

supplemental conditions which are 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:

(1) Comply with all applicable provisions of this subpart;

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

(3)(i) If the garbage is regulated under §330.401, remove garbage from a means of conveyance only in tight, covered, leak-proof receptacles;

(ii) If the garbage is regulated under §330.402, transport garbage interstate in packaging approved by the Administrator;

(4) Move the garbage only to a facility approved by the Administrator; and

(5) At the approved facility, dispose of the garbage in a manner approved by the Administrator and described in the compliance agreement.

(c) Approval for a compliance agreement may be denied at any time if the Administrator determines that the applicant has not met or is unable to meet the requirements set forth in this subpart. Prior to denying any application for a compliance agreement, APHIS will provide notice to the applicant thereof, and will provide the applicant with an opportunity to demonstrate or achieve compliance with requirements.

(d) Any compliance agreement may be canceled, either orally or in writing, by an inspector whenever the inspector finds that the person who has entered into the compliance agreement has failed to comply with this subpart. If the cancellation is oral, the cancellation and the reasons for the cancellation will be confirmed in writing as promptly as circumstances allow. Any person whose compliance agreement has been canceled 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 canceled. 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.

(e) Where a compliance agreement is denied or canceled, the person who entered into or applied for the compliance agreement may be prohibited, at the discretion of the Administrator, from handling or disposing of regulated garbage.

(Approved by the Office of Management and Budget under control numbers 0579–0015, 0579–0054, and 0579–0292)

PART 331—POSSESSION, USE, AND TRANSFER OF SELECT AGENTS AND TOXINS

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AUTHORITY: 7 U.S.C. 8401; 7 CFR 2.22, 2.80, and 371.3.

SOURCE: 70 FR 13278, Mar. 18, 2005, unless otherwise noted.

§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 U.S. 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, 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 U.S. Department of Health and Human Services.

Diagnosis. The analysis of specimens for the purpose of identifying or confirming the presence or characteristics of a select agent or toxin, provided that such analysis is directly related to protecting the public health or safety, animal health or animal products, or plant health or plant products.

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

HHS Secretary. The Secretary of the Department of Health and Human Services or his or her designee, unless otherwise specified.

HHS select agent and/or toxin. A biological agent or toxin listed in 42 CFR 73.3.

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

Information security. Protecting information and information systems from unauthorized access, use, disclosure, disruption, modification, or destruction in order to provide:

(1) *Integrity*, which means guarding against improper information modi-

fication or destruction, and includes ensuring information authenticity;

(2) *Confidentiality*, which means preserving authorized restrictions on access and disclosure, including means for protecting personal privacy and proprietary information; and

(3) *Availability*, which means ensuring timely and reliable access to and use of information.

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 select agents or toxins, under conditions prescribed by the Administrator.

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

Recombinant nucleic acids. (1) Molecules that are constructed by joining nucleic acid molecules and that can replicate in a living cell (i.e., recombinant nucleic acids); or

(2) Molecules that result from the replication of those described in paragraph (1) of this definition.

Responsible official. The individual designated by an entity with the authority and control to ensure compliance with the regulations in this part.

Security barrier. A physical structure that is designed to prevent entry by unauthorized persons, animals, or materials.

Select agent and/or toxin. A biological agent or toxin listed in § 331.3.

Specimen. Samples of material from humans, animals, plants, or the environment, or isolates or cultures from such samples, for diagnosis, verification, or proficiency testing.

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.

Synthetic nucleic acids. (1) Molecules that are chemically or by other means synthesized or amplified, including those that are chemically or otherwise

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modified but can base pair with naturally occurring nucleic acid molecules (i.e., synthetic nucleic acids); or

(2) Molecules that result from the replication of those described in paragraph (1) of this definition.

Toxin. The toxic material or product of plants, animals, microorganisms (including, but not limited to, bacteria, viruses, fungi, 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 U.S. Department of Agriculture.

Verification. The demonstration of obtaining established performance (e.g., accuracy, precision, and the analytical sensitivity and specificity) specifications for any procedure used for diagnosis.

[70 FR 13278, Mar. 18, 2005, as amended at 77 FR 61074, Oct. 5, 2012]

§ 331.2 Purpose and scope.

This part implements the provisions of the Agricultural Bioterrorism Protection Act of 2002 setting forth the requirements for possession, use, and transfer of select agents and toxins. The biological agents and toxins listed in this part have the potential to pose a severe threat to plant health or plant products.

§ 331.3 PPQ select agents and toxins.

(a) Except as provided in paragraphs (d) and (e) of this section, the Administrator has determined that 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.

(b) PPQ select agents and toxins:

Peronosclerospora philippinensis
(*Peronosclerospora sacchari*);
Phoma glycinicola (formerly *Pyrenochaeta glycinis*);
Ralstonia solanacearum;
Rathayibacter toxicus;

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Sclerophthora rayssiae;
Synchytrium endobioticum;
Xanthomonas oryzae.

(c) Genetic elements, recombinant and/or synthetic nucleic acids, and recombinant and/or synthetic organisms:

(1) Nucleic acids that can produce infectious forms of any of the select agent viruses listed in paragraph (b) of this section.

(2) Recombinant and/or synthetic nucleic acids that encode for the functional forms of any toxin listed in paragraph (b) of this section if the nucleic acids:

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

(ii) Are in a vector or recombinant host genome and can be expressed *in vivo* or *in vitro*.

(3) Select agents and toxins listed in paragraph (b) of this section that have been genetically modified.

(d) Select agents or toxins that meet any of the following criteria are excluded from the requirements of this part:

(1) Any select agent or toxin that is in its naturally occurring environment, provided that the agent or toxin has not been intentionally introduced, cultivated, collected, or otherwise extracted from its natural source.

(2) Nonviable select agents or non-functional toxins.

(3) Any subspecies of *Ralstonia solanacearum* except race 3, biovar 2 and all subspecies of *Sclerophthora rayssiae* except var. *zeae*, provided that the individual or entity can verify that the agent is within the exclusion category.

(e) An attenuated strain of a select agent or an inactive form of a select toxin may be excluded from the requirements of this part based upon a determination by the Administrator that the attenuated strain or inactivated toxin does not pose a severe threat to plant health or plant products.

(1) To apply for exclusion, an individual or entity must submit a written request and supporting scientific information. A written decision granting or denying the request will be issued. An exclusion will be effective upon notification to the applicant. Exclusions will be listed on the National Select Agent