

individual who owns or controls the entity; and

(ii) The entity otherwise meets all of the requirements of this part.

(2) Notwithstanding the provisions in paragraph (a) of this section, APHIS may issue a provisional registration certificate to individuals and entities that did not possess listed biological agents or toxins as of February 11, 2003, if, as of November 12, 2003:

(i) The Attorney General has received all of the information, including fingerprint cards, required by the Attorney General to conduct a security risk assessment of the entity, including any individual who owns or controls the entity;

(ii) The entity otherwise meets all of the requirements of this part; and

(iii) The Administrator finds that circumstances warrant such action in the interest of the health of plants or plant products or national security.

(3) A provisional registration certificate will be effective until APHIS either issues a certificate of registration or suspends or revokes the provisional registration.

(c) Notwithstanding the provisions in paragraph (a) of this section, APHIS may issue a provisional grant of access for individuals identified by an entity as having a legitimate need to handle or use agents or toxins listed in § 331.3 if, as of November 12, 2003, the Attorney General has received all of the information, including fingerprint cards, required by the Attorney General to conduct a security risk assessment of that individual. A provisional grant of access will be effective until APHIS grants or denies access to biological agents or toxins listed in § 331.3.

[68 FR 62220, Nov. 3, 2003]

§ 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 United States 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, 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.

Centers for Disease Control and Prevention (CDC). The Centers for Disease Control and Prevention of the United States Department of Health and Human Services.

Diagnostic laboratory. A laboratory facility that receives specimens for the purpose of determining the identities of pests, pathogens, contaminants, or causes of disease.

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

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

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

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

Responsible official. The individual designated by an entity to act on its behalf. This individual must have the authority and control to ensure compliance with the regulations in this part.

Specimen. A sample of material collected for use in testing, such as plant tissues (e.g., stems, seeds, flowers, pollen, leaves, roots, fruits, tubers, tissue

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