

Proposed Rules

Federal Register

Vol. 62, No. 240

Monday, December 15, 1997

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

9 CFR Part 85

[Docket No. 96-013-1]

Official Pseudorabies Tests

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Proposed rule.

SUMMARY: We are proposing to amend the pseudorabies regulations by adding the glycoprotein I Particle Concentration Fluorescence Immunoassay test to the list of official pseudorabies tests and allow its use as an approved differential test. We are proposing to take this action based on a finding that the sensitivity and specificity of the glycoprotein I Particle Concentration Fluorescence Immunoassay test are equivalent to those of official tests for the diagnosis of pseudorabies. This proposed change would allow the glycoprotein I Particle Concentration Fluorescence Immunoassay test to be used as an official pseudorabies test to qualify certain pseudorabies vaccinated swine for interstate movement to destinations other than slaughter or a quarantined herd or quarantined feedlot. Adding the glycoprotein I Particle Concentration Fluorescence Immunoassay test to the list of official pseudorabies tests would also allow its use for the testing of nonvaccinated swine.

DATES: Consideration will be given only to comments received on or before February 13, 1998.

ADDRESSES: Please send an original and three copies of your comments to Docket No. 96-013-1, Regulatory Analysis and Development, PPD, APHIS, Suite 3C03, 4700 River Road Unit 118, Riverdale, MD 20737-1238. Please state that your comments refer to Docket No. 96-013-1. Comments received may be inspected at USDA, room 1141, South Building, 14th Street and Independence Avenue SW.,

Washington, DC, between 8 a.m. and 4:30 p.m., Monday through Friday, except holidays. Persons wishing to inspect comments are requested to call ahead on (202) 690-2817 to facilitate entry into the comment reading room.

FOR FURTHER INFORMATION CONTACT: Dr. Arnold C. Taft, Senior Staff Veterinarian, Swine Health Staff, VS, APHIS, 4700 River Road Unit 43, Riverdale, MD 20737-1231, (301) 734-4916; or e-mail: ataft@aphis.usda.gov.

SUPPLEMENTARY INFORMATION:

Background

Pseudorabies is a contagious, infectious, and communicable disease of livestock, primarily swine, and other animals. The disease, also known as Aujeszky's disease, mad itch, and infectious bulbar paralysis, is caused by a herpes virus. The Animal and Plant Health Inspection Service's (APHIS') regulations in 9 CFR part 85 (referred to below as the regulations) govern the interstate movement of swine and other livestock (cattle, sheep, and goats) in order to help prevent the spread of pseudorabies.

For the purposes of interstate movement, the regulations separate swine into four basic categories: (1) Swine infected with or exposed to pseudorabies; (2) pseudorabies vaccinated swine (except swine from qualified negative gene-altered vaccinated herds) not known to be infected with or exposed to pseudorabies; (3) swine not vaccinated for pseudorabies and not known to be infected with or exposed to pseudorabies; and (4) swine from qualified negative gene-altered vaccinated herds. Provisions governing the interstate movement of swine from each category are found in §§ 85.5, 85.6, 85.7, and 85.8, respectively.

Paragraphs (a) and (b) of § 85.6 provide that pseudorabies vaccinate swine, except swine from qualified negative gene-altered vaccinated herds, that are not known to be infected with or exposed to pseudorabies may be moved interstate directly to slaughter or to a quarantined herd or quarantined feedlot under certain specified conditions. Paragraph (c) of § 85.6 further provides that such pseudorabies vaccinate swine may be moved interstate to destinations other than slaughter or a quarantined herd or quarantined feedlot if the swine have

been vaccinated for pseudorabies with a glycoprotein I (gpl) deleted gene-altered pseudorabies vaccine and they are accompanied by a certificate that is delivered to the consignee. The regulations in § 85.6(c) also require that the certificate contain certain additional information, specifically: (1) The identification of each swine; (2) a statement that each swine was vaccinated with a gpl deleted gene-altered pseudorabies vaccine; (3) a statement that each swine has been subjected to an approved differential pseudorabies test no more than 30 days prior to the interstate movement and has been found negative; (4) the date of the approved differential pseudorabies tests; and (5) the name of the laboratory that conducted the approved differential pseudorabies test. Currently, the regulations provide only for the use of the gpl enzyme-linked immunosorbent assay (ELISA) as an approved differential pseudorabies test to qualify swine for interstate movement under § 85.6(c).

The Committee on Diagnostics and Interpretive Serology of the American Association of Veterinary Laboratory Diagnosticians (AAVLD) has recognized that the sensitivity and specificity of the gpl Particle Concentration Fluorescence Immunoassay (PCFIA) test are equivalent to those of official tests for the diagnosis of pseudorabies. Based on that finding, we are proposing to add the gpl PCFIA test to the list of official pseudorabies tests in § 85.1 and allow its use as an approved differential pseudorabies test to qualify swine for interstate movement under § 85.6(c).

Adding the gpl PCFIA test as an official pseudorabies test would also mean that the gpl PCFIA test would be available for testing nonvaccinated swine to determine their pseudorabies status. As noted above, the AAVLD has recognized that the sensitivity and specificity of the gpl PCFIA test are equivalent to those of official tests for the diagnosis of pseudorabies. The gpl PCFIA test is specific for antibodies to the glycoprotein I present in the pseudorabies virus; nonvaccinated swine, as well as swine vaccinated with a gpl-deleted vaccine, would not produce positive results to the gpl PCFIA test unless the swine were infected with pseudorabies. Designating the gpl PCFIA test as an official pseudorabies test would enable swine

producers to use a single test on both gpl vaccinates and nonvaccinated swine.

Executive Order 12866 and Regulatory Flexibility Act

This proposed rule has been reviewed under Executive Order 12866. For this action, the Office of Management and Budget has waived its review process required by Executive Order 12866.

This proposed rule would amend the pseudorabies regulations by adding the gpl PCFIA test to the list of official pseudorabies tests. This proposed change would allow the gpl PCFIA test to be used as an official pseudorabies test to qualify certain pseudorabies vaccinated swine for interstate movement to destinations other than slaughter or a quarantined herd or quarantined feedlot. Adding the gpl PCFIA test to the list of official pseudorabies tests would also allow its use for the testing on nonvaccinated swine.

The total U.S. inventory of hogs and pigs was approximately 56 million, valued at \$5.283 billion, in 1996. The gross income of the inventory is approximately \$11 billion. More than 99 percent of swine producers are considered to be small entities. According to the standard set by the Small Business Administration for agricultural producers, a producer with less than \$0.5 million annually in sales qualifies as a small entity.

Nearly 95 percent of the swine inventory within the United States has not yet achieved pseudorabies-free status. The addition of this new test would provide an extra choice of official pseudorabies test for those who raise swine, when a test is required for interstate movement. Testing costs would be incurred only when an owner chose to move gpl vaccinates interstate to destinations other than slaughter or a quarantined herd or quarantined feedlot, since pseudorabies vaccinated swine do not require a test prior to interstate movement for slaughter or to a quarantined herd or quarantined feedlot. The cost of the gpl PCFIA test is within the range of the currently available tests. The test is highly automated and those laboratories that have the test kit would be expected to accomplish the testing on large numbers of samples with greater speed. The test results have been found to produce fewer false negatives, reducing the need for tracebacks. The positive effect of having accurate results in a short time would be beneficial in all stages of pseudorabies eradication.

The provisions of this proposed rule that would allow the use of the gpl

PCFIA test to determine the pseudorabies status of nonvaccinated swine are not expected to have a significant economic impact on the owners of nonvaccinated swine, as it only introduces an additional pseudorabies testing tool to ensure the health of the U.S. swine population. It is likely, though, that since the new gpl PCFIA test may be slightly higher in cost than other testing tools that are on the market, most owners of nonvaccinated swine would continue using less expensive official pseudorabies test until the cost of the gpl PCFIA test became comparable to that of other official tests.

Under these circumstances, the Administrator of the Animal and Plant Health Inspection Service has determined that this action would 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 proposed rule has been reviewed under Executive Order 12988, Civil Justice Reform. If this proposed rule is adopted: (1) All State and local laws and regulations that are in conflict with this rule will be preempted; (2) no retroactive effect will be given to this rule; and (3) administrative proceedings will not be required before parties may file suit in court challenging this rule.

Paperwork Reduction Act

This proposed rule contains no new information collection or recordkeeping requirements under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

List of Subjects in 9 CFR Part 85

Animal diseases, Livestock, Quarantine, Reporting and recordkeeping requirements, Transportation.

Accordingly, 9 CFR part 85 would be amended as follows:

PART 85—PSEUDORABIES

1. The authority citation for part 85 would continue to read as follows:

Authority: 21 U.S.C. 111, 112, 113, 115, 117, 120, 121, 123–126, 134b, and 134f; 7 CFR 2.22, 2.80, and 371.2(d).

§ 85.1 [Amended]

2. In § 85.1, in the definition of *official pseudorabies test*, in the second sentence, item 6 would be amended by adding the words “, including the gpl PCFIA test” immediately after the word “Test”.

§ 85.6 [Amended]

3. Section 85.6 would be amended as follows:

a. In paragraph (c)(2)(iii), the words “or a gpl Particle Concentration Fluorescence Immunoassay (PCFIA)” would be added immediately after the word “(ELISA)”.

b. In paragraph (c)(2)(iv), the words “or the gpl PCFIA” would be added immediately after the word “ELISA”.

c. In paragraph (c)(2)(v), the words “or the gpl PCFIA” would be added immediately after the word “ELISA”.

Done in Washington, DC, this 9th day of December 1997.

Craig A. Reed,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 97–32658 Filed 12–12–97; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Airspace Docket No. 96–ANM–15]

RIN 2120–AA66

Proposed Modification of VOR Federal Airway V–465

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking.

SUMMARY: This action proposes to modify Federal Airway 465 (V–465) by lowering the floor of a portion of the airway from 12,400 feet mean sea level (MSL) to 1,200 feet above the surface. This action also proposes to establish a new segment of V–465 between Billings, Montana, and Miles City, Montana. The FAA is proposing this action to support an instrument approach procedure that is being developed for the Jackson Hole Airport, Wyoming, and to enhance aircraft operations management in the Jackson Hole, Wyoming, area.

DATES: Comments must be received on or before January 28, 1998.

ADDRESSES: Send comments on the proposal in triplicate to: Manager, Air Traffic Division, ANM–500, Docket No. 96–ANM–15, Federal Aviation Administration, 1601 Lind Avenue, SW., Renton, WA 98055–4056. The