

Proposed Rules

Federal Register

Vol. 75, No. 145

Thursday, July 29, 2010

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

7 CFR Part 331

9 CFR Part 121

[Docket No. APHIS-2009-0070]

RIN 0579-AD09

Agricultural Bioterrorism Protection Act of 2002; Biennial Review and Republication of the Select Agent and Toxin List; Reorganization of the Select Agent and Toxin List

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Advance notice of proposed rulemaking and request for comments.

SUMMARY: In accordance with the Agricultural Bioterrorism Protection Act of 2002, we are soliciting public comment regarding the list of select agents and toxins that have the potential to pose a severe threat to animal or plant health, or to animal or plant products. The Act requires the biennial review and republication of the list of select agents and toxins and the revision of the list as necessary. Accordingly, we are soliciting public comment on the current list of select agents and toxins in our regulations and suggestions regarding any addition or reduction of the animal or plant pathogens currently on the list of select agents. In addition, we are soliciting public comment on the potential reorganization of the list of select agents and toxins based on the relative potential of each select agent or toxin to be misused to adversely affect human, plant or animal health. Such tiering of the list could allow for the application of different security measures for those select agents or toxins which pose a higher risk to animal or plant health if they were to be stolen or otherwise misused.

DATES: We will consider all comments that we receive on or before August 30, 2010.

ADDRESSES: You may submit comments by either of the following methods:

• Federal eRulemaking Portal: Go to (<http://www.regulations.gov/fdmspublic/component/main?main=DocketDetail&d=APHIS-2009-0070>) to submit or view comments.

• Postal Mail/Commercial Delivery: Please send two copies of your comment to Docket No. APHIS-2009-0070, Regulatory Analysis and Development, PPD, APHIS, Station 3A-03.8, 4700 River Road Unit 118, Riverdale, MD 20737-1238. Please state that your comment refers to Docket No. APHIS-2009-0070.

Reading Room: 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.

Other Information: Additional information about APHIS and its programs is available on the Internet at (<http://www.aphis.usda.gov>).

FOR FURTHER INFORMATION CONTACT: Ms. Aimee M. Hyten, Compliance Manager, APHIS Agriculture Select Agent Program, PPQ, APHIS, 4700 River Road Unit 2, Riverdale, MD 20737-1236; (301) 734-5281.

SUPPLEMENTARY INFORMATION:

Background

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 provides for the regulation of certain biological agents and toxins that have the potential to pose a severe threat to both human and animal health, to animal health, to plant health, or to animal and plant products. The Animal and Plant Health Inspection Service (APHIS) has the primary responsibility for implementing the provisions of the Act within the Department of Agriculture (USDA). Veterinary Services (VS) select agents and toxins, listed in 9 CFR 121.3, are those that have been determined to have the potential to pose a severe threat to animal health or animal products. Plant Protection and Quarantine (PPQ) select agents and toxins, listed in 7 CFR 331.3,

are those that have been determined to have the potential to pose a severe threat to plant health or plant products. Overlap select agents and toxins, listed in 9 CFR 121.4, are those that have been determined to pose a severe threat to public health and safety, to animal health, or to animal products. Overlap select agents are subject to regulation by both APHIS and the Centers for Disease Control and Prevention, which has the primary responsibility for implementing the provisions of the Act for the Department of Health and Human Services.

Title II, Subtitle B of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (which is cited as the "Agricultural Bioterrorism Protection Act of 2002" and 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 the Secretary 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 in the list, the Act requires that the following criteria be considered:

- 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 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.

Paragraph (a)(2) of section 212 of the Act requires the Secretary to review and republish the list of select agents and toxins every 2 years and to revise the list as necessary. To fulfill this statutory mandate, PPQ and VS each convene separate interagency working groups in order to review the lists of PPQ and VS select agents and toxins, as well as any overlap select agents and toxins, and develop recommendations regarding possible changes to the list using the four criteria for listing found in the Act. In this document, we are asking for

comments on the current list¹ of select agents and toxins and on any other significant pathogens so as to inform the working groups as they begin the biennial review process.

Reorganization of Current List of Select Agents and Toxins

We are also seeking public comment regarding potential reorganization of the list of select agents and toxins. Recent reports by the National Academies, the Executive Order 13486 Working Group, and the National Science Advisory Board for Biosecurity have recommended tiering the list of select agents and toxins based on the relative potential of each to be misused. If implemented, such tiering could allow for the application of different security measures for those select agents or toxins that pose a higher risk to animal or plant health if they were to be stolen or otherwise misused.

For those commenters who believe tiering the list of select agents and toxins is advisable, we also welcome recommendations as to what criteria should be used to designate high risk select agents and toxins. For example, potential tiering of the select agent and toxin list could reflect one or more of the following:

- The relative ease with which a particular select agent or toxin might be disseminated or transmitted from one animal to another or into the environment where it could produce a deleterious effect upon animal or plant health;
- The potential for high animal or plant mortality rates;
- The potential for a major animal or plant health impact;
- Select agents or toxins whose misuse might result in public panic or other social or economic disruption;
- Select agents or toxins whose use might require Federal, State, and/or local officials to take special action in planning for major animal or plant health disasters.

Additionally, we are interested in any potential corresponding changes to the security requirements of the current regulations that would be necessary to provide appropriate protection of higher tier select agents or toxins and whether such changes should be prescriptive or performance based.

At the conclusion of the working group review process, we will publish another document in the **Federal Register** either republishing the lists of select agents and toxins in 7 CFR 331.3,

9 CFR 121.3, and 9 CFR 121.4 or proposing changes to one or more of the lists. The document may also include reorganization of the lists of select agents and toxins via tiering of the select agents or toxins themselves and/or tiered security requirements.

This action 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.

Authority: 7 U.S.C. 8401; 7 CFR 2.22, 2.80, 371.3, and 371.4.

Done in Washington, DC, this 22nd day of July 2010.

John Ferrell

Deputy Under Secretary for Marketing and Regulatory Programs.

[FR Doc. 2010-18581 Filed 7-28-10; 8:45 am]

BILLING CODE 3410-34-S

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA-2010-0725; Directorate Identifier 2010-NE-18-AD]

RIN 2120-AA64

Airworthiness Directives; Pratt & Whitney PW4000 Series Turbofan Engines; Correction

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM); correction.

SUMMARY: The FAA is correcting a proposed airworthiness directive (AD) which published in the **Federal Register**. That proposed AD would apply to Pratt & Whitney PW4000 series turbofan engines. The docket number is incorrect in all three of its locations. This document corrects those references. In all other respects, the original document remains the same.

DATES: This correction is effective July 29, 2010.

FOR FURTHER INFORMATION CONTACT: James Gray, Aerospace Engineer, Engine Certification Office, FAA, Engine and Propeller Directorate, 12 New England Executive Park, Burlington, MA 01803; e-mail: james.e.gray@faa.gov; telephone (781) 238-7742; fax (781) 238-7199.

SUPPLEMENTARY INFORMATION: On June 3, 2010 (75 FR 31330), we published a proposed AD, FR Doc. 2010-13314, in the **Federal Register**. That proposed AD applies to Pratt & Whitney PW4000 series turbofan engines. We need to make the following correction:

On page 31330, in the third column, under 14 CFR part 39, "Docket No. FAA-2010-0384" is corrected to read "FAA-2010-0725."

On page 31331, in the first column, under **SUPPLEMENTARY INFORMATION**, in the sixth and seventh lines, "Docket No. FAA 2010-0384" is corrected to read "FAA-2010-0725."

On page 31331, in the third column, under § 39.13 [Amended], in the fourth and fifth lines, "Docket No. FAA 2010-0384" is corrected to read "FAA-2010-0725."

Issued in Burlington, Massachusetts, on July 23, 2010.

Francis A. Favara,

Manager, Engine and Propeller Directorate, Aircraft Certification Service.

[FR Doc. 2010-18628 Filed 7-28-10; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA-2010-0634; Airspace Docket No. 10-AWP-8]

Proposed Establishment of Class E Airspace; Clifton/Morenci, AZ

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to establish Class E airspace at Greenlee County Airport, Clifton/Morenci, AZ. To accommodate aircraft using a new Area Navigation (RNAV) Global Positioning System (GPS) Standard Instrument Approach Procedure (SIAP) at Greenlee County Airport. The FAA is proposing this action to enhance the safety and management of aircraft operations at the airport.

DATES: Comments must be received on or before September 13, 2010.

ADDRESSES: Send comments on this proposal to the U.S. Department of Transportation, Docket Operations, M-30, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue, SE., Washington, DC 20590; telephone (202) 366-9826. You must identify FAA Docket No. FAA-2010-0634; Airspace Docket No. 10-AWP-8, at the beginning of your comments. You may also submit comments through the Internet at <http://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT: Eldon Taylor, Federal Aviation Administration, Operations Support Group, Western Service Center, 1601

¹ You may view the lists of select agents and toxins on the Internet at (<http://www.regulations.gov/fdmspublic/component/main?main=DocketDetail&d=APHIS-2009-0070>).