

§ 83.6

will receive the fish; or the State or other regulatory authority responsible for oversight of the environment in which the fish will be introduced.

(4) The name, address, and phone number of the shipping or transportation company.

(5) The species and number of the fish.

(6) The lot (or other) identification of the shipment.

(7) The name, address, and phone number of the approved laboratory that performed the testing required by § 83.6.

(i) The number of fish tested;

(ii) The assay(s) used for testing; and

(iii) The test results.

(8) The date the certificate was issued.

(9) The type of water source according to § 83.6(c).

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§ 83.6 Testing requirements.

(a) A facility can demonstrate freedom from VHS through negative testing results provided by an approved laboratory. Testing must meet the following conditions:

(1) Be conducted with a sample size that provides for a 95 percent confidence level of detecting a 2 percent prevalence of infection in the facility.

(i) Facilities with cultured fish of VHS-regulated species which can document a 2-year history of negative testing for VHS virus, can conduct testing at a sampling level to provide a 95 percent confidence level of detecting a 5 percent prevalence of infection in the facility. Such testing must be conducted twice a year, with at least 3 months between tests.

(ii) Facilities with cultured fish of VHS-regulated species which can document a 4-year history of negative testing for VHS virus can conduct testing at a sampling level to provide a 95 percent confidence level of detecting a 10 percent prevalence of infection in the facility. Such testing must be conducted twice a year, with at least 3 months between tests.

(iii) Such facilities must be on a secure water source, and document that any VHS-regulated species in the facility that originated in VHS-regulated

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States or Canadian provinces originate from facilities of the same or higher health status.

(2) Include virus isolation or other assays authorized by the Administrator, using appropriate cell lines to detect VHS virus, if present. All suspect VHS cytopathic effects must be positively identified as VHS through molecular assays and/or genetic sequencing.

(3) Use proportional numbers of each VHS-regulated fish species which might be present in the facility.

(4) Be conducted at water temperatures between 50 and 72 °F, or at other times or under environmental conditions when VHS is most likely to be detected, if present.

(b) When APHIS adds a new species to the list of VHS-regulated species after a facility has been determined to be free of VHS in accordance with paragraph (a) of this section, the facility must conduct additional testing on fish of the newly listed species, if present in the facility, and the fish must be free of VHS virus for the facility to retain its free status. VHS testing must be conducted on each newly listed species with a sample size that provides for a 95 percent confidence level of detecting a 2 percent prevalence of infection in the facility.

(c) For VHS-regulated fish maintained on a secure water source, test results will be *valid* for 6 months from the date of sample collection provided that no fish of a lesser or unknown health status are introduced into the facility. Test results for fish held on a water source that is not a secure water source will be valid for 30 days from the date of sample collection.

§ 83.7 Shipping containers; cleaning and disinfection.

(a) All live fish that are to be moved interstate in accordance with § 83.3(a) must be moved in new containers or in containers that have been cleaned and disinfected.

(1) Cleaning and disinfection of shipping containers must be monitored by the accredited veterinarian or State, Tribal, or Federal competent authority for aquatic animal health who issues the ICI.

(2) Cleaning and disinfection must be sufficient to neutralize any VHS virus to which shipping containers may have been exposed.

(3) The cleaning and disinfection protocols used must be referenced in the ICI or in a separate cleaning and disinfection certificate accompanying the shipment.

(b) [Reserved]

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PART 85—PSEUDORABIES

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AUTHORITY: 7 U.S.C. 8301-8317; 7 CFR 2.22, 2.80, and 371.4.

SOURCE: 44 FR 10309, Feb. 16, 1979, unless otherwise noted.

§ 85.1 Definitions.

For purposes of this part, the following terms mean:

Accredited veterinarian. A veterinarian approved by the Administrator in accordance with the provisions of part 161 of this title to perform functions specified in parts 1, 2, 3, and 11 of subchapter A, and subchapters B, C, and D of this chapter, and to perform functions required by cooperative

state-federal disease control and eradication programs.

Administrator. The Administrator, Animal and Plant Health Inspection Service, or any person authorized to act for the Administrator.

Animal and Plant Health Inspection Service. The Animal and Plant Health Inspection Service of the United States Department of Agriculture (APHIS or Service).

Approved differential pseudorabies test. Any test for the diagnosis of pseudorabies that: (a) Can distinguish vaccinated swine from infected swine; (b) Is produced under license from the Secretary of Agriculture under the Virus-Serum-Toxin Act of March 4, 1913, and subsequent amendments (21 U.S.C. 151 *et seq.*) with indications for use in the Cooperative State-Federal Pseudorabies Eradication Program; and (c) Is conducted in a laboratory approved by the Administrator.¹

Approved livestock market. A stockyard, livestock market, buying station, concentration point or any other premises under State or Federal veterinary supervision where swine are assembled for sale or sale purposes, and which has

¹The names and addresses of laboratories approved by the Administrator to conduct approved differential pseudorabies tests are published in the Notices Section of the FEDERAL REGISTER. A list of approved laboratories is also available upon request from the Animal and Plant Health Inspection Service, Veterinary Services, Operational Support, 4700 River Road Unit 33, Riverdale, Maryland 20737-1231. State, Federal, and university laboratories will be approved by the Administrator when he or she determines that the laboratory: (a) Employs personnel trained at the National Veterinary Services Laboratories assigned to supervise the testing; (b) follows standard test protocols; (c) meets check test proficiency requirements; and (d) will report all test results to State and Federal animal health officials. Before the Administrator may withdraw approval of any laboratory for failure to meet any of these conditions, the Administrator must give written notice of the proposed withdrawal to the director of the laboratory, and must give the director an opportunity to respond. If there are conflicts as to any material fact, a hearing will be held to resolve the conflict.