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 in-
formation 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 re-
leased;
(iii) The time and duration of the re-
lease;
(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 poten-
tially 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 ap-
peal a denial, revocation, or suspension
of registration under this part. The ap-
peal must be in writing, state the fac-
tual basis for the appeal, and be sub-
mitted to the Administrator within 30
calendar days of the decision.

(b) An individual may appeal a de-
rial, 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 cal-
endar days of the decision.

(c) The Administrator's decision con-
titutes final agency action.

[77 FR 61081, Oct. 5, 2012]

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.


§ 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 collec-
tions 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 commu-
nicable 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 busi-
ness 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, part-
nership, 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 im-
ported into the United States or trans-
ported 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 sec-
tion for importation of organisms for
which an import permit has been
issued pursuant to part 102 of this sub-
chapter or for transportation of orga-
nisms produced at establishments li-
censed under part 102 of this sub-
chapter. As a condition of issuance of
permits under this section, the per-
mittee shall agree in writing to observe
the safeguards prescribed by the Ad-
ministrator 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 dis-
cretion, 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 ad-
dress 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

§ 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 per-
mittee, 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 transport-
ation or that such importation or transpor-
tation for any other reason may result in the introduction or dis-
semination 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
tagious, infectious or commu-

nicable disease of animals (including
poultry).

(b) In cases of wilfulness or where the
public health, interest or safety so re-
quires, 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 pro-
cedings under part 123 of this sub-
chapter 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

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 promul-
gated in subpart H of part 1, subtitle A,
title 7, Code of Federal Regulations,
are the Rules of Practice applicable to
adjudicatory, administrative pro-
cedings 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 determina-
tion.
124.22 Revision of regulatory review period
determination.
124.23 Final action on regulatory review pe-
riod determination.