Assisting PTO in determining eligibility for patent term restoration;

(2) Determining the length of a product's regulatory review period;

(3) If petitioned, reviewing and ruling on due diligence challenges to APHIS's regulatory review period determinations; and

(4) Conducting hearings to review initial APHIS findings on due diligence challenges.

(b) The regulations in this part are designed to be used in conjunction with regulations issued by PTO concerning patent term extension which may be found at 37 CFR 1.710 through 1.791.

[58 FR 11369, Feb. 25, 1993, as amended at 64 FR 43045, Aug. 9, 1999]

§ 124.2 Definitions.

Animal and Plant Health Inspection Service (APHIS). The agency in the Department of Agriculture responsible for licensing veterinary biological products under the Virus-Serum-Toxin Act.

Applicant. Any person who submits an application or an amendment or supplement to an application under 35 U.S.C. 156 seeking extension of the term of a patent.