

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

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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 laboratories¹ 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

¹However, 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.

²A 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.

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

³A 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.