Docket No. 89-211). During the public comment period that preceded the publication of that final rule, several commenters requested that APHIS allow the use of approved differential tests to qualify individual gene-altered vaccinates for interstate movement in the same way as nonvaccinated swine may be qualified for interstate movement with an official pseudorabies serologic test under the regulations in §85.7. APHIS declined, noting that the HerdCheck anti-pseudorabies gpX enzyme-linked immunosorbent assay (ELISA) test, which was the only approved differential pseudorabies test being conducted in APHIS-approved laboratories at that time, had been recommended as a diagnostic test for herds, and not for individual swine, by the American Association of Veterinary Laboratory Diagnosticians (AAVLD), the United States Animal Health Association (USAHA), and the test's manufacturer because the test was less sensitive than standard serological procedures in detecting pseudorabies virus antibodies.

Following the publication of the May 1990 final rule, APHIS approved several laboratories to conduct the gpI ELISA test, thus making two gene-altered vaccine/test combinations available to swine producers in the United States. The gpI ELISA test is more sensitive than the gpX ELISA test and has become the approved differential test used by the majority of those swine producers who have chosen to vaccinate their swine for pseudorabies.

The AAVLD's Committee on Diagnostic and Interpretative Serology has recognized that the sensitivity and specificity of the gpI ELISA test is equivalent to that of official tests for the diagnosis of pseudorabies. Based on that finding, the committee recommended that APHIS designate the gpI ELISA approved differential test as an official pseudorabies test and allow its use to qualify individual swine vaccinated with the gpI-deleted pseudorabies vaccine (referred to below as gpI vaccinates) for interstate movement.

Therefore, we are proposing to allow, under certain conditions, the use of the gpI ELISA test as an official pseudorabies test to qualify gpI vaccinates that are not from a qualified negative gene-altered vaccinated herd for interstate movement to destinations other than slaughter or a quarantined herd or quarantined feedlot. The AAVLD did not change its recommendation regarding other differential pseudorabies tests, so the gpI ELISA test is the only approved differential pseudorabies test included in this proposal. Additionally, we are

not proposing to make any changes to the regulations pertaining to swine from qualified negative gene-altered vaccinated herds. Rather, we are proposing to designate the gpI ELISA approved differential test as an official pseudorabies test to allow individual gpI vaccinates to qualify for general interstate movements (i.e., interstate movements to destinations other than slaughter, feedlots, quarantined herds, or quarantined feedlots) under provisions similar to those of §85.7(c), which allow nonvaccinated swine not known to be infected with or exposed to pseudorabies to qualify for general interstate movements.

For a gpI vaccinate that is not from a qualified negative gene-altered vaccinated herd to be moved interstate to destinations other than slaughter or a quarantined herd or quarantined feedlot, we are proposing to require that the swine be subjected to a gpI ELISA approved differential test, with negative results, within 30 days prior to the interstate movement. Given the sensitivity of the gpI ELISA test and the fact that the regulations require that the test be conducted in a laboratory approved by APHIS, we believe that any gpI vaccinates infected with pseudorabies would be detected as a result of the testing, thus ensuring that pseudorabies-infected swine would not be moved interstate without appropriate controls.

To document the required testing proposed above, and to provide a record regarding the identity, health status, origin, and destination of individual gpI vaccinates (i.e., not from a qualified negative gene-altered vaccinated herd) moving interstate to destinations other than slaughter or a quarantined herd or quarantined feedlot, we are further proposing to require that such gpI vaccinates be accompanied by a certificate during the interstate movement and that the certificate be delivered to the person receiving the swine. The certificate would be issued by an APHIS representative, State representative, or accredited veterinarian prior to the interstate movement.

As set forth in the definition of *certificate* in § 85.1, a *certificate* must state:

- The number and description of the swine to be moved;
- That the swine to be moved are not known to be infected with or exposed to pseudorabies;
- The purpose for which the swine are to be moved;
- The points of origin and destination; and
 - The consignor and consignee.

Our proposed amendment would require that, in addition to the information described in § 85.1, the certificate also state:

- The identification required by the regulations in 9 CFR 71.19;
- That each animal to be moved was vaccinated for pseudorabies with the glycoprotein I (gpI) gene-altered pseudorabies vaccine;
- That each animal to be moved was subjected to an approved differential pseudorabies test within 30 days prior to the interstate movement and was found negative;
- The date of the approved differential pseudorabies test; and
- The name of the laboratory that conducted the approved differential pseudorabies test.

The proposed certificate requirement would ensure that there was an official record of the testing and interstate movement of individual gpI vaccinates and would enable an official pseudorabies epidemiologist to trace the movements of the gpI vaccinates forward from their farm of origin or back from their present location should an investigation become necessary.

The definition of *certificate* currently states that a certificate is issued for "the interstate movement of swine that

* * are not pseudorabies vaccinates, except for official gene-altered pseudorabies vaccinates from a qualified negative gene-altered vaccinated herd." Because this proposal contains provisions for the issuance of certificates for the interstate movement of gpI vaccinates that are not from a qualified negative gene-altered vaccinated herd, we would amend the definition of *certificate* to include gpI vaccinates in the scope of the definition.

Adding the gpI ELISA test as an official pseudorabies test would also mean that the gpI ELISA 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 gpI ELISA test is equivalent to that of official tests for the diagnosis of pseudorabies. The gpI ELISA test is specific for antibodies to the glycoprotein I present in the pseudorabies virus; nonvaccinated swine, as well as swine vaccinated with a gpI-deleted vaccine, would not produce positive results to the gpI ELISA test unless the swine were infected with pseudorabies. Designating the gpI ELISA test as an official pseudorabies test would enable swine producers to use a single test on both gpI vaccinates and nonvaccinated swine.