

## § 331.2

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

Registry Web site at <http://www.selectagents.gov/>.

(2) If an excluded attenuated strain or inactivated toxin is subjected to any manipulation that restores or enhances its virulence or toxic activity, the resulting select agent or toxin will be subject to the requirements of this part.

(f) Any select agent or toxin seized by a Federal law enforcement agency will be excluded from the requirements of this part during the period between seizure of the agent or toxin and the transfer or destruction of such agent or toxin provided that:

(1) As soon as practicable, the Federal law enforcement agency transfers the seized agent or toxin to an entity eligible to receive such agent or toxin or destroys the agent or toxin by a recognized sterilization or inactivation process.

(2) The Federal law enforcement agency safeguards and secures the seized agent or toxin against theft, loss, or release, and reports any theft, loss, or release of such agent or toxin.

(3) The Federal law enforcement agency reports the seizure of the select agent or toxin to APHIS or CDC. The seizure must be reported within 24 hours by telephone, facsimile, or e-mail. This report must be followed by submission of APHIS/CDC Form 4 within 7 calendar days after seizure of the select agent or toxin. A copy of the completed form must be maintained for 3 years.

(4) The Federal law enforcement agency reports the final disposition of the select agent or toxin to APHIS or CDC by submission of APHIS/CDC Form 4. A copy of the completed form must be maintained for 3 years.

[70 FR 13278, Mar. 18, 2005, as amended at 73 FR 61331, Oct. 16, 2008; 77 FR 61075, Oct. 5, 2012]

#### § 331.4 [Reserved]

#### § 331.5 Exemptions.

(a) Diagnostic laboratories and other entities that possess, use, or transfer a select agent or toxin that is contained in a specimen presented for diagnosis or verification will be exempt from the requirements of this part for such

agent or toxin contained in the specimen, provided that:

(1) Unless directed otherwise by the Administrator, within 7 calendar days after identification, the agent or toxin is transferred in accordance with § 331.16 or destroyed on-site by a recognized sterilization or inactivation process;

(2) The agent or toxin is secured against theft, loss, or release during the period between identification of the agent or toxin and transfer or destruction of such agent or toxin, and any theft, loss, or release of such agent or toxin is reported; and

(3) The identification of the agent or toxin is immediately reported to APHIS or CDC by telephone, facsimile, or e-mail. This report must be followed by submission of APHIS/CDC Form 4 within 7 calendar days after identification. Less stringent reporting may be required during agricultural emergencies or outbreaks, or in endemic areas. A copy of APHIS/CDC Form 4 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 plant health or plant products. An individual or entity 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.