

# Rules and Regulations

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## DEPARTMENT OF AGRICULTURE

### Animal and Plant Health Inspection Service

#### 7 CFR Part 301

[Docket No. 02-029-2]

#### Citrus Canker; Removal of Quarantined Area

**AGENCY:** Animal and Plant Health Inspection Service, USDA.

**ACTION:** Affirmation of interim rule as final rule.

**SUMMARY:** We are adopting as a final rule, without change, an interim rule that amended the citrus canker regulations by removing a portion of Manatee County, FL, from the list of quarantined areas. The regulations require that an area be free from citrus canker for a period of at least 2 years before it may be removed from the list of quarantined areas. Surveys have shown that the Duette area of Manatee County, FL, has been free of citrus canker since February 4, 2000. The interim rule removed restrictions on the interstate movement of regulated articles from that portion of Manatee County, FL.

**EFFECTIVE DATE:** The interim rule became effective on May 8, 2002.

**FOR FURTHER INFORMATION CONTACT:** Mr. Stephen Poe, Operations Officer, Surveillance and Emergency Programs Planning and Coordination, PPQ, APHIS, 4700 River Road Unit 134, Riverdale, MD 20737-1231; (301) 734-8899.

#### SUPPLEMENTARY INFORMATION:

##### Background

In an interim rule effective and published in the **Federal Register** on May 8, 2002 (67 FR 30769-30771, Docket No. 02-029-1), we amended the citrus canker regulations in 7 CFR part

301 by removing a portion of Manatee County, FL, from the list of quarantined areas in § 301.75-4(a). The regulations require that an area be free from citrus canker for a period of at least 2 years before it may be removed from the list of quarantined areas, and surveys have shown that the 41-square-mile Duette area in eastern Manatee County, FL, has been free of citrus canker since February 4, 2000. Therefore, the interim rule removed restrictions on the interstate movement of regulated articles from that area.

Comments on the interim rule were required to be received on or before July 8, 2002. We did not receive any comments. Therefore, for the reasons given in the interim rule, we are adopting the interim rule as a final rule.

This action also affirms the information contained in the interim rule concerning Executive Order 12866 and the Regulatory Flexibility Act, Executive Orders 12372 and 12988, and the Paperwork Reduction Act.

Further, for this action, the Office of Management and Budget has waived its review under Executive Order 12866.

#### List of Subjects in 7 CFR Part 301

Agricultural commodities, Plant diseases and pests, Quarantine, Reporting and recordkeeping requirements, and Transportation.

#### PART 301—DOMESTIC QUARANTINE NOTICES

Accordingly, we are adopting as a final rule, without change, the interim rule that amended 7 CFR part 301 and that was published at 67 FR 30769-30771 on May 8, 2002.

**Authority:** 7 U.S.C. 166, 7711, 7712, 7714, 7731, 7735, 7751, 7752, 7753, and 7754; 7 CFR 2.22, 2.80, and 371.3.

Section 301.75-15 also issued under Sec. 204, Title II, Pub. L. 106-113, 113 Stat. 1501A-293; sections 301.75-15 and 301.75-16 also issued under Sec. 203, Title II, Pub. L. 106-224, 114 Stat. 400 (7 U.S.C. 1421 note).

Done in Washington, DC, this 7th day of August 2002.

**Peter Fernandez,**

*Acting Administrator, Animal and Plant Health Inspection Service.*

[FR Doc. 02-20330 Filed 8-9-02; 8:45 am]

**BILLING CODE 3410-34-P**

## DEPARTMENT OF AGRICULTURE

### Animal and Plant Health Inspection Service

#### 7 CFR Part 331

#### 9 CFR Part 121

[Docket No. 02-082-1]

RIN 0579-AB47

#### Agricultural Bioterrorism Protection Act of 2002; Listing of Biological Agents and Toxins and Requirements and Procedures for Notification of Possession

**AGENCY:** Animal and Plant Health Inspection Service, USDA.

**ACTION:** Interim rule and request for comments.

**SUMMARY:** In accordance with the Agricultural Bioterrorism Protection Act of 2002, we are establishing, by regulation, an initial list of biological agents and toxins determined to have the potential to pose a severe threat to animal or plant health, or to animal or plant products. The Act requires that all persons in possession of any listed biological agent or toxin must, within 60 days of the publication of this interim rule, notify the Secretary of such possession. This interim rule establishes the initial list of biological agents and toxins and provides guidance on the manner in which the required notice is to be provided.

**DATES:** This interim rule is effective August 12, 2002. We will consider all comments that we receive on or before October 11, 2002.

**ADDRESSES:** You may submit comments by postal mail/commercial delivery or by e-mail. If you use postal mail/commercial delivery, please send four copies of your comment (an original and three copies) to: Docket No. 02-082-1, Regulatory Analysis and Development, PPD, APHIS, Station 3C71, 4700 River Road Unit 118, Riverdale, MD 20737-1238. Please state that your comment refers to Docket No. 02-082-1. If you use e-mail, address your comment to [regulations@aphis.usda.gov](mailto:regulations@aphis.usda.gov). Your comment must be contained in the body of your message; do not send attached files. Please include your name and address in your message and "Docket No. 02-082-1" on the subject line.

You may read any comments that we receive on this docket in our reading room. The reading room is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 690-2817 before coming.

APHIS documents published in the **Federal Register**, and related information, including the names of organizations and individuals who have commented on APHIS dockets, are available on the Internet at <http://www.aphis.usda.gov/ppd/rad/webrepor.html>.

**FOR FURTHER INFORMATION CONTACT:** For information concerning the regulations in 7 CFR part 331, contact Dr. Arnold T. Tschanz, Senior Staff Officer, Regulatory Coordination, Plant Health Programs, PPQ, APHIS, 4700 River Road Unit 141, Riverdale, MD 20737-1236, (301) 734-8790.

For information concerning the regulations in 9 CFR part 121, contact Dr. Denise Spencer, Senior Staff Veterinarian, Technical Trade Services, National Center for Import and Export, VS, APHIS, 4700 River Road Unit 40, Riverdale, MD 20737-1231, (301) 734-3277.

#### SUPPLEMENTARY INFORMATION:

##### Background

The President signed into law the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Pub. L. 107-188) on June 12, 2002. Title II of Public Law 107 188, "Enhancing Controls on Dangerous Biological Agents and Toxins" (sections 201 through 231), provides for the regulation of certain biological agents and toxins by the Department of Health and Human Services (subtitle A, sections 201-204) and the Department of Agriculture (subtitle B, sections 211-213), and provides for interagency coordination between the two departments regarding overlap agents and toxins (subtitle C, section 221). Subtitle D (section 231) provides for criminal penalties regarding certain biological agents and toxins. For the Department of Health and Human Services, the Centers for Disease Control and Prevention (CDC) has been designated as the agency with primary responsibility for implementing the provisions of the Act; the Animal and Plant Health Inspection Service (APHIS) is the agency fulfilling that role for the Department of Agriculture (USDA).

In subtitle B (which is cited as the "Agricultural Bioterrorism Protection Act of 2002," referred to below as the Act), section 212(a) provides, in part, that the Secretary of Agriculture (the Secretary) must establish by regulation a list of each biological agent and each toxin that she determines has the potential to pose a severe threat to animal or plant health, or to animal or plant products. In determining whether to include an agent or toxin on the list, the Act requires the Secretary to consider:

- The effect of exposure to the agent or toxin on animal or plant health, and on the production and marketability of animal or plant products;
- The pathogenicity of the agent or the toxicity of the toxin and the methods by which the agent or toxin is transferred to animals or plants;
- The availability and effectiveness of pharmacotherapies and prophylaxis to treat and prevent any illness caused by the agent or toxin; and
- Any other criteria that the Secretary considers appropriate to protect animal or plant health, or animal or plant products.

The Act also calls on the Secretary to consult with appropriate Federal departments and agencies and with scientific experts representing appropriate professional groups.

Under section 213(a) of the Act, the Secretary must, not later than 60 days after the Act's date of enactment (*i.e.*, by August 11, 2002), promulgate an interim final rule that establishes the initial list required under section 212(a). The Act further requires (under section 213(b)) that all persons in possession of any listed biological agent or toxin must, within 60 days of the publication of that interim rule, notify the Secretary of such possession; the Act provides that the interim rule establishing the list must also furnish written guidance on the manner in which the required notice is to be provided.

In accordance with the statutory requirements discussed above, this interim rule establishes the initial lists of biological agents and toxins and sets out the manner in which persons in possession of listed agents and toxins are to provide notice of such possession. To accomplish this, we are establishing new parts in the Code of Federal Regulations (CFR), one part in the plant-related provisions of title 7, chapter III, and one part in the animal-related provisions of title 9, chapter I.

The two new parts, 7 CFR part 331 and 9 CFR part 121, are both titled "Possession of Biological Agents and Toxins" and are constructed similarly: Each contains a section that provides

definitions for specific terms used in the part, a section in which the list of biological agents and toxins is set out, and a section that provides guidance on the manner in which the required notice is to be provided. The main difference between the two parts is in the lists: The regulations in 7 CFR part 331 list only those agents and toxins determined to have the potential to pose a severe threat to plant health or to the production and marketability of plant products, while the regulations in 9 CFR part 121 list those agents and toxins determined to have the potential to pose a severe threat to both human and animal health ("overlap agents and toxins"), to animal health, or to the production and marketability of animal products. These new parts are discussed in detail below.

##### Definitions

Both 7 CFR part 331 and 9 CFR part 121 begin with a definitions section, §§ 331.1 and 121.1, respectively. With one exception, the terms defined in each section are the same. Specifically, we define the terms *biological agent*, *facility*, *person*, *responsible facility official*, and *toxin* in both parts, while the term *overlap agent or toxin* is defined only in 9 CFR 121.1 (this term is not applicable to the plant-related regulations in 7 CFR part 331).

The definitions of *biological agent* and *toxin* are taken from 18 U.S.C. 178. Section 212(l) of the Act provides that "[t]he terms 'biological agent' and 'toxin' have the meanings given such terms in section 178 of title 18, United States Code." Thus, we define *biological agent* as "any microorganism, virus, infectious substance, or biological product that may be engineered as a result of biotechnology, or any naturally occurring or bioengineered component of any such microorganism, virus, infectious substance, or biological product, 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." *Toxin* is defined as "the toxic material of plants, animals, microorganisms, viruses, fungi, or infectious substances, or a recombinant molecule, whatever its origin or method of production, including: (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."

In 9 CFR 121.1, we also define the term *overlap agent or toxin*. The definition we use is based on the definition provided for the term “select agent” in the CDC’s regulations in 42 CFR 72.6(j). In appendix A to 42 CFR part 72, CDC provides a list of 36 select agents, 18 of which are microorganisms or toxins that pose a risk to both human and animal health. Those 18 microorganisms and toxins are listed as “overlap agents or toxins” in our regulations in § 121.2(a) and are characterized in the same manner by CDC for the purposes of carrying out its responsibilities under the Act.

Given that the agents and toxins listed in § 121.2(a) were drawn from the CDC’s list of select agents, we believe that it is appropriate to adapt the CDC definition of the term “select agent” for use as our definition of the term “overlap agent or toxin” in order to provide regulated entities with a consistent frame of reference. Therefore, in 9 CFR 121.1, *overlap agent or toxin* is defined as “a microorganism (including a virus, bacterium, fungus, rickettsia) or toxin that poses a risk to both human and animal health and that is listed in § 121.2(a). The term also includes: (1) Genetically modified microorganisms or genetic elements from organisms listed in § 121.2(a), shown to produce or encode for a factor associated with a disease; and (2) genetically modified microorganisms or genetic elements that contain nucleic acid sequences coding for any of the toxins listed in § 121.2(a), or their toxic subunits.”

The remaining three terms, which are defined in both 7 CFR 331.1 and 9 CFR 121.1, are *facility*, *responsible facility official*, and *person*. Like our definition of *overlap agent or toxin*, our regulations define the first two terms in the same manner as they are defined in CDC’s regulations in 42 CFR 72.6(j) in order to provide a consistent frame of reference. *Facility* is defined as “any individual or government agency, university, corporation, company, partnership, society, association, firm, or other legal entity located at a single geographic site that may transfer or receive through any means a biological agent or toxin subject to this part.” Generally speaking, “a single geographic site” can be viewed as the complex of buildings and laboratories at a single mailing address.

*Responsible facility official* is defined as “an official authorized to transfer and receive biological agents or toxins covered by this part on behalf of a facility. This person should be either a safety officer, a senior management official of the facility, or both. The responsible facility official should not

be an individual who actually transfers or receives a biological agent or toxin at the facility.” For the purposes of clarity, the definition of this term in 9 CFR 121.1 includes the words “including overlap agents and toxins” after the words “authorized to transfer and receive biological agents or toxins.”

We have defined *person* as “any individual, firm, corporation, company, society, or association; any Federal, State, or local governmental entity; or any organized group of any of the foregoing.” Where this term is defined elsewhere in our regulations in titles 7 and 9, the scope of the definition is limited to individuals, companies, and other legal entities. However, section 212(l)(5) of the Act, in defining “person,” stipulates that the term includes Federal, State, and local governmental entities.

#### *Lists of Biological Agents and Toxins*

The initial lists of biological agents and toxins required under section 212(a)(1) of the Act are located in 7 CFR 331.2 and 9 CFR 121.2. The Act requires that these lists be reviewed and republished biennially, or more often as needed, and revised as necessary.

The list of nine biological agents and toxins provided in 7 CFR 331.2 was compiled by APHIS’ Plant Protection and Quarantine (PPQ) program. The listed agents and toxins are viruses, bacteria, or fungi that can pose a severe threat to a number of important crops, including potatoes, rice, soybeans, corn, citrus, and stone fruit. PPQ staff, after internal discussions and a review of several existing or proposed lists of plant pathogens that potentially pose a severe threat to plant health or plant products, requested input from USDA’s Agricultural Research Service, Forest Service, and Cooperative State Research, Education, and Extension Service, and consulted with the American Phytopathological Society. The resulting list of agents and toxins identified as potentially posing a severe threat to plant health or plant products is as follows:

*Liberobacter africanus*, *Liberobacter asiaticus*  
*Peronosclerospora philippinensis*  
*Phakopsora pachyrhizi*  
 Plum pox potyvirus  
*Ralstonia solanacearum* Race 3  
*Sclerophthora rayssiae* var. *zeae*  
*Synchytrium endobioticum*  
*Xanthomonas oryzae* pv. *oryzicola*  
*Xylella fastidiosa* (citrus variegated chlorosis strain)

The list of 18 overlap agents and toxins in 9 CFR 121.2(a) was, as noted previously, drawn from CDC’s list of 36

select agents, the 18 listed in our regulations being those select agents that pose a risk to both human and animal health. In June 2002, CDC convened an interagency working group to review the list of 36 select agents and develop recommendations regarding possible changes to that list. CDC has reviewed those recommendations and intends publish a document in the **Federal Register** to solicit comments from the public on potential changes to its list of select agents. Because the process of changing the list of select agents is still in its initial stages at the time this interim rule is being published, the list of overlap agents and toxins found in 9 CFR 121.2(a) reflects the select agent list promulgated by CDC in October 1996. The overlap agents and toxins listed in 9 CFR 121.2(a) are:

*Bacillus anthracis*  
*Brucella abortus*, *B. melitensis*, *B. suis*  
*Burkholderia (Pseudomonas) mallei*  
*Burkholderia (Pseudomonas) pseudomallei*  
*Clostridium botulinum*  
*Coccidioides immitis*  
*Coxiella burnetii*  
 Eastern equine encephalitis virus  
 Equine morbillivirus (Hendra virus)  
*Francisella tularensis*  
 Rift Valley fever virus  
 Venezuelan equine encephalitis virus  
 Aflatoxins  
 Botulinum toxins  
*Clostridium perfringens* epsilon toxin  
 Shigatoxin  
 Staphylococcal enterotoxins  
 T-2 toxin

The 23 agents and toxins listed in 9 CFR 121.2(b) include the causative agents of 14 of the 15 diseases classified by the Office International des Epizooties (OIE) as “List A” diseases. (The causative agent of the fifteenth List A disease, Rift Valley fever, is an overlap agent listed in § 121.2(a).) List A diseases are, according to OIE, those transmissible diseases that have the potential for very serious and rapid spread, irrespective of national borders, that are of serious socioeconomic or public health consequence and that are of major importance in the international trade of animals and animal products. The diseases drawn from OIE’s List A are:

African horsesickness  
 African swine fever  
 Bluetongue (exotic)  
 Classical swine fever  
 Contagious bovine pleuropneumonia  
 Foot-and-mouth disease  
 Highly pathogenic avian influenza  
 Lumpy skin disease  
 Newcastle disease (exotic)  
 Peste des petits ruminants

Rinderpest  
 Sheep pox and goat pox  
 Swine vesicular disease  
 Vesicular stomatitis (exotic)

Five of the remaining nine agents and toxins listed in 9 CFR 121.2(b) are OIE List B diseases, *i.e.*, transmissible diseases that are considered to be of socioeconomic and/or public health importance within countries and that are significant in the international trade of animals and animal products. The List B diseases included in 9 CFR 121.2(b) are:

Bovine spongiform encephalopathy  
*Cowdria ruminantium* (heartwater)  
 Japanese encephalitis virus  
 Malignant catarrhal fever  
 Contagious caprine pleuropneumonia

The four remaining diseases/disease agents—two restricted foreign animal pathogens (Akabane virus and camel pox virus) and two emerging paramyxoviruses (Menangle virus and Nipah virus)—were included on the list in 9 CFR 121.2(b) based on our determination that they potentially pose a severe threat to animal health or animal products.

#### *Exemptions From the Notification Requirement*

Under section 212(g)(1)(C) of the Act, certain products that are, bear, or contain overlap agents or toxins may be exempted from regulation if those products have been cleared, approved, licensed, or registered pursuant to one of the following acts:

- The Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 *et seq.*);
- Section 351 of Public Health Service Act (42 U.S.C. 262);
- The Act commonly known as the Virus-Serum-Toxin Act (the eighth paragraph under the heading “Bureau of Animal Industry” in the Act of March 4, 1913; 21 U.S.C. 151–159); or
- The Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 131 *et seq.*).

Paragraph (b) of § 213 of the Act extends that exemption provision to the notification requirements that are the subject of this interim rule. Therefore, the regulations 9 CFR 121.2(c) provide that persons possessing products that are, bear, or contain overlap agents or toxins listed in 9 CFR 121.2(a) will be exempt from the notification requirements of 9 CFR 121.3 if the products have been cleared, approved, licensed, or registered pursuant to one of the acts cited above.

Because the exemption under section 212(g)(1)(C) of the Act is limited to overlap agents and toxins, none of which appear in 7 CFR 331.2, we have

not included those exemption provisions in the regulations in 7 CFR part 331. Further, while the Act, in section 212(g)(2), does provide general authority for exemptions not involving overlap agents or toxins when the Secretary determines that such exemptions are consistent with protecting animal and plant health and animal and plant products, no determination has yet been made with regard to exemptions other than those discussed above.

#### *Notification Requirements and Procedures*

Under section 213(b) of the Act, all persons (unless exempt under section 212(g) of the Act) in possession of a listed biological agent or toxin must notify the Secretary of such possession not later than 60 days after the date on which the interim rule required under section 212(a)(1) of the Act—*i.e.*, this interim rule—is promulgated. Therefore, 7 CFR 331.3 and 9 CFR 121.3 both provide that any person or facility that possesses any listed biological agent or toxin must notify APHIS of such possession by 60 days after the publication date of this interim rule. However, the regulations in 9 CFR 121.3 provide that persons possessing overlap agents or toxins listed in § 121.2(a)—which, as noted previously, are among CDC’s select agents—must provide the required notification by September 10, 2002, which is the date that notice must be provided to CDC under subtitle A of Public Law 107–188. Further, the regulations in 9 CFR 121.3 make note of the exemptions discussed above and state that notification is not required for those products that meet the criteria of 9 CFR 121.2(c). The regulations in both 7 CFR 331.3 and 9 CFR 121.3 indicate the form to be used to provide the required notification (one form will be used for notification under 7 CFR part 331, and a different form will be used for notification under 9 CFR part 121) and explain where copies of each form may be obtained.

To facilitate the notification process, both sections provide that a single form should be submitted for each facility by a responsible facility official designated by the facility to ensure management oversight of the notification requirement, and that the responsible facility official should consult with others in the facility (*e.g.*, principal investigators) in order to obtain the information necessary to complete the notification form. The responsible facility official must review and sign the notification form and will be the individual contacted by APHIS if any

questions arise concerning the facility’s response.

Finally, both sections provide a mailing address for the submission of completed forms, as well as a telephone number to call if assistance in completing the form is required.

#### **Immediate Action**

Immediate action is necessary in order for USDA to comply with the requirements of Title II, subtitle B, of Public Law 107–188, which requires the publication of this interim rule not later than August 11, 2002. Under these circumstances, the Administrator has determined that prior notice and opportunity for public comment are contrary to the public interest and that there is good cause under 5 U.S.C. 553 for making this rule effective less than 30 days after publication in the **Federal Register**.

We will consider comments that are received within 60 days of publication of this rule in the **Federal Register**. After the comment period closes, we will publish another document in the **Federal Register**. The document will include a discussion of any comments we receive and any amendments we are making to the rule as a result of the comments.

#### **Executive Order 12866 and Regulatory Flexibility Act**

This rule has been reviewed under Executive Order 12866. The rule has been determined to be significant for the purposes of Executive Order 12866 and, therefore, has been reviewed by the Office of Management and Budget.

In this interim rule, we are establishing, by regulation, an initial list of biological agents and toxins determined to have the potential to pose a severe threat to animal or plant health, or to animal or plant products. The Agricultural Bioterrorism Protection Act of 2002 requires that all persons in possession of any listed biological agent or toxin must, within 60 days of the publication of this interim rule, notify the Secretary of such possession. This interim rule establishes the initial list of biological agents and toxins and provides guidance on the manner in which the required notice is to be provided.

The Regulatory Flexibility Act requires that agencies specifically consider the economic effects of their rules on small entities. We expect that the entities that will be affected by this rule will be laboratories and other institutions conducting research and related activities that involve the use of the biological agents and toxins listed in this rule. Most affected entities (apart

from Federal or State governmental entities) could be considered as falling under North American Industry Classification System (NAICS) code 541710, "Research and Development in the Physical, Engineering, and Life Sciences." The small business size standard established by the Small Business Administration for NAICS 541710 is 500 or fewer employees. Potentially affected entities could also fall under NAICS 541990, "All Other Professional, Scientific and Technical Services," and NAICS 611310, "Colleges, Universities and Professional Schools." The small business size standard for both of those classifications is annual receipts of \$6 million or less.

Given that this interim rule simply requires that persons possessing a listed biological agent or toxin provide notice to APHIS of such possession, we do not expect that this rule will have any substantive economic effect on any entities, large or small. We expect that any costs associated with this rule will be limited to the staff time expended in completing a notification form. This rule provides for the submission of only one form for each facility, which should limit the amount of time necessary for the preparation of a facility's response. Further, we would expect that any facility handling the kinds of biological agents and toxins listed in this rule would have a database or other records containing a listing of agents and toxins currently in the facility. Therefore, we anticipate that any personnel costs resulting from compliance with this rule should be minimal.

The benefit of this action is enhanced protection of the U.S. agricultural sector as APHIS will have a detailed inventory of biological agents and toxins that could pose a threat to the sector.

Under these circumstances, the Administrator of the Animal and Plant Health Inspection Service has determined that this action will not have a significant economic impact on a substantial number of small entities.

#### **Executive Order 12372**

This program/activity is listed in the Catalog of Federal Domestic Assistance under No. 10.025 and is subject to Executive Order 12372, which requires intergovernmental consultation with State and local officials. (See 7 CFR part 3015, subpart V.)

#### **Executive Order 12988**

This rule has been reviewed under Executive Order 12988, Civil Justice Reform. This rule: (1) Preempts all State and local laws and regulations that are inconsistent with this rule; (2) has no retroactive effect; and (3) does not

require administrative proceedings before parties may file suit in court challenging this rule.

#### **Paperwork Reduction Act**

In accordance with section 3507(j) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the information collection and recordkeeping requirements included in this interim rule have been submitted for emergency approval to the Office of Management and Budget (OMB). OMB has assigned control numbers 0579-0201 and 0579-0204 to the information collection and recordkeeping requirements.

We plan to request continuation of that approval for 6 months. Please send written comments on the 6-month approval request to the following addresses: (1) Office of Information and Regulatory Affairs, OMB, Attention: Desk Officer for APHIS, Washington, DC 20503; and (2) Docket No. 02-082-1, Regulatory Analysis and Development, PPD, APHIS, Station 3C71, 4700 River Road Unit 118, Riverdale, MD 20737-1238. Please state that your comments refer to Docket No. 02-082-1 and send your comments within 60 days of publication of this rule.

This rule establishes an initial list of biological agents and toxins determined to have the potential to pose a severe threat to animal or plant health, or to animal or plant products, and requires that all persons in possession of any listed biological agent or toxin must, within 60 days of the publication of this interim rule, notify the Secretary of such possession.

Two forms have been developed to provide the means by which persons in possession of listed agents or toxins will notify the Secretary of such possession. The first form, "Notification of Possession of Select Agents or High Consequence Livestock Pathogens and Toxins," was developed jointly by APHIS and the Centers for Disease Control and Prevention and will be used by persons possessing those agents and toxins determined to have the potential to pose a severe threat to human health, to both human and animal health ("overlap agents and toxins"), to animal health, or to the production and marketability of animal products. The second form, PPQ form 655, was developed by APHIS and will be used by persons possessing those agents and toxins determined to have the potential to pose a severe threat to plant health or to the production and marketability of plant products. We expect that the scope and nature of the research required to complete PPQ form 655 will be less complex than that associated with the first form, thus we have

estimated a smaller reporting burden per response for this form.

We are soliciting comments from the public concerning our information collection and recordkeeping requirements. These comments will help us:

(1) Evaluate whether the information collection is necessary for the proper performance of our agency's functions, including whether the information will have practical utility;

(2) Evaluate the accuracy of our estimate of the burden of the information collection, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the information collection on those who are to respond (such as through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology; *e.g.*, permitting electronic submission of responses).

*For "Notification of Possession of Select Agents or High Consequence Livestock Pathogens and Toxins," (OMB Control No. 0579-0201):*

*Estimate of burden:* Public reporting burden for this collection of information is estimated to average 2 hours per response.

*Respondents:* Researchers, universities, research and development organizations, diagnostic laboratories, and other entities that possess listed agents and toxins determined to have the potential to pose a severe threat to human health, to both human and animal health, or to the production and marketability of animal products.

*Estimated annual number of respondents:* 50,000.

*Estimated annual number of responses per respondent:* 1.

*Estimated annual number of responses:* 50,000.

*Estimated total annual burden on respondents:* 100,000 hours.

*For PPQ form 655 (OMB Control No. 0579-0204):*

*Estimate of burden:* Public reporting burden for this collection of information is estimated to average 0.5 hours per response.

*Respondents:* Researchers, universities, research and development organizations, diagnostic laboratories, and other entities that possess listed agents and toxins determined to have the potential to pose a severe threat to plant health or to the production and marketability of plant products.

*Estimated annual number of respondents:* 1,000.

*Estimated annual number of responses per respondent:* 1.

*Estimated annual number of responses:* 1,000.

*Estimated total annual burden on respondents:* 500 hours.

(Due to averaging, the total annual burden hours may not equal the product of the annual number of responses multiplied by the reporting burden per response.)

Copies of this information collection can be obtained from Mrs. Celeste Sickles, APHIS' Information Collection Coordinator, at (301) 734-7477.

### List of Subjects

#### 7 CFR Part 331

Agricultural research, Laboratories, Plant diseases and pests, Reporting and recordkeeping requirements.

#### 9 CFR Part 121

Agricultural research, Animal diseases, Laboratories, Medical research, Reporting and recordkeeping requirements.

Accordingly, we are amending 7 CFR chapter III by removing the heading for reserved part 331 and adding a new part 331; and we are amending 9 CFR chapter I, subchapter E, by adding a new part 121 to read as follows:

#### 7 CFR Chapter III

### PART 331—POSSESSION OF BIOLOGICAL AGENTS AND TOXINS

#### Sec.

331.1 Definitions.

331.2 List of biological agents and toxins.

331.3 Notification requirements and procedures.

**Authority:** Secs. 211-213, Title II, Pub. L. 107-188, 116 Stat. 647 (7 U.S.C. 8401).

#### § 331.1 Definitions.

**Biological agent.** Any microorganism, virus, infectious substance, or biological product that may be engineered as a result of biotechnology, or any naturally occurring or bioengineered component of any such microorganism, virus, infectious substance, or biological product, 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.

**Facility.** Any individual or government agency, university, corporation, company, partnership, society, association, firm, or other legal

entity located at a single geographic site that may transfer or receive through any means a biological agent or toxin subject to this part.

**Person.** Any individual, firm, corporation, company, society, or association; any Federal, State, or local governmental entity; or any organized group of any of the foregoing.

**Responsible facility official.** An official authorized to transfer and receive biological agents or toxins covered by this part on behalf of a facility. This person should be either a safety officer, a senior management official of the facility, or both. The responsible facility official should not be an individual who actually transfers or receives a biological agent or toxin at the facility.

**Toxin.** The toxic material of plants, animals, microorganisms, viruses, fungi, or infectious substances, or a recombinant molecule, whatever its origin or method of production, including:

- (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.

#### § 331.2 List of biological agents and toxins.

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 the production and marketability of plant products. Any person who possesses any listed agent or toxin or, in the case of a listed disease, the causative agent of that disease, must notify the Animal and Plant Health Inspection Service of that possession in accordance with § 331.3.

*Liberobacter africanus*, *Liberobacter asiaticus*  
*Peronosclerospora philippinensis*  
*Phakopsora pachyrhizi*  
 Plum pox potyvirus  
*Ralstonia solanacearum* Race 3  
*Sclerophthora rayssiae* var. *zeae*  
*Synchytrium endobioticum*  
*Xanthomonas oryzae* pv. *oryzicola*  
*Xylella fastidiosa* (citrus variegated chlorosis strain)

#### § 331.3 Notification requirements and procedures.

(a) Any person or facility that possesses any biological agent or toxin listed in § 331.2 must notify the Animal and Plant Health Inspection Service (APHIS) of such possession by October 11, 2002. Notice must be provided using Plant Protection and Quarantine (PPQ) form 655, which may be obtained by

calling PPQ at (301) 734-8896. The form is also available on the Internet at <http://www.aphis.usda.gov/ppq/permits>.

(b) Each facility should designate a responsible facility official to complete PPQ form 655, and a single form that reflects all listed agents and toxins possessed by all persons within the facility should be submitted for each facility. The responsible facility official for each facility should consult with others in the facility (e.g., principal investigators) in order to obtain the information necessary to complete the notification form. The responsible facility official must review and sign the notification form and will be the individual contacted by APHIS if any questions arise concerning the facility's response.

(c) Completed forms must be mailed to: U.S. Department of Agriculture, Animal and Plant Health Inspection Service, Plant Protection and Quarantine, Permits and Risk Assessment, 4700 River Road Unit 133, Riverdale, Md 20737-1236.

(d) Assistance in completing the form may be requested by calling (301) 734-8896.

(Approved by the Office of Management and Budget under control number 0579-0204)

#### 9 CFR Chapter I

### PART 121—POSSESSION OF BIOLOGICAL AGENTS AND TOXINS

#### Sec.

121.1 Definitions.

121.2 List of biological agents and toxins.

121.3 Notification requirements and procedures.

**Authority:** Secs. 211-213, Title II, Pub. L. 107-188, 116 Stat. 647 (7 U.S.C. 8401).

#### § 121.1 Definitions.

**Biological agent.** Any microorganism, virus, infectious substance, or biological product that may be engineered as a result of biotechnology, or any naturally occurring or bioengineered component of any such microorganism, virus, infectious substance, or biological product, 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.

**Facility.** Any individual or government agency, university, corporation, company, partnership, society, association, firm, or other legal entity located at a single geographic site that may transfer or receive through any

means a biological agent or toxin subject to this part.

*Overlap agent or toxin.* A microorganism (including a virus, bacterium, fungus, rickettsia) or toxin that poses a risk to both human and animal health and that is listed in § 121.2(a). The term also includes:

(1) Genetically modified microorganisms or genetic elements from organisms listed in § 121.2(a), shown to produce or encode for a factor associated with a disease; and

(2) Genetically modified microorganisms or genetic elements that contain nucleic acid sequences coding for any of the toxins listed in § 121.2(a), or their toxic subunits.

*Person.* Any individual, firm, corporation, company, society, or association; any Federal, State, or local governmental entity; or any organized group of any of the foregoing.

*Responsible facility official.* An official authorized to transfer and receive biological agents or toxins, including overlap agents and toxins, covered by this part on behalf of a facility. This person should be either a safety officer, a senior management official of the facility, or both. The responsible facility official should not be an individual who actually transfers or receives a biological agent or toxin at the facility.

*Toxin.* The toxic material of plants, animals, microorganisms, viruses, fungi, or infectious substances, or a recombinant molecule, whatever its origin or method of production, including:

(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.

#### § 121.2 List of biological agents and toxins.

The biological agents and toxins listed in this section have been determined to have the potential to pose a severe threat to both human and animal health, to animal health, or to the production and marketability of animal products. Unless exempted under paragraph (c) of this section, any person who possesses any listed agent or toxin or, in the case of a listed disease, the causative agent of that disease, must notify the Animal and Plant Health Inspection Service of that possession in accordance with § 121.3.

(a) *Overlap agents and toxins.*

(1) *Bacillus anthracis.*

(2) *Brucella abortus, B. melitensis, B. suis.*

(3) *Burkholderia (Pseudomonas) mallei.*

(4) *Burkholderia (Pseudomonas) pseudomallei.*

(5) *Clostridium botulinum.*

(6) *Coccidioides immitis.*

(7) *Coxiella burnetii.*

(8) Eastern equine encephalitis virus.

(9) Equine morbillivirus (Hendra virus).

(10) *Francisella tularensis.*

(11) Rift Valley fever virus.

(12) Venezuelan equine encephalitis virus.

(13) Aflatoxins.

(14) Botulinum toxins.

(15) *Clostridium perfringens* epsilon toxin.

(16) Shigatoxin.

(17) Staphylococcal enterotoxins.

(18) T-2 toxin.

(b) *Animal agents and toxins.*

African horsesickness virus

African swine fever

Akabane virus

Avian influenza (highly pathogenic)

Bluetongue virus (exotic)

Bovine spongiform encephalopathy agent

Camel pox virus

Classical swine fever

*Cowdria ruminantium* (heartwater)

Foot-and-mouth disease virus

Goat pox virus

Japanese encephalitis virus

Lumpy skin disease virus

Malignant catarrhal fever

Menangle virus

*Mycoplasma capricolum* /M. F38/M.

*mycoides capri* (contagious caprine pleuropneumonia)

*Mycoplasma mycoides mycoides* (contagious bovine pleuropneumonia)

Newcastle disease virus (exotic)

Nipah virus

Peste des petits ruminants

Rinderpest virus

Sheep pox

Swine vesicular disease virus

Vesicular stomatitis (exotic)

(c) *Exemptions.* Persons possessing products that are, bear, or contain overlap agents or toxins listed in paragraph (a) of this section will be exempt from the notification requirements of § 121.3 if the products have been cleared, approved, licensed, or registered pursuant to:

(1) The Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 *et seq.*);

(2) Section 351 of Public Health Service Act (42 U.S.C. 262);

(3) The Act commonly known as the Virus-Serum-Toxin Act (the eighth paragraph under the heading "Bureau of Animal Industry" in the Act of March 4, 1913; 21 U.S.C. 151-159); or

(4) The Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 131 *et seq.*).

#### § 121.3 Notification requirements and procedures.

(a) Any person or facility that possesses any biological agent or toxin listed in § 121.2(b) must notify the Animal and Plant Health Inspection Service (APHIS) of such possession by October 11, 2002. Any person or facility that possesses any biological agent or toxin listed in § 121.2(a) that is not exempt under § 121.2(c) must notify APHIS of such possession by September 10, 2002. Notice must be provided using the form "Notification of Possession of Select Agents or High Consequence Livestock Pathogens and Toxins." A machine-readable version of the form may be obtained by calling (866) 567-4232. An alternate version of the form is available on the Internet at <http://www.aphis.usda.gov/vs/ncie>.

(b) Each facility should designate a responsible facility official to complete the form, and a single form that reflects all listed agents and toxins possessed by all persons within the facility should be submitted for each facility. The responsible facility official for each facility should consult with others in the facility (*e.g.*, principal investigators) in order to obtain the information necessary to complete the notification form. The responsible facility official must review and sign the notification form and will be the individual contacted by APHIS if any questions arise concerning the facility's response.

(c) Completed forms must be mailed to: Analytical Sciences, Inc., Attn: FSO P.O. Box 341809, Bethesda, MD 20827-1809.

(d) Assistance in completing the form available on the Internet may be requested by calling (301) 734-3222. Assistance in completing the machine-readable form may be obtained by calling (866) 567-4232.

(Approved by the Office of Management and Budget under control number 0579-0201)

Done in Washington, DC, this 7th day of August, 2002.

**Bill Hawks,**

*Under Secretary for Marketing and Regulatory Programs.*

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