§ 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 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 glycines);
Ralstonia solanacearum, race 3, biovar 2;
Rathayibacter toxicus;
Sclerophthora rayssiae var. zeae;
Synchytrium endobioticum;
Xanthomonas oryzae;
Xylella fastidiosa (citrus variegated chlorosis strain).

(c) Genetic elements, recombinant nucleic acids, and recombinant 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 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.
(e) An attenuated strain of a select agent or toxin may be excluded from the requirements of this part based upon a determination that the attenuated strain does not pose a severe threat to plant health or plant products.
   (1) To apply for an 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 of the applicant. Exclusions will be published periodically in the notice section of the Federal Register and will be listed on the Internet at http://www.aphis.usda.gov/programs/ag_selectagent/index.html.
   (2) If an excluded attenuated strain is subjected to any manipulation that restores or enhances its virulence, the resulting select agent or toxin will be subject to the requirements of this part.
   (3) An individual or entity may make a written request to the Administrator for reconsideration of a decision denying an exclusion application. The written request for reconsideration must state the facts and reasoning upon which the individual or entity relies 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.
(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.
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