# 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 to allow, under certain conditions, swine vaccinated with a gpI-deleted genealtered pseudorabies vaccine, but that are not from a qualified negative genealtered vaccinated herd, to be moved interstate to destinations other than slaughter or a quarantined herd or quarantined feedlot. This proposed rule would also allow the use of the gpI ELISA test to determine the pseudorabies status of nonvaccinated swine.

In December of 1993, there were 235,840 swine operations in the United States with a total inventory of about 56.8 million head. The value of the total swine inventory was estimated to be about \$4.3 billion (Agricultural Statistics Board, National Agricultural Statistics Service, U.S. Department of Agriculture, "Hogs and Pigs," December 29, 1993). We believe that about 99 percent of all swine operations in the United States would be considered small entities.

We estimate that there are approximately 25,000 domestic swine herds that contain vaccinated animals. Of those herds, there are only about 250 qualified negative gene-altered vaccinated herds. The provisions of this proposed rule pertaining to gpI vaccinates would have an economic impact only on the owners of gpI vaccinates that are not part of a qualified negative gene-altered herd. There are currently no provisions for the interstate movement of gpI vaccinates that are not part of a qualified negative gene-altered herd to destinations other than slaughter, quarantined herds, or quarantined feedlots, so this proposed rule would have the effect of opening up new markets for the owners of such swine. Testing costs would be incurred only when an owner chose to move gpI 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. We expect that swine owners would accept the costs of testing with the gpI ELISA test if they felt the economic opportunities afforded by the new markets balanced or outweighed

the costs associated with the interstate movement.

The provisions of this proposed rule that would allow the use of the gpI ELISA test to determine the pseudorabies status of nonvaccinated swine are not expected to have a significant economic impact on the owners of nonvaccinated swine. Although the gpI ELISA test costs from \$0.50 to \$1.00 more per test than the official serologic tests currently used to determine the pseudorabies status of nonvaccinated swine, its use to test nonvaccinated swine would be optional. It is likely, therefore, that most owners of nonvaccinated swine would continue using less expensive official pseudorabies tests until the cost of the gpI ELISA 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 12778**

This proposed rule has been reviewed under Executive Order 12778, 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**

In accordance with the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 et seq.), the information collection or recordkeeping requirements included in this proposed rule will be submitted for approval to the Office of Management and Budget. Please send written comments to the Office of Information and Regulatory Affairs, OMB, Attention: Desk Officer for APHIS, Washington, DC 20503. Please send a copy of your comments to: (1) Chief, Regulatory Analysis and Development, PPD, APHIS, USDA, P.O. Drawer 810, Riverdale, MD 20738, and (2) Clearance Officer, OIRM, USDA, room 404-W, 14th Street and Independence Avenue SW., Washington, DC 20250.

# List of Subjects in 9 CFR Part 85

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

Accordingly, 9 CFR part 85 would be revised to read 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, 134f; 7 CFR 2.17, 2.51, and 371.2(d).

# §85.1 [Amended]

- 2. In § 85.1, in the definition of certificate, the first sentence would be amended by adding the words "vaccinated with a glycoprotein I (gpI) deleted gene-altered pseudorabies vaccine or" immediately after the words "gene-altered pseudorabies vaccinates".
- 3. In § 85.1, in the definition of official pseudorabies test, in the second sentence, item 4 would be amended by adding the words "other than the glycoprotein I (gpl) ELISA test" immediately after the word "tests".
- 4. In § 85.6, a new paragraph (c) would be added to read as set forth below:
- § 85.6 Interstate movement of pseudorabies vaccinate swine, except swine from qualified negative gene-altered herds, not known to be infected with or exposed to pseudorabies.
- (c) General movements. Swine vaccinated for pseudorabies with a glycoprotein I (gpI) deleted gene-altered pseudorabies vaccine and not known to be infected with or exposed to pseudorabies, but that are not from a qualified negative gene-altered vaccinated herd, may be moved interstate to destinations other than those set forth in paragraphs (a) and (b) of this section only if:
- (1) The swine are accompanied by a certificate and such certificate is delivered to the consignee; and
- (2) The certificate, in addition to the information described in § 85.1, states:
  (i) The identification required by § 71.19 of this chapter; (ii) that each animal to be moved was vaccinated for pseudorabies with a gpI-deleted genealtered pseudorabies vaccine; (iii) that each animal to be moved was subjected to a gpI enzyme-linked immunosorbent assay (ELISA) approved differential pseudorabies test no more than 30 days prior to the interstate movement and was found negative; (iv) the date of the gpI ELISA approved differential pseudorabies test; and (v) the name of