

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).

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[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]

## PART 331—POSSESSION OF BIOLOGICAL AGENTS AND TOXINS

Sec.

331.1 Definitions.

331.2 List of biological agents and toxins.

331.3 Notification requirements and procedures.

AUTHORITY: Secs. 211-213, Title II, Pub. L. 101-188, 116 Stat. 647 (7 U.S.C. 8401).

SOURCE: 67 FR 52388, Aug. 12, 2002, unless otherwise noted.

### § 331.1 Definitions.

*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.

*Facility.* Any individual or government agency, university, corporation, company, partnership, society, association, firm, or other legal entity located at a single geographic site that may transfer or receive through any means a biological agent or toxin subject to this part.

*Person.* Any individual, firm, corporation, company, society, or association; any Federal, State, or local governmental entity; or any organized group of any of the foregoing.

*Responsible facility official.* An official authorized to transfer and receive biological agents or toxins covered by this part on behalf of a facility. This person should be either a safety officer, a senior management official of the facility, or both. The responsible facility official should not be an individual who actually transfers or receives a biological agent or toxin at the facility.

*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.

[67 FR 52388, Aug. 12, 2002, as amended at 67 FR 60519, Sept. 26, 2002]

## § 331.2

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

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 the production and marketability of plant products. Any person who possesses any listed agent or toxin or, in the case of a listed disease, the causative agent of that disease, must notify the Animal and Plant Health Inspection Service of that possession in accordance with § 331.3.

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

### § 331.3 Notification requirements and procedures.

(a) Any person or facility that possesses any biological agent or toxin listed in § 331.2 must notify the Animal and Plant Health Inspection Service (APHIS) of such possession by October 11, 2002. Notice must be provided using Plant Protection and Quarantine (PPQ) form 655, which may be obtained by calling PPQ at (301) 734-8896. The form is also available on the Internet at <http://www.aphis.usda.gov/ppq/permits>.

(b) Each facility should designate a responsible facility official to complete PPQ form 655, and a single form that reflects all listed agents and toxins possessed by all persons within the facility should be submitted for each facility. The responsible facility official for each facility should consult with others in the facility (*e.g.*, principal investigators) in order to obtain the information necessary to complete the notification form. The responsible facility official must review and sign the notification form and will be the individual contacted by APHIS if any questions arise concerning the facility's response.

(c) Completed forms must be mailed to: U.S. Department of Agriculture, Animal and Plant Health Inspection Service, Plant Protection and Quarantine, Permits and Risk Assessment,

4700 River Road Unit 133, Riverdale, Md 20737-1236.

(d) Assistance in completing the form may be requested by calling (301) 734-8896.

(Approved by the Office of Management and Budget under control number 0579-0204)

EFFECTIVE DATE NOTE: At 67 FR 76925, Dec. 13, 2002, part 331 was revised, effective Feb. 11, 2003. For the convenience of the user, the revised text follows:

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

Sec.

- 331.0 Effective and applicability dates.
- 331.1 Definitions.
- 331.2 Purpose and scope.
- 331.3 List of biological agents and toxins.
- 331.4 Exemptions.
- 331.5 Registration; who must register.
- 331.6 Registration; general provisions.
- 331.7 Denial, revocation, or suspension of registration.
- 331.8 Registration; how to register.
- 331.9 Responsibilities of the responsible official.
- 331.10 Restricting access to biological agents and toxins.
- 331.11 Biocontainment and security plan.
- 331.12 Training.
- 331.13 Transfer of biological agents and toxins.
- 331.14 Records.
- 331.15 Inspections.
- 331.16 Notification in the event of theft, loss, or release of a biological agent or toxin.
- 331.17 Administrative review.

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

#### § 331.0 Effective and applicability dates.

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) through (f) 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