

practicable, to the proceedings in admiralty, except that either party may demand trial by jury of any issue of fact joined in any case, and all such proceedings shall be at the suit of and in the name of the United States.

[52 FR 30135, Aug. 13, 1987, as amended at 56 FR 66784, Dec. 26, 1991]

PART 121—POSSESSION, USE, AND TRANSFER OF BIOLOGICAL AGENTS AND TOXINS

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SOURCE: 67 FR 76931, Dec. 13, 2002, unless otherwise noted.

§ 121.0 Effective and applicability dates.

(a) The regulations in this part are effective on February 11, 2003. On and after that date, any person possessing, using, or transferring any agent or toxin listed in § 121.3 must be in compliance with the provisions of this part. However, so as not to disrupt research or educational projects involving listed agents or toxins that were underway as of the effective date of this part, any person possessing such agents or toxins as of the effective date (current possessors) will be afforded additional time

to reach full compliance with this part. Any provision not specifically cited in paragraphs (a)(1) through (a)(6) of this section will be applicable as of February 11, 2003. In addition, any person who does not possess listed agents or toxins by the effective date of this part, but who wishes to initiate a research or educational project prior to November 12, 2003, must be in compliance with the provisions of this part that are applicable for current possessors at the time of application, as provided in paragraphs (a)(1) through (a)(5) of this section.

(1) During the period from February 11, 2003, to November 12, 2003, biological agents or toxins listed in § 121.3 may only be transferred to an individual or entity that is not registered under this part if:

(i) The individual or entity is registered by CDC for that specific overlap agent or toxin in accordance with 42 CFR part 72; or

(ii) The individual or entity has been issued a permit by the Administrator under part 122 of this subchapter to import or move interstate that specific agent or toxin. If an individual or entity has not been issued a permit under part 122 of this subchapter, the individual or entity may apply for a permit. To receive an agent or toxin, an individual or entity will also be required to submit APHIS Form 2041, in accordance with § 121.14(c). Because USDA permits do not cover intrastate movement, unless registered by CDC under 42 CFR part 72, an individual or entity may not receive a listed agent or toxin that is being moved intrastate until that individual or entity is registered in accordance with this part.

(2) By March 12, 2003, the responsible official must submit the registration application package as required in § 121.9. In addition, the responsible official must submit to the Attorney General the names and identifying information for the responsible official; alternate responsible official, where applicable; entity; and, where applicable, the individual who owns or controls the entity.

(3) By April 11, 2003, the responsible official must submit to the Attorney General the names and identifying information for all individuals whom the

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responsible official has identified as having a legitimate need to handle or use listed agents or toxins, and who have the appropriate training and skills to handle such agents or toxins, as required in § 121.11.

(4) By June 12, 2003, the responsible official must submit the security section of the Biosafety and Security Plan required in § 121.12 to APHIS or, for overlap agents or toxins, to APHIS or CDC.

(5) By September 12, 2003, the responsible official must implement the security section of the Biosafety and Security Plan, as required in § 121.12, and provide security training in accordance with 9 CFR 121.13.

(6) By November 12, 2003, the registration application process must be complete and the entity in full compliance with the regulations in this part, except as otherwise provided in paragraphs (b) and (c) of this section.

(b) *Provisional registration.* (1) Notwithstanding the provisions in paragraph (a) of this section, APHIS may issue a provisional registration certificate to current possessors if, as of November 12, 2003:

(i) The Attorney General has received all of the information, including fingerprint cards, required by the Attorney General to conduct a security risk assessment of the entity, including any individual who owns or controls the entity; and

(ii) The entity otherwise meets all of the requirements of this part.

(2) Notwithstanding the provisions in paragraph (a) of this section, APHIS may issue a provisional registration certificate to individuals and entities that did not possess listed biological agents or toxins as of February 11, 2003, if, as of November 12, 2003:

(i) The Attorney General has received all of the information, including fingerprint cards, required by the Attorney General to conduct a security risk assessment of the entity, including any individual who owns or controls the entity;

(ii) The entity otherwise meets all of the requirements of this part; and

(iii) The Administrator finds that circumstances warrant such action in the interest of the health of plants or plant products or national security.

(3) A provisional registration certificate will be effective until APHIS either issues a certificate of registration or suspends or revokes the provisional registration.

(c) Notwithstanding the provisions in paragraph (a) of this section, APHIS may issue a provisional grant of access for individuals identified by an entity as having a legitimate need to handle or use agents or toxins listed in § 121.3 if, as of November 12, 2003, the Attorney General has received all of the information, including fingerprint cards, required by the Attorney General to conduct a security risk assessment of that individual. A provisional grant of access will be effective until APHIS grants or denies access to biological agents or toxins listed in § 121.3.

[68 FR 62220, Nov. 3, 2003]

§ 121.1 Definitions.

Administrator. The Administrator, Animal and Plant Health Inspection Service, or any person authorized to act for the Administrator.

Animal and Plant Health Inspection Service (APHIS). The Animal and Plant Health Inspection Service of the United States Department of Agriculture.

Attorney General. The Attorney General of the United States or any person authorized to act for the Attorney General.

Biological agent. Any microorganism (including, but not limited to, bacteria, viruses, fungi, rickettsiae, or protozoa), or infectious substance, or any naturally occurring, bioengineered, or synthesized component of any such microorganism or infectious substance, capable of causing:

(1) Death, disease, or other biological malfunction in a human, an animal, a plant, or another living organism;

(2) Deterioration of food, water, equipment, supplies, or material of any kind; or

(3) Deleterious alteration of the environment.

Centers for Disease Control and Prevention (CDC). The Centers for Disease Control and Prevention of the United States Department of Health and Human Services.

Clinical laboratory. A laboratory facility that receives patients and collects

specimens for processing or shipping to another laboratory.

Diagnostic laboratory. A laboratory facility that receives specimens for the purpose of determining the identities of pests, pathogens, contaminants, or causes of disease.

Entity. Any government agency (Federal, State, or local), academic institution, corporation, company, partnership, society, association, firm, sole proprietorship, or other legal entity.

Import. To move into, or the act of movement into, the territorial limits of the United States.

Interstate. From one State into or through any other State, or within the District of Columbia, Guam, the Virgin Islands of the United States, or any other territory or possession of the United States.

Overlap agent or toxin. Any microorganism (including, but not limited to, bacteria, viruses, fungi, rickettsiae, or protozoa) or toxin that poses a risk to both human and animal health and that is listed in §121.3(b).

Permit. A written authorization by the Administrator to import or move interstate biological agents or toxins, under conditions prescribed by the Administrator.

Proficiency testing. A sponsored, time-limited analytical trial whereby one or more analytes, previously confirmed by the sponsor, are submitted to the testing laboratory for analysis and where final results are graded, scores are recorded and provided to participants, and scores for participants are evaluated for acceptance.

Responsible official. The individual designated by an entity to act on its behalf. This individual must have the authority and control to ensure compliance with the regulations in this part.

Specimen. A sample of material collected for use in testing, such as tissues, gastrointestinal contents, feces, bodily fluids (blood, serum, etc.), soil, water, feed or feed ingredients, swabs, cultures, and suspensions.

State. Any of the several States of the United States, the Commonwealth of the Northern Mariana Islands, the Commonwealth of Puerto Rico, the District of Columbia, Guam, the Virgin Islands of the United States, or any

other territory or possession of the United States.

Toxin. The toxic material or product of plants, animals, microorganisms (including, but not limited to, bacteria, viruses, fungi, rickettsiae, or protozoa), or infectious substances, or a recombinant or synthesized molecule, whatever their origin and method of production, and includes:

(1) Any poisonous substance or biological product that may be engineered as a result of biotechnology produced by a living organism; or

(2) Any poisonous isomer or biological product, homolog, or derivative of such a substance.

United States. All of the States.

USDA. The United States Department of Agriculture.

§ 121.2 Purpose and scope.

(a) This part sets forth the requirements for possession, use, and transfer of biological agents or toxins that have been determined to have the potential to pose a severe threat to both human and animal health, to animal health, or to animal products. The purpose of this part is to ensure the safe handling of such agents or toxins, and to protect against the use of such agents or toxins in domestic or international terrorism or for any other criminal purpose.

(b) Accordingly, this part provides that any individual or entity that possesses, uses, or transfers any agent or toxin listed in §121.3 must register in accordance with §121.7. To register, each entity must designate an individual who has the authority and control to ensure compliance with the regulations to be the responsible official. The responsible official must complete and submit the registration application package to APHIS or, for overlap agents or toxins, to APHIS or CDC. As part of registration, the responsible official, the entity, and, where applicable, the individual who owns or controls such entity will be subject to a security risk assessment by the Attorney General.

(c) The responsible official is responsible for ensuring compliance with the safety procedures in this part, including implementing the Biosafety and Security Plan in accordance with §121.12, providing the proper training

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to individuals who handle or use agents or toxins listed in § 121.3, and providing proper laboratory facilities to contain and dispose of such agents or toxins. In addition, the responsible official is responsible for ensuring compliance with the safeguard and security measures in this part, including restricting access to only those individuals who have a legitimate need to handle or use agents or toxins and who have been approved in accordance with § 121.11, and transferring such agents or toxins only to registered individuals or entities in accordance with § 121.13.

§ 121.3 List of biological agents and toxins.

(a) Except as provided in paragraphs (f) and (g) of this section, the Administrator has determined that the biological agents and toxins listed in this section have the potential to pose a severe threat to both human and animal health, to animal health, or to animal products.

(b) *Overlap agents and toxins.*

Bacillus anthracis
Botulinum neurotoxins
Botulinum neurotoxin producing species of *Clostridium*
Brucella abortus
Brucella melitensis
Brucella suis
Burkholderia mallei
Burkholderia pseudomallei
Clostridium botulinum
Clostridium perfringens epsilon toxin
Coccidioides immitis
Coxiella burnetii
Eastern equine encephalitis virus
Francisella tularensis
Hendra virus
Nipah virus
Rift Valley fever virus
Shigatoxin
Staphylococcal enterotoxins
T-2 toxin
Venezuelan equine encephalitis virus

(c) Genetic elements, recombinant nucleic acids, and recombinant organisms of overlap agents or toxins:

(1) Biological agent viral nucleic acids (synthetic or naturally derived, contiguous or fragmented, in host chromosomes or in expression vectors) that can encode infectious and/or replication competent forms of any of the biological agent viruses.

(2) Nucleic acids (synthetic or naturally derived) that encode for the func-

tional form(s) of any of the toxins listed in paragraph (b) of this section, if the nucleic acids:

(i) Are in a vector or host chromosome;

(ii) Can be expressed *in vivo* or *in vitro*; or

(iii) Are in a vector or host chromosome and can be expressed *in vivo* or *in vitro*.

(3) Viruses, bacteria, fungi, and toxins listed in paragraph (b) of this section that have been genetically modified.

(d) *Animal agents and toxins.*

African horse sickness virus
African swine fever virus
Akabane virus
Avian influenza virus (highly pathogenic)
Bluetongue virus (exotic)
Bovine spongiform encephalopathy agent
Camel pox virus
Classical swine fever virus
Cowdria ruminantium (Heartwater)
Foot-and-mouth disease virus
Goat pox virus
Japanese encephalitis virus
Lumpy skin disease virus
Malignant catarrhal fever virus (exotic)
Menangle virus
Mycoplasma capricolum/M. F38/M. *mycoides capri* (contagious caprine pleuropneumonia)
Mycoplasma mycoides mycoides (contagious bovine pleuropneumonia)
Newcastle disease virus (VVND)
Peste des petits ruminants virus
Rinderpest virus
Sheep pox virus
Swine vesicular disease virus
Vesicular stomatitis virus (exotic)

(e) The Administrator has determined that it would be impractical to regulate a biological agent or toxin that is in its naturally occurring environment. Therefore, any biological agent or toxin listed in this section that is in its naturally occurring environment will not be subject to the requirements of this part, provided that the biological agent or toxin has not been intentionally introduced, cultivated, collected, or otherwise extracted from its natural source.

(f) The Administrator has determined that biological agents or toxins that meet any of the following criteria do not have the potential to pose a severe threat to both human and animal health, or to animal health or animal products. Therefore, an individual or

entity that only possesses, uses, or transfers an agent or toxin that meets any of the following criteria will not be subject to the requirements of this part:

(1) Nonviable agents or fixed tissues that are, bear, or contain agents or toxins listed in this section.¹

(2) Genetic elements or subunits of agents or toxins listed in paragraph (d) of this section, if the genetic elements or subunits are not capable of causing disease.²

(3) Overlap toxins under the control of a principal investigator (or equivalent), if the total aggregate amount does not, at any time, exceed the following amounts: 0.5 mg of Botulinum neurotoxins (types A-G), 100 mg of *Clostridium perfringens* epsilon toxin, 100 mg of Shigatoxin, 5 mg of Staphylococcal enterotoxins, and 1,000 mg of T-2 toxin.

(g) *Attenuated strains.* Attenuated strains of biological agents listed in this section may not have the potential to pose a severe threat to both human and animal health, to animal health, or to animal products. Thus, an individual or entity may request review by the Administrator to determine whether a specific attenuated strain poses a severe threat to both human and animal health, or to animal health or animal products. For overlap agents, an individual or entity may request review by APHIS or CDC.

(1) If APHIS or CDC determines that a specific attenuated strain does not pose a severe threat to human and animal health, or to animal health or animal products, an individual or entity will not be subject to the requirements of this part. This determination will be limited to the specific attenuated strain and to the specific activities involving that attenuated strain.

(2) An individual or entity may request a review by writing to the Administrator or, for overlap agents, by writing to the Administrator or CDC.³

¹However, the importation and interstate movement of these genetic elements or subunits of listed agents or toxins are still subject to the permit requirements under part 122 of this subchapter.

²See footnote 1.

³A request to review an attenuated strain may be mailed to National Center for Import and Export, VS, APHIS, 4700 River Road Unit

(3) If it is determined that a specific attenuated strain does not pose a severe threat, APHIS or CDC will notify the applicant and publish a notice in the FEDERAL REGISTER.

(4) An individual or entity may request reconsideration of an adverse decision in writing to the Administrator. The request for reconsideration must state all of the facts and reasons upon which the individual or entity relies upon to show the decision was incorrect. The Administrator will grant or deny the request for reconsideration as promptly as circumstances allow and will state, in writing, the reasons for the decision. If there is a conflict as to any material fact, the individual or entity may request a hearing to resolve the conflict.

§ 121.4 Exemptions for overlap agents or toxins.

(a) Clinical or diagnostic laboratories and other entities possessing, using, or transferring overlap agents or toxins that are contained in specimens presented for diagnosis or verification will be exempt from the requirements of this part, provided that:

(1) The identification of such agents or toxins is immediately reported to APHIS or CDC, and to other appropriate authorities when required by Federal, State, or local law; and

(2) Within 7 days after identification, the agents or toxins are transferred or inactivated, and APHIS Form 2040 is submitted to APHIS or CDC.⁴ During agricultural emergencies or outbreaks, or in endemic areas, the Administrator may require less frequent reporting. A

40, Riverdale, MD 20737-1231; or faxed to (301) 734-3652. For overlap agents, a request for review may be mailed to the above address or to Select Agent Program, Centers for Disease Control and Prevention, 1600 Clifton Road, NE, Mail Stop E 79, Atlanta, GA 30333; or faxed to (404) 498-2265.

⁴A clinical or diagnostic laboratory, or other entity, may immediately notify APHIS by faxing (301) 734-3652. APHIS Form 2040 may be obtained by calling APHIS at (301) 734-3277 or by calling CDC at (404) 498-2265. The form is also available on the Internet at <http://www.aphis.usda.gov/vs/ncie.bta.html> or <http://www.cdc.gov/od/ohs/lrsat.htm>. The completed form may be mailed or faxed to APHIS or CDC, as provided in footnote 3.

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copy of the completed form must be maintained for 3 years.

(b) Clinical or diagnostic laboratories and other entities possessing, using, or transferring overlap agents or toxins that are contained in specimens presented for proficiency testing will be exempt from the requirements of this part, provided that:

(1) The identification of such agents or toxins, and their derivatives, is immediately reported to the APHIS or CDC, and to other appropriate authorities when required by Federal, State, or local law; and

(2) Within 90 days of receipt, the agents or toxins are transferred or inactivated, and APHIS Form 2040 is submitted to APHIS or CDC. A copy of the completed form must be maintained for 3 years.

(c) Unless the Administrator by order determines that additional regulation of a specific product is necessary to protect animal or plant health, or animal or plant products, an individual or entity possessing, using, or transferring products that are, bear, or contain overlap agents or toxins will be exempt from the requirements of this part if the products have been cleared, approved, licensed, or registered pursuant to:

(1) The Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 *et seq.*);

(2) Section 351 of Public Health Service Act (42 U.S.C. 262);

(3) The Virus-Serum-Toxin Act (21 U.S.C. 151-159); or

(4) The Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 131 *et seq.*).

(d) An individual or entity possessing, using, or transferring investigational products that are, bear, or contain overlap agents or toxins may be exempt from the requirements of this part if such product is being used in an investigation authorized by any Federal law and the Administrator determines that additional regulation under this part is not necessary to protect animal or plant health, and animal or plant products.

(1) An individual or entity possessing, using, or transferring such investigational products may apply for an exemption from the requirements of

this part by submitting APHIS Form 2042 to APHIS or CDC.

(2) For investigational products authorized under any of the Federal laws specified in paragraph (c) of this section, the Administrator shall make a determination regarding an exemption within 14 days after receipt of the application and notification that the investigation has been authorized under a Federal law.

(e) The Administrator may exempt an individual or entity from the requirements of this part, in whole or in part, for 30 days if it is necessary to respond to a domestic or foreign agricultural emergency involving an overlap agent or toxin. The Administrator may extend the exemption once for an additional 30 days.

(f) Upon request of the Secretary of Health and Human Services, the Administrator may exempt an individual or entity from the requirements of this part, in whole or in part, for 30 days if the Secretary of Health and Human Services has granted an exemption for a public health emergency involving an overlap agent or toxin. The Administrator may extend the exemption once for an additional 30 days.

§ 121.5 Exemptions for animal agents and toxins.

(a) Diagnostic laboratories and other entities possessing, using, or transferring agents or toxins that are contained in specimens presented for diagnosis or verification will be exempt from the requirements of this part, provided that:

(1) The identification of such agents or toxins is immediately reported to the Administrator and to other appropriate authorities when required by Federal, State, or local law; and

(2) Within 7 days after identification, the agents or toxins are transferred or inactivated, and APHIS Form 2040 is submitted to the Administrator.⁵ During agricultural emergencies or outbreaks, or in endemic areas, the Administrator may require less frequent

⁵A diagnostic laboratory or other entity must immediately notify APHIS by faxing (301) 734-3652. APHIS Form 2040 may be obtained by calling (301) 734-3277. The form is also available on the Internet at <http://>

reporting. A copy of the completed form must be maintained for 3 years.

(b) Diagnostic laboratories and other entities possessing, using, or transferring agents or toxins that are contained in specimens presented for proficiency testing will be exempt from the requirements of this part, provided that:

(1) The identification of such agents or toxins, and their derivatives, is immediately reported to the Administrator, and to other appropriate authorities when required by Federal, State, or local law; and

(2) Within 90 days of receipt, the agent or toxins are transferred or inactivated, and APHIS Form 2040 is submitted to the Administrator. A copy of the completed form must be maintained for 3 years.

(c) An individual or entity receiving diagnostic reagents and vaccines that are, bear, or contain listed agents or toxins, also known as high consequence livestock pathogens or toxins, that are produced at USDA diagnostic facilities will be exempt from the requirements of this part.

(d) Unless the Administrator by order determines that additional regulation is necessary to protect animal health or animal products, an individual or entity possessing, using, or transferring products that are, bear, or contain listed agents or toxins will be exempt from the requirements of this part if the products have been cleared, approved, licensed, or registered pursuant to:

(1) The Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 *et seq.*);

(2) Section 351 of Public Health Service Act (42 U.S.C. 262);

(3) The Virus-Serum-Toxin Act (21 U.S.C. 151-159); or

(4) The Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 131 *et seq.*).

(e) An individual or entity possessing, using, or transferring experimental products that are, bear, or contain listed agents or toxins may be exempt from the requirements of this

part if such product is being used in an investigation authorized by any Federal law and the Administrator determines that additional regulation under this part is not necessary to protect animal or plant health, and animal or plant products. An individual or entity possessing, using, or transferring such experimental products may apply for an exemption from the requirements of this part by submitting APHIS Form 2042 to APHIS.

(f) In addition to the exemptions provided in paragraphs (a) through (e) of this section, the Administrator may grant a specific exemption upon a showing of good cause and upon his or her determination that such exemption is consistent with protecting animal health and animal products. An individual or entity that possesses, uses, or transfers agents or toxins may request in writing an exemption from the requirements of this part. If granted, such exemptions are valid for a maximum of 3 years; thereafter, an individual or entity must request a new exemption. If a request for exemption is denied, an individual or entity may request reconsideration in writing to the Administrator. The request for reconsideration must state all of the facts and reasons upon which the individual or entity relies to show that the exemption was wrongfully denied. The Administrator will grant or deny the request for reconsideration as promptly as circumstances allow and will state, in writing, the reasons for the decision. If there is a conflict as to any material fact, the individual or entity may request a hearing to resolve the conflict.⁶

§ 121.6 Registration; who must register.

(a) Unless exempted under §§ 121.4 or 121.5, any individual or entity that possesses, uses, or transfers any agent or toxin listed in § 121.3 must register with APHIS or, for overlap agents or toxins, APHIS or CDC.

(b) Each entity must designate an individual to be its responsible official.

www.aphis.usda.gov/vs/ncie.bta.html. The completed form may be mailed to National Center for Import and Export, VS, APHIS, 4700 River Road Unit 40, Riverdale, MD 20737-1231; or faxed to (301) 734-3652.

⁶ A request for exemption may be mailed to National Center for Import and Export, VS, APHIS, 4700 River Road Unit 40, Riverdale, MD 20737-1231; or faxed to (301) 734-3652.

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The responsible official must have the authority and control to ensure compliance with the regulations. The responsible official must complete and sign the registration application package, and will be the individual contacted by APHIS or CDC if any questions arise concerning the application or subsequent compliance with the regulations in this part. As part of registration, the responsible official and the entity will be subject to a security risk assessment by the Attorney General. While most registrants are likely to be entities, in the event that an individual applies for and is granted a certificate of registration, APHIS will consider the individual to be the responsible official.

(c) An entity may designate one or more individuals to be an alternate responsible official, who may act for the responsible official when he/she is unavailable. These individuals must have the authority and control to ensure compliance with the regulations when acting as the responsible official. These individuals will also be subject to a security risk assessment by the Attorney General as part of registration.

§ 121.7 Registration; general provisions.

(a) Unless exempted under §§ 121.4 or 121.5, an individual or entity shall not possess, use, or transfer any agent or toxin listed in § 121.3 without a certificate of registration issued by APHIS or CDC.

(b) A certificate of registration may be issued upon:

(1) Approval of the responsible official; the alternate responsible official, where applicable; the entity; and, where applicable, the individual who owns or controls the entity following a security risk assessment by the Attorney General;⁷ and

(2) Approval of the biosafety, containment, and security of the entity. The entity's biosafety, containment, and security procedures must be commensurate with the risk of the agent or toxin, given its intended use. APHIS or

CDC will review the Biosafety and Security Plan, and may inspect and evaluate the premises and records to determine compliance with the regulations and the biosafety, containment, and security requirements; and

(3) A determination by the Administrator that the individual or entity seeking to register has a lawful purpose to possess, use, or transfer such agents or toxins.

(c) For overlap agents, APHIS and CDC will review applications for registration and amendments to a certificate of registration, and a certificate of registration or amendment to a certificate of registration will only be issued if APHIS and CDC concur.

(d) A certificate of registration will be valid for only the specific agents or toxins listed in the certificate and specific activities and locations. A certificate of registration may cover more than one listed agent or toxin, and it may be amended to cover additional listed agents or toxins.

(e) A certificate of registration may be amended to reflect changed circumstances (e.g., replacement of the responsible official, changes in ownership or control of the entity,⁸ changes in the activities involving the agent or toxin). The responsible official must immediately notify the agency that issued the certificate of registration, either APHIS or CDC, of such changes in circumstances that occur after submission of the application for registration or after receipt of a certificate of registration.

(f) If a responsible official wishes to discontinue possessing, using, or transferring a particular agent or toxin, the responsible official may inactivate the agent or toxin or he/she may transfer the agent or toxin to a registered individual or entity in accordance with § 121.13. The responsible official must notify APHIS or, for overlap agents or toxins, APHIS or CDC, 5 business days prior to the planned inactivation so that we may have the opportunity to observe the inactivation of the agents or toxins. APHIS or CDC will notify

⁷The security risk assessment of the entity and the individual who owns or controls such entity may be waived for Federal, State, or local governmental agencies.

⁸Any change in ownership or control of an entity will require a security risk assessment for the new individual(s) who owns or controls the entity.

the responsible official if we wish to observe the inactivation of the agents or toxins.

(g) A certificate of registration will be valid for a maximum of 3 years.

§ 121.8 Denial, revocation, or suspension of registration.

(a) APHIS may deny an application for registration or revoke registration if:

(1) The Attorney General identifies the responsible official, entity, or individual who owns or controls the entity as within any of the categories described in 18 U.S.C. 175b; or

(2) The Attorney General identifies the responsible official, entity, or individual who owns or controls the entity as 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; or

(3) The responsible official does not have a lawful purpose to possess, use, or transfer agents or toxins listed in § 121.3; or

(4) The responsible official is an individual who handles or uses agents or toxins listed in § 121.3 and he/she does not have the necessary training or skills to handle such agents or toxins; or

(5) The entity does not meet the biosafety, containment, and security requirements prescribed by the Administrator;⁹ or

(6) There are egregious or repeated violations of the biosafety, containment, or security requirements; or

(7) The Administrator determines that such action is necessary to protect animal or plant health, and animal or plant products.

(b) For overlap agents or toxins, APHIS or CDC shall deny an applica-

tion for registration or revoke registration if the Attorney General identifies the responsible official, entity, or individual who owns or controls the entity as within any of the categories described in 18 U.S.C. 175b. APHIS or CDC may also deny registration or revoke registration for the reasons set forth in paragraphs (a)(2) through (a)(7) of this section.

(c) APHIS may summarily revoke or suspend registration for any of the reasons set forth in paragraphs (a) and (b) of this section.

(d) APHIS will notify the responsible official in writing if an application for registration is denied or a certificate of registration is revoked or suspended. For overlap agents or toxins, APHIS or CDC will notify the responsible official in writing if an application for registration is denied or a certificate of registration is revoked or suspended.

(e) Denial of an application for registration, revocation of registration, and suspension of registration may be appealed under § 121.17.

§ 121.9 Registration; how to register.

(a) To apply for a certificate of registration, the responsible official must submit all of the information and documentation required in the registration application package to APHIS, including the name, source, and characterization data for each agent or toxin to be registered. For overlap agents or toxins, the responsible official must submit all of the information and documentation required in the registration package to either APHIS or CDC. The responsible official must submit the registration application package to APHIS in cases where he/she is seeking registration for both animal and overlap agents and toxins.

(b) For animal agents and toxins, the registration application package may be obtained by calling (301) 734-3277 or faxing a request to (301) 734-3652. It is also available on the Internet at <http://www.aphis.usda.gov/vs/ncie.bta.html>. The completed registration application package must be mailed to National Center for Import and Export, VS, APHIS, 4700 River Road Unit 40, Riverdale, MD 20737-1231. Assistance in completing the registration application

⁹If registration is denied for this reason, we may provide technical assistance and guidance.

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may be requested by calling (301) 734-3277.

(c) For overlap agents and toxins, the registration application package may be obtained by contacting APHIS, as set forth in paragraph (b) of this section, or by calling CDC at (404) 498-2255; faxing a request to (404) 498-2265; or writing to Select Agent Program, Centers for Disease Control and Prevention, 1600 Clifton Road, NE, Mail Stop E 79, Atlanta, GA 30333. It is also available on the Internet at <http://www.cdc.gov/od/ohs/lrsat.htm>. The completed registration application package may be mailed to APHIS at the address provided in paragraph (b) of this section or to CDC's Select Agent Program at the address provided in this paragraph. Assistance in completing the registration application may be requested by calling APHIS or CDC at the telephone numbers provided in this section.

§ 121.10 Responsibilities of the responsible official.

(a) The responsible official is responsible for ensuring compliance with the regulations, including:

(1) Developing and implementing a Biosafety and Security Plan in accordance with § 121.12;

(2) Allowing only approved individuals within the entity to have access to any agents or toxins listed in § 121.3 in accordance with § 121.11;

(3) Providing appropriate training in biosafety, containment, and security procedures for all personnel in accordance with § 121.13;

(4) Transferring agents or toxins only to registered individuals or entities in accordance with § 121.14;

(5) Ensuring that all visitors are informed of and follow the entity's security requirements and procedures;

(6) Notifying APHIS or, for overlap agents or toxins, APHIS or CDC, of changes in circumstances in accordance with § 121.7;

(7) Providing timely notice of any theft, loss, or release of a biological agent or toxin in accordance with § 121.17;

(8) Maintaining detailed records of information necessary to give a complete accounting of all of the activities

related to agents or toxins listed in § 121.3 in accordance with § 121.15.

(b) In addition to the requirements in paragraph (a) of this section, the responsible official for a diagnostic laboratory or other entities possessing, using, or transferring agents or toxins listed in § 121.3 that are contained in specimens presented for diagnosis must immediately report the identification of such agents or toxins to the Administrator and to other appropriate authorities when required by Federal, State, or local law.¹⁰ During agricultural emergencies or outbreaks, or in endemic areas, the Administrator may require less frequent reporting.

(c) In addition to the requirements in paragraph (a) of this section, the responsible official must ensure that the following experiments are not conducted unless approved by the Administrator, after consultation with experts:

(1) Experiments utilizing recombinant DNA that involve the deliberate transfer of a pathogenic trait or drug resistance trait to biological agents that are not known to acquire the trait naturally, if such acquisition could compromise the use of the drug to control disease agents in humans, veterinary medicine, or agriculture.

(2) Experiments involving the deliberate formation of recombinant DNA containing genes for the biosynthesis of toxins lethal for vertebrates at an LD₅₀<100 ng/kg body weight.

§ 121.11 Restricting access to biological agents and toxins.

(a) An individual may not have access to biological agents or toxins listed in § 121.3 unless approved by APHIS or CDC. APHIS will grant, limit, or deny access of individuals to listed agents or toxins. APHIS or CDC will grant, limit, or deny access of individuals to overlap agents or toxins.

(b) The responsible official is responsible for ensuring that only approved individuals within the entity have access to any agents or toxins listed in

¹⁰A diagnostic laboratory or other entity must immediately notify APHIS by faxing (301) 734-3652.

§ 121.3. The responsible official must request such access for only those individuals who have a legitimate need to handle or use agents or toxins, and who have the appropriate training and skills to handle such agents or toxins.

(c) The responsible official must provide appropriate training in biosafety, containment, and security procedures to all individuals with access to agents and toxins listed in § 121.3.

(d) For each individual identified by the responsible official as having a legitimate need to handle or use agents or toxins, the responsible official must submit that individual's name and identifying information to APHIS and the Attorney General. For overlap agents or toxins, the responsible official must submit this information to either APHIS or CDC and the Attorney General.

(e) In addition, the responsible official must submit information about the individual's training and skills to APHIS or, for overlap agents or toxins, APHIS or CDC (e.g., curriculum vitae for principal investigators and researchers, and a description of training completed by support personnel).

(f) APHIS may expedite the access approval process for individuals upon request by the responsible official and a showing of good cause (e.g., public health or agricultural emergencies, national security, impending expiration of a research grant, a short-term visit by a prominent researcher).

(g) APHIS will notify the responsible official if an individual is granted full or limited access, or denied access to listed agents or toxins. APHIS will also notify the individual if he/she is denied access or granted only limited access. For overlap agents or toxins, APHIS or CDC will provide the necessary notification.

(h) APHIS may deny or limit access of an individual to listed agents or toxins if:

(1) The Attorney General identifies the individual as within any of the categories described in 18 U.S.C. 175b;

(2) The Attorney General identifies the individual as reasonably suspected by any Federal law enforcement or intelligence agency of committing a crime set forth in 18 U.S.C. 2332b(g)(5); knowing involvement with an organi-

zation 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 being an agent of a foreign power as defined in 50 U.S.C. 1801;

(3) The individual does not have a legitimate need to handle listed agents or toxins;

(4) The individual does not have the necessary training or skills to handle listed agents or toxins;

(5) The Administrator determines that such action is necessary to protect animal health or animal products.

(i) For overlap agents or toxins, APHIS or CDC will deny an individual access to such agents or toxins if the Attorney General identifies the individual as within any of the categories described in 18 U.S.C. 175b. APHIS or CDC may also deny or limit access of an individual for the reasons set forth in paragraphs (f)(2) through (f)(5) of this section.

(j) An individual may appeal the Administrator's decision to deny or limit access under § 121.17.

(k) Access approval is valid for 5 years; thereafter, the responsible official shall request renewal of access approval every 5 years for as long as the individual needs access to agents or toxins listed in § 121.3.

(l) The responsible official must immediately notify APHIS or, for overlap agents or toxins, APHIS or CDC, when an individual's access to agents or toxins listed in § 121.3 is terminated by the entity and the reasons therefore.

§ 121.12 Biosafety and security plan.

(a) As a condition of registration, the responsible official must develop and implement a Biosafety and Security Plan.¹¹ The Biosafety and Security Plan must contain sufficient information and documentation to describe the biosafety and containment procedures, and the security systems and procedures. The plan must be commensurate with the risk of the agent or toxin, given its intended use.

¹¹ Technical assistance and guidance may be obtained by calling (301) 734-3277.

(1) *Biosafety and containment procedures.*¹² The biosafety and containment procedures must be sufficient to contain the agent or toxin (e.g., physical structure and features of the entity, and operational and procedural safeguards). At a minimum, the plan must address containment, personnel safety and health, and inventory control.

(2) *Security systems and procedures.*¹³ The security systems and procedures must be designed according to a site-specific risk assessment and must provide graded protection in accordance with the threat posed by the agent or toxin.

(i) The site-specific risk assessment should involve a threat assessment and risk analysis in which threats are defined, vulnerabilities examined, and risks associated with those vulnerabilities are identified.

(ii) The security systems and procedures must be tailored to address site-specific characteristics and requirements, ongoing programs, and operational needs and must mitigate the risks identified under paragraph (a)(2)(i) of this section.

(iii) The plan must describe inventory control procedures, personnel suitability for those individuals with access to agents or toxins listed in § 121.3, physical security, and cybersecurity. The plan must also contain provisions for routine cleaning, maintenance, and repairs; provisions for securing the area (e.g., card access, key pads, locks) and protocols for changing access numbers or locks fol-

lowing staff changes; procedures for loss or compromise of keys, passwords, combinations, etc.; procedures for reporting suspicious persons or activities, loss or theft of listed agents or toxins, release of listed agents or toxins, or alteration of inventory records; provisions for the control of access to containers where listed agents and toxins are stored; and procedures for reporting and removing unauthorized persons.

(iv) With respect to areas containing listed agents or toxins, an entity or individual must adhere to the following security requirements or implement measures to achieve an equivalent or greater level of security as the provisions below:

(A) Allow unescorted access only to approved individuals who are performing a specifically authorized function during hours required to perform that job;

(B) Allow individuals not approved under § 121.11 to conduct routine cleaning, maintenance, repairs, and other non-laboratory functions only when escorted and continually monitored by approved individuals;

(C) Provide for the control of access to containers where listed agents and toxins are stored by requiring that such containers be locked when not in the direct view of an approved individual and by using other monitoring measures, as needed;

(D) Require the inspection of all packages upon entry and exit;

(E) Establish a protocol for intra-entity transfers, including provisions for ensuring that the packaging and movement, is conducted under the supervision of an approved individual;

(F) Require that approved individuals do not share with any other person their unique means of accessing the area or listed agents or toxins; and

(G) Require that approved individuals immediately report any of the following to the responsible official:

(1) Any loss or compromise of keys, passwords, combinations, etc.;

(2) Any suspicious persons or activities;

(3) Any loss or theft of listed agents or toxins;

(4) Any release of a listed agent or toxin; and

¹²For guidance on biosafety and containment procedures, see the CDC/NIH publication, "Biosafety in Microbiological and Biomedical Laboratories" (4th ed. 1999).

¹³For guidance, see the USDA Departmental Manual No. 9610-001, "USDA Security Policies and Procedures for Biosafety Level-3 Facilities" (August 30, 2002). The manual may be obtained by calling (301) 734-3277. The manual is also available on the Internet at <http://www.usda.gov/ocio/directives/DM/DM9610-001.htm>. See also Appendix F, "Biosafety in Microbiological and Biomedical Laboratories," in Morbidity and Mortality Weekly Report (2002). This document may be obtained by writing to Select Agent Program, Centers for Disease Control and Prevention, 1600 Clifton Road, NE, Mail Stop E 79, Atlanta, GA 30333. It is also available on the Internet at <http://www.cdc.gov/mmwr>.

(5) Any sign that inventory and use records for listed agents and toxins have been altered or otherwise compromised.

(3) *Incident response procedures.*¹⁴ The Biosafety and Security Plan must also include incident response plans for containment breach, security breach, inventory violations, non-biological incidents such as workplace violence, and cybersecurity breach. The incident response plans must address personnel safety and health, containment, inventory control, and notification of managers and responders. The incident response plans must also address such events as bomb threats, severe weather (floods, hurricanes, tornadoes), earthquakes, power outages, and other natural disasters or emergencies.

(b) The Biosafety and Security Plan must be reviewed, performance tested, and updated annually. The plan must also be reviewed and revised, as necessary, after any incident.

§ 121.13 Training.

(a) The responsible official must provide appropriate training in biosafety, containment, and security procedures to all individuals with access to agents and toxins listed in § 121.3.

(b) The responsible official must provide information and training to an individual at the time the individual is assigned to work with a listed agent or toxin. The responsible official must provide refresher training annually.

§ 121.14 Transfer of biological agents and toxins.

Biological agents and toxins listed in § 121.3 may only be transferred to individuals or entities registered to possess, use, or transfer that particular agent or toxin. However, the sender of an agent or toxin may be an individual or entity that has a certificate of registration for the agent or toxin, an individual or entity that is exempt from the requirements of this part, or an individual or entity located outside of the United States. Biological agents or toxins may only be transferred under

the conditions of this section and must be authorized by APHIS or, for overlap agents or toxins, by APHIS or CDC, prior to the transfer.

(a) *Importation and interstate movement.* In addition to the permit required under part 122 of this subchapter, biological agents or toxins listed in § 121.3 may be imported or moved interstate only with the prior authorization of APHIS or, for overlap agents or toxins, APHIS or CDC. To obtain such authorization, the sender and the responsible official for the recipient must complete and submit APHIS Form 2041 to APHIS or CDC, in accordance with paragraph (c) of this section.

(b) *Intrastate movement.* Biological agents or toxins listed in § 121.3 may be moved intrastate only with the prior authorization of APHIS or, for overlap agents or toxins, APHIS or CDC. To obtain such authorization, the sender and the responsible official for the recipient must complete and submit APHIS Form 2041 to APHIS or CDC, in accordance with paragraph (c) of this section.

(c) *APHIS Form 2041; process and procedures.* (1) Prior to each transfer, the responsible official for the recipient and sender must complete APHIS Form 2041, and the sender must submit the form to APHIS or, for overlap agents or toxins, to APHIS or CDC.¹⁵

(2) APHIS or CDC will authorize the transfer based on a finding that the recipient has a certificate of registration covering the transfer of the listed agent or toxin.

(3) The responsible official for the recipient must notify the agency authorizing the transfer (either APHIS or CDC) and the sender upon receipt of the agent or toxin by mailing or faxing

¹⁵ APHIS Form 2041 may be obtained by calling APHIS at (301) 734-3277 or by calling CDC at (404) 498-2265. The form is also available on the Internet at <http://www.aphis.usda.gov/vs/ncie.bta.html> or <http://www.cdc.gov/od/ohs/lrsat.htm>. APHIS Form 2041 may be mailed to National Center for Import and Export, VS, APHIS, 4700 River Road Unit 40, Riverdale, MD 20737-1231; or faxed to (301) 734-3652. For overlap agents and toxins, it may be mailed to the above address or to Select Agent Program, Centers for Disease Control and Prevention, 1600 Clifton Road, NE, Mail Stop E 79, Atlanta, GA 30333; or faxed to (404) 498-2265.

¹⁴ The requirements in this paragraph do not supercede or preempt the enforcement of emergency response requirements imposed by other statutes or regulations.

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a completed APHIS Form 2041 to APHIS or CDC within 2 business days.

(4) The responsible official for the recipient must notify APHIS or CDC immediately if the agent or toxin has not been received within 48 hours after the expected delivery or if the package containing the agent or toxin is leaking or has been damaged.

(d) The sender must comply with all applicable laws governing packaging and shipping.

§ 121.15 Records.

(a) The responsible official must maintain complete, up-to-date records of information necessary to give an accounting of all of the activities related to agents or toxins listed in §121.3. Such records must include the following:

- (1) The Biosafety and Security Plan;
- (2) A current list of all individuals with access to agents or toxins listed in §121.3;
- (3) Training records for individuals with access to such agents or toxins;
- (4) Accurate and current inventory records (including source and characterization data);
- (5) Permits and transfer documents (APHIS Form 2041) issued by APHIS and CDC;
- (6) Security records (e.g., transactions from automated access control systems, testing and maintenance of security systems, visitor logs);
- (7) Biosafety, containment, and security incident reports.

(b) The responsible official must maintain such records for 3 years.

(c) All records must be produced upon request to APHIS or CDC inspectors, and appropriate Federal, State, or local law enforcement authorities.

§ 121.16 Inspections.

(a) To ensure compliance with the regulations, any APHIS or CDC inspector must be allowed, without previous notification, to enter and inspect the entire premises, all materials and equipment, and all records required to be maintained by this part.

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

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the biosafety, containment, and security requirements.

§ 121.17 Notification in the event of theft, loss, or release of a biological agent or toxin.

(a) The responsible official must orally notify APHIS and appropriate Federal, State, or local law enforcement agencies immediately upon discovery of the theft or loss of agents or toxins listed in §121.3. The oral notification must be followed by a written report (APHIS Form 2043) within 7 days.

(b) The responsible official must orally notify APHIS immediately upon discovery that a release of an agent or toxin has occurred outside of the biocontainment area. The oral notification shall be followed by a written report (APHIS Form 2043) within 7 days. Upon notification and a finding that the release poses a threat to animal or plant health, or animal or plant products, APHIS will notify relevant Federal, State, and local authorities, and the public, if necessary. If the release involves an overlap agent or toxin, APHIS will also notify the Secretary of Health and Human Services.

(c) The responsible official must orally notify APHIS of a theft, loss, or release of an agent or toxin by calling (866) 994-5698. A copy of APHIS Form 2043 may be obtained by writing to National Center for Import and Export, VS, APHIS, 4700 River Road Unit 40, Riverdale, MD 20737-1231; or by calling (301) 734-3277. The form is also available on the Internet at <http://www.aphis.usda.gov/vs/ncie.bta.html>. APHIS Form 2043 may be mailed to the same address or faxed to (301) 734-3652.

§ 121.18 Administrative review.

An individual or entity may appeal a denial or revocation of registration under this part. An individual who has been denied access to listed agents or toxins or who has been granted only limited access to listed agents or toxins under this part may appeal that decision.¹⁶ The appeal must be in writing and submitted to the Administrator

¹⁶An entity may not appeal the denial or limitation of an individual's access to listed agents or toxins.

within 30 days of the decision. The appeal must state all of the facts and reasons upon which the individual or entity disagrees with the decision. Where the denial or revocation of registration or the denial or limitation of an individual's access approval is based solely upon an identification by the Attorney General, APHIS will forward the request for review 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 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, 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