as currently complying with the applicable laws for environmental protection.

(5) *Carrier* means the principal operator of a means of conveyance.

(j) *Compliance agreement and cancellation.* (1) Any person engaged in the business of handling or disposing of regulated garbage must first enter into a compliance agreement with the Animal and Plant Health Inspection Service (APHIS). Compliance agreement forms (PPQ Form 519) are available without charge from local USDA/APHIS/Plant Protection and Quarantine offices, which are listed in telephone directories.

(2) A person who enters into a compliance agreement, and employees or agents of that person, shall comply with the following conditions and any supplemental conditions which shall be listed in the compliance agreement, as deemed by the Administrator to be necessary to prevent the dissemination into or within the United States of plant pests and livestock or poultry diseases:

(i) Comply with the provisions of 7 CFR 330.400;

(ii) Allow APHIS inspectors access to all records maintained by the person regarding handling or disposal of regulated garbage, and to all areas where handling or disposal of regulated garbage occurs;

(iii) Remove regulated garbage from a means of conveyance only in tight, leak-proof receptacles;

(iv) Move the receptacles of regulated garbage only to a facility approved in accordance with §330.400(g)(2); and

(v) At the approved facility, dispose of the regulated garbage only through incineration, sterilization, grinding into a sewage system approved in accordance with §330.400(g)(2), or in any other manner approved by the Administrator and described in the compliance agreement.

(3) Approval for a compliance agreement may be denied at any time if the Administrator determines that the requirements set forth in this subpart are not met, after notice of, and the reasons for, the proposed denial of the approval, and an opportunity to demonstrate or achieve compliance with such requirements, has been afforded to the compliance agreement applicant.

(4) Any compliance agreement may be canceled in writing by the Administrator whenever it is found that the person who has entered into the compliance agreement has failed to comply with this subpart. Any person whose compliance agreement has been cancelled may appeal the decision, in writing, within 10 days after receiving written notification of the cancellation. The appeal must state all of the facts and reasons upon which the person relies to show that the compliance agreement was wrongfully cancelled. As promptly as circumstances allow, the Administrator will grant or deny the appeal, in writing, stating the reasons for the decision. A hearing will be held to resolve any conflict as to any material fact. Rules of practice concerning a hearing will be adopted by the Administrator. This administrative remedy must be exhausted before a person can file suit in court challenging the cancellation of a compliance agreement.

(5) Where a compliance agreement is denied or cancelled, regulated garbage may continue to be unloaded from a means of conveyance and disposed of at an approved facility in accordance with §330.400(g)(1).

(Approved by the Office of Management and Budget under control number 0579–0054)

[39 FR 32320, Sept. 6, 1974, as amended at 43 FR 39954, Sept. 8, 1978; 45 FR 80268, Dec. 4, 1980; 48 FR 57466, Dec. 30, 1983; 58 FR 66248, Dec. 20, 1993; 62 FR 19903, Apr. 24, 1997; 66 FR 21058, Apr. 27, 2001; 68 FR 6342, Feb. 7, 2003]

# PART 331—POSSESSION, USE, AND TRANSFER OF BIOLOGICAL AGENTS AND TOXINS

Sec.

AUTHORITY: Secs. 211–213, Title II, Pub. L. 107–188, 116 Stat. 647 (7 U.S.C. 8401).

SOURCE: 67 FR 76925, Dec. 13, 2002, unless otherwise noted.

### §331.0 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 §331.3 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 individual or entity 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 §331.3 may only be transferred to an individual or entity that is not registered under this part if the individual or entity has been issued a permit by the Administrator under part 330 of this chapter to import or move interstate that specific agent or toxin. If an individual or entity has not been issued a permit under part 330 of this chapter, 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 §331.13(c). Because USDA permits do not cover intrastate movement, 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 §331.8. 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 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 §331.10.

(4) By June 12, 2003, the responsible official must submit to APHIS the security section of the Biocontainment and Security Plan required in §331.11.

(5) By September 12, 2003, the responsible official must implement the security section of the Biocontainment and Security Plan, as required in §331.11, and provide security training in accordance with 7 CFR 331.12.

(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 §331.3 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 §331.3.

[68 FR 62220, Nov. 3, 2003]

### §331.1 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.

*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.

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

*PPQ.* The Plant Protection and Quarantine Programs of the Animal and Plant Health Inspection Service

*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 plant tissues (*e.g.*, stems, seeds, flowers, pollen, leaves, roots, fruits, tubers, tissue

cultures, protoplasts), soil, water, 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.

### §331.2 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 plant health or to plant 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 §331.3 must register in accordance with §331.6. 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. 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 Biocontainment and Security Plan in accordance with §331.11, providing the proper training to individuals who handle or use agents or toxins listed in §331.3, 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 §331.10, and transferring such agents or toxins only to registered individuals or entities in accordance with §331.13.

### §331.3 List of biological agents and toxins.

(a) The biological agents and toxins listed in this section have been determined to have the potential to pose a severe threat to plant health or to plant products.

*Liberobacter africanus*, *Liberobacter asiaticus*
*Peronosclerospora philippinensis*
*Phakopsora pachyrhizi*
Plum pox potyvirus
*Ralstonia solanacearum*, race 3, biovar 2
*Sclerophthora rayssiae* var. *zeae*
*Synchytrium endobioticum*
*Xanthomonas oryzae* pv. *oryzicola*
*Xylella fastidiosa* (citrus variegated chlorosis strain)

(b) 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.

(c) 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 plant health or to plant 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 that are, bear, or contain listed agents or toxins;

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

### § 331.4 Exemptions.

(a) Diagnostic laboratories[1] 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.[2] During agricultural emergencies or outbreaks, or in endemic areas, the Administrator may require less frequent reporting. A copy of the completed form must be maintained for 3 years.

(b) In addition to the exemption provided in paragraph (a) 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 or plant health, and animal or plant 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.[3]

### § 331.5 Registration; who must register.

(a) Unless exempted under § 331.4, any individual or entity that possesses, uses, or transfers any agent or toxin listed in § 331.3 must register with APHIS.

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

[1] However, diagnostic laboratories and other persons will still be required to obtain a permit under part 330 of this chapter in order to import or move interstate any listed agent or toxin.

[2] A diagnostic laboratory or other person must immediately notify APHIS by calling (301) 734–5519. APHIS Form 2040 may be obtained by calling (301) 734–5519 or faxing a request to (301) 734–8700. The form is also available on the Internet at *http://www.aphis.usda.gov/ppq/permits.* The completed form may be mailed to Biological and Technical Services, PPQ, APHIS, 4700 River Road Unit 133, Riverdale, MD 20737–1236; or faxed to (301) 734–8700.

[3] A request for exemption may be mailed to biological and Technical Services, PPQ, APHIS, 4700 River road Unit 133, Riverdale, MD 20737–1236; or faxed to (301) 734–8700.

official, who may act for the responsible official when he/she is unavailable. This individual must have the authority and control to ensure compliance with the regulations when acting for the responsible official. This individual will also be subject to a security risk assessment by the Attorney General as part of registration.

### § 331.6 Registration; general provisions.

(a) Unless exempted under this part, an individual or entity shall not possess, use, or transfer any agent or toxin listed in § 331.3 without a certificate of registration issued by APHIS.

(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 controls the entity following a security risk assessment by the Attorney General;[4] and

(2) Approval of the containment and security of the entity. The entity's containment and security procedures must be commensurate with the risk of the agent or toxin, given its intended use. APHIS will review the Biocontainment and Security Plan, and may inspect and evaluate the premises and records to determine compliance with the regulations and the 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) A certificate of registration will be valid for only the specific agents or toxins listed on 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.

(d) 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,[5] changes in the activities involving the agent or toxin). The responsible official must immediately notify APHIS of such changes in circumstances that occur after submission of the application for registration or after receipt of a certificate of registration.

(e) 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 individuals or entities in accordance with § 331.12. The responsible official must notify APHIS 5 business days prior to the planned inactivation so that we may have the opportunity to observe the inactivation of the agents or toxins. We will notify the responsible official if we wish to observe the inactivation of the agents or toxins.

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

### § 331.7 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 the 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 the 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,

[4] The 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.

[5] Any 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.

or transfer agents or toxins listed in § 331.3; or

(4) The responsible official is an individual who handles or uses listed agents or toxins 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 containment and security requirements prescribed by the Administrator;[6] or

(6) There are egregious or repeated violations of the 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) APHIS may summarily revoke or suspend registration for any of the reasons set forth in paragraph (a) of this section.

(c) APHIS will notify the responsible official in writing if an application for registration is denied or a certificate of registration is revoked or suspended.

(d) Denial of an application for registration, revocation of registration, and suspension of registration may be appealed under § 331.16.

### § 331.8 Registration; how to register.

(a) To apply for a certificate of registration, an individual or entity 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.

(b) The registration application package may be obtained by calling (301) 734–5519 or faxing a request to (301) 734–8700. It is also available on the Internet at *http://www.aphis.usda.gov/ppq/permits.* The completed registration application package may be mailed to APHIS, Plant Protection and Quarantine, Biological and Technical Services, 4700 River Road Unit 133, Riverdale, MD 20737–1236; or faxed to (301) 734–8700. Assistance in completing the registration application may be requested by calling (301) 734–5519.

### § 331.9 Responsibilities of the responsible official.

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

(1) Developing and implementing a Biocontainment and Security Plan in accordance with § 331.11;

(2) Allowing only approved individuals within the entity to have access to any agents or toxins listed in § 331.3 in accordance with § 331.10;

(3) Providing appropriate training in containment and security procedures for all personnel in accordance with § 331.12;

(4) Transferring agents or toxins only to registered individuals or entities in accordance with § 331.13;

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

(6) Notifying APHIS of changes in circumstances in accordance with § 331.6;

(7) Providing timely notice of any theft, loss, or release of a biological agent or toxin in accordance with § 331.16;

(8) Maintaining detailed records of information necessary to give a complete accounting of all of the activities related to agents or toxins listed in § 331.3 in accordance with § 331.14.

(b) In addition to the requirements in paragraph (a) of this section, the responsible official for a diagnostic laboratory or other entity possessing, using, or transferring agents or toxins listed in § 331.3 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.[7] During agricultural emergencies or outbreaks, or in endemic areas, the Administrator may require less frequent reporting.

### § 331.10 Restricting access to biological agents and toxins.

(a) An individual may not have access to biological agents or toxins listed in § 331.3 unless approved by APHIS.

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

[7] A diagnostic laboratory or other person must immediately notify APHIS by calling (301) 734–5519.

APHIS will grant, limit, or deny access of individuals to listed 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 § 331.3. The responsible official must request such access for only those individuals who have 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.

(c) The responsible official must provide appropriate training in containment and security procedures to all individuals with access to agents and toxins listed in § 331.3, in accordance with § 331.12.

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

(e) In addition, the responsible official must submit information about the individual's training and skills to APHIS (*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.*, 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.

(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 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 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 plant health or plant products.

(i) An individual may appeal the Administrator's decision to deny or limit access under § 331.15.

(j) 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 § 331.3.

(k) The responsible official must immediately notify APHIS when an individual's access to listed agents or toxins is terminated by the entity and the reasons therefor.

### § 331.11 Biocontainment and security plan.

(a) As a condition of registration, an individual or entity must develop and implement a Biocontainment and Security Plan.[8] The Biocontainment and Security Plan must contain sufficient information and documentation to describe the 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.

(1) *Containment procedures.* The 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 and inventory control.

[8] Technical assistance and guidance may be obtained by calling (301) 734–5519.

(2) *Security systems and procedures.*[9] 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 § 331.3, physical security, and cybersecurity. The plan must also contain provisions for securing the area (*e.g.,* card access, key pads, locks) and protocols for changing access numbers or locks following 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; provisions for routine cleaning, maintenance, and repairs; 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 § 331.10 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

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

(3) *Incident response procedures.*[10] The Biocontainment and Security Plan must also include incident response plans for containment breach, security

[9] For 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) 734–5519. 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.*

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

breach, inventory violations, non-biological incidents such as workplace violence, and cybersecurity breach. The incident response plans must address 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 Biocontainment and Security Plan must be reviewed, performance tested, and updated annually. The plan must also be reviewed and revised, as necessary, after any incident.

### § 331.12 Training.

(a) The responsible official must provide appropriate training in containment and security procedures to all individuals with access to agents and toxins listed in § 331.3.

(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.

### § 331.13 Transfer of biological agents and toxins.

Biological agents and toxins listed in § 331.3 may only be transferred to an individual or entity 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 prior to the transfer.

(a) *Importation and interstate movement.* In addition to the permit required under part 330 of this chapter, biological agents or toxins listed in § 331.3 may be imported or moved interstate only with the prior authorization of APHIS. To obtain such authorization, the sender and the responsible official for the recipient must complete and submit APHIS Form 2041 to APHIS, in accordance with paragraph (c) of this section.

(b) *Intrastate movement.* Biological agents or toxins listed in § 331.3 may be moved intrastate only with the prior authorization of APHIS. To obtain authorization, the sender and the responsible official for the recipient must complete and submit APHIS Form 2041 to APHIS prior to each transfer, in accordance with paragraph (c) of this section.

(c) *APHIS Form 2041; process and procedures.* (1) Prior to each transfer, the sender and the responsible official for the recipient must complete APHIS Form 2041, and the sender must submit the form to APHIS.[11]

(2) APHIS 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 entity must notify APHIS and the sender upon receipt of the agent or toxin by mailing or faxing a completed APHIS Form 2041 within 2 business days.

(4) The responsible official for the recipient must notify APHIS 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.

### § 331.14 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 § 331.3. Such records must include the following:

(1) The Biocontainment and Security Plan;

[11] APHIS Form 2041 may be obtained by calling (301) 734–5519 or faxing a request to (301) 734–8700. The form is also available on the Internet at *http://www.aphis.usda.gov/ppq/permits.* APHIS Form 2041 may be mailed to Biological and Technical Services, PPQ, APHIS, 4700 River Road Unit 133, Riverdale, MD 20737–1236; or faxed to (301) 734–8700.

(2) A current list of all individuals with access to agents or toxins listed in § 331.3;

(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;

(6) Security records (*e.g.*, transactions from automated access control systems, testing and maintenance of security systems, visitor logs); and

(7) 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 inspectors, and appropriate Federal, State, or local law enforcement authorities.

### § 331.15 Inspections.

(a) To ensure compliance with the regulations, any APHIS 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 may inspect and evaluate their premises and records to ensure compliance with the regulations and the containment and security requirements.

### § 331.16 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 § 331.3. 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 must 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.

(c) The responsible official must orally notify APHIS of a theft, loss, or release of an agent or toxin by calling (301) 734–5519. A copy of APHIS Form 2043 may be obtained by writing to Biological and Technical Services, PPQ, APHIS, 4700 River Road Unit 133, Riverdale, MD 20737–1236, or by calling (301) 734–5519. APHIS Form 2043 may be mailed to the same address or faxed to (301) 734–8700.

### § 331.17 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.[12] The appeal must be in writing and submitted to the Administrator 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 340—INTRODUCTION OF ORGANISMS AND PRODUCTS ALTERED OR PRODUCED THROUGH GENETIC ENGINEERING WHICH ARE PLANT PESTS OR WHICH THERE IS REASON TO BELIEVE ARE PLANT PESTS

Sec.



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