

the person to whom the permit or special permit has been issued a written explanation of why the permit or special permit is to be or was withdrawn.

(c) *Appeals.* Denial or withdrawal of a permit or special permit may be appealed to the Administrator within 10 days after receipt of the written notice of denial or withdrawal. The appeal must be in writing³ and must state all of the facts and reasons upon which the person relies to show that the permit or special permit was wrongfully denied or withdrawn. The Administrator will grant or deny the appeal, in writing, explaining all of the reasons for the decision, as promptly as circumstances allow. In cases where there is a conflict as to any material fact, the person denied a permit or special permit, or from whom a permit or special permit is withdrawn, shall be given an opportunity for a hearing with respect to the merits or validity of the denial or withdrawal in accordance with rules of practice adopted for the proceeding.

(Approved by the Office of Management and Budget under control number 0579-0116)

PART 83—VIRAL HEMORRHAGIC SEPTICEMIA

Sec.

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

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³See footnote 10 to § 82.13.

§ 83.1 Definitions.

Accredited veterinarian. A veterinarian who is approved by the Administrator, in accordance with part 161 of this chapter, to perform official animal health work of the Animal and Plant Health Inspection Service specified in subchapters A, B, C, and D of this chapter; and to perform work 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.

Anadromous fish. Fish that are born and spawn in freshwater, but which spend part of their lifecycle in salt-water.

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

APHIS representative. A veterinarian or other individual employed by APHIS who is authorized to perform the services required by this part.

Approved laboratory. A laboratory authorized by a State, Tribal, or Federal competent authority for aquatic animal health to perform assays for the detection of VHS virus.

Catch-and-release fishing. Fishing for pleasure or for recreational purposes, including tournaments, organized fishing competitions, fishing derbies, or other types of contests where individuals catch, compare, and release live VHS-regulated fish. This term excludes VHS-regulated fish used, or intended to be used, as live bait.

Competent authority. The State, Tribal, or Federal entity with the legal responsibility for ensuring or supervising the implementation of aquatic animal health measures.

Cultured fish. Fish of the same species and age class, originating from the same broodstock and on the same water supply, whose care is partly or totally managed from the first life stage onwards.

Department. The United States Department of Agriculture (USDA).

Interstate. From one State into or through any other State.

Interstate Certificate of Inspection (ICI). An official document issued by an accredited veterinarian or a State,

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Tribal, or Federal competent authority in the originating State that certifies that the fish being moved interstate originated from a facility that has been found free of VHS virus.

Moved (movement). Shipped, transported, delivered, or otherwise aided, induced, or caused to be moved.

Person. Any individual, corporation, company, association, firm, partnership, society, or joint stock company, or other legal entity.

Secure water source. A biosecure water supply that does not contain pathogens or has not had the opportunity to be contaminated with pathogens. Biosecure water supplies include well, spring, or borehole water; surface water that does not contain fish populations; or water that has been treated to eliminate aquatic animal pathogens.

State. Any of the 50 States, the Commonwealth of Puerto Rico, the Commonwealth of the Northern Mariana Islands, the District of Columbia, and any territories and possessions of the United States.

State animal health official. The State official responsible for livestock, disease control, and eradication programs.

VHS-regulated area. Any State or portion of a State listed in accordance with § 83.4.

VHS-regulated fish. Any fish species listed in accordance with § 83.4.

VHS virus. Any North American (type IV) strain of viral hemorrhagic septicemia (VHS) virus, a rhabdovirus of fish.

Viral hemorrhagic septicemia (VHS). A disease caused by infection with VHS virus.

§ 83.2 General restrictions.

Live VHS-regulated fish may not be moved interstate from a VHS-regulated area except in compliance with this part.

§ 83.3 Interstate movement of live VHS-regulated fish species from VHS-regulated areas.

(a) Except as provided in paragraphs (b) through (e) of this section, live VHS-regulated fish, including fish moved to live fish markets, may only be moved interstate from a VHS-regulated area if the fish originated from a facility that has been found free of the

VHS virus in accordance with § 83.6 and the fish are accompanied by an Interstate Certificate of Inspection (ICI) issued by an accredited veterinarian or a State, Tribal, or Federal competent authority for aquatic animal health.

(b) Live VHS-regulated fish may be moved interstate directly to a slaughtering establishment provided that:

(1) The fish are accompanied by a VS Form 1–27;

(2) The fish are transported in sealed conveyances;

(3) The slaughtering establishment meets the following conditions:

(i) The slaughtering establishment discharges its waste water to a municipal sewage system that includes waste water disinfection sufficient to neutralize any VHS virus or to either a non-discharging settling pond or a settling pond that disinfects, according to all applicable local, State, and Federal regulations, sufficiently to neutralize any VHS virus.

(ii) Offal, including carcasses, from the slaughtering establishment is either rendered or composted.

(4) Any water used to transport the fish is disposed of in a municipal sewage system that includes waste water disinfection sufficient to neutralize any VHS virus or to either a non-discharging settling pond or a settling pond that disinfects, according to all applicable local, State, and Federal regulations, sufficiently to neutralize any VHS virus.

(c) Live VHS-regulated fish may be moved interstate for research or diagnostic purposes provided that:

(1) The fish are accompanied by a VS Form 1–27;

(2) The fish are transported in sealed conveyances;

(3) The facility that receives the fish meets the following conditions:

(i) The facility discharges its waste water to a municipal sewage system that includes waste water disinfection sufficient to neutralize any VHS virus or to either a non-discharging settling pond or a settling pond that disinfects, according to all applicable local, State, and Federal regulations, sufficiently to neutralize any VHS virus.

(ii) Offal, including carcasses, from the facility is either rendered or composted.

(4) Any water used to transport the fish is disposed to a municipal sewage system that includes waste water disinfection sufficient to neutralize any VHS virus or to either a non-discharging settling pond or a settling pond that disinfects, according to all applicable local, State, and Federal regulations, sufficiently to neutralize any VHS virus.

(d) Live VHS-regulated fish may be moved interstate during catch-and-release fishing.

(e) The Administrator may, on a case-by-case basis, permit the interstate movement of fish not otherwise provided for in this part, under such conditions as the Administrator may prescribe in each case to prevent the introduction and dissemination of VHS.

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§ 83.4 VHS-regulated fish and VHS-regulated areas.

(a)(1) APHIS will list as a VHS-regulated fish any fish species found in freshwater to be susceptible to the North American (type IV) strain of VHS virus under natural (*i.e.*, non-controlled) conditions of exposure and from which VHS virus has been isolated in cell culture or other assay determined by the Administrator to be adequate to detect VHS virus, with confirmation of strain identity through genetic sequencing. Anadromous fish that have migrated into freshwater and from which VHS strain type IV(a) has been isolated will not be considered VHS-regulated fish.

(2) If APHIS determines that, in accordance with the criteria in paragraph (a)(1) of this section, a species should be added to the list of VHS-regulated species, APHIS will publish a notice in the FEDERAL REGISTER announcing that determination.

(b)(1) APHIS will list as a VHS-regulated area each State or portion of a State from which VHS virus has been detected in any VHS-regulated fish species (with or without clinical signs of disease) in a water source that is not a secure water source, or which the Administrator determines should be regulated based on criteria such as inadequate surveillance or movement re-

quirements, or other epidemiologic information.

(2) If the Administrator determines that a State or portion of a State meets the criteria in paragraph (b)(1) of this section, APHIS will publish a notice of its decision in the FEDERAL REGISTER and take comments from the public. The designation as a VHS-regulated area will become effective upon publication of this notice. After reviewing the comments, APHIS will issue a second notice in the FEDERAL REGISTER announcing its decision on whether or not the designation as a VHS-regulated area will remain in effect.

(c) APHIS maintains the lists of VHS-regulated fish and VHS-regulated areas on the APHIS aquaculture Web site at http://www.aphis.usda.gov/animal_health/animal_dis_spec/aquaculture. The lists may be obtained from the Animal and Plant Health Inspection Service, Veterinary Services, National Aquaculture Program, 4700 River Road Unit 46, Riverdale, MD 20737-1231.

§ 83.5 Interstate Certificate of Inspection (ICI).

(a) Live VHS-regulated fish moved interstate in accordance with § 83.3(a) must be accompanied by an ICI issued by an accredited veterinarian or a State, Tribal, or Federal competent authority for aquatic animal health. An ICI will be valid for 30 days from the date of issuance.

(b) The ICI must state that:

(1) The live fish were inspected by the accredited veterinarian or a State, Tribal, or Federal competent authority for aquatic animal health within 72 hours prior to shipment, and were found to be free of any clinical signs of disease consistent with VHS.

(2) The live fish covered by the ICI originated in an area or facility that has demonstrated freedom from VHS in accordance with § 83.6.

(c) The ICI must include the following information:

(1) The name, address, and phone number of the owner or owner's agent.

(2) The name, address, and phone number of the facility in which the fish originated.

(3) The name, address, and phone number of the person or facility who

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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).

(Approved by the Office of Management and Budget under control number 0579–0340)

§ 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

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

Sec.

- 85.1 Definitions.
- 85.2 Notice relating to the existence of the contagion of pseudorabies.
- 85.3 General restriction.
- 85.4 Interstate movement of livestock.
- 85.5 Interstate movement of infected swine or exposed swine.
- 85.6 Interstate movement of pseudorabies vaccinate swine, except swine from qualified negative gene-altered vaccinated herds, not known to be infected with or exposed to pseudorabies.
- 85.7 Interstate movement of swine not vaccinated for pseudorabies and not known to be infected with or exposed to pseudorabies.
- 85.8 Interstate movement of swine from a qualified negative gene-altered vaccinated herd.
- 85.9 Other interstate movements.
- 85.10 Interstate movement of swine semen and swine embryos for insemination or implantation into swine.
- 85.11 Permits and certificates.
- 85.12 Cleaning and disinfecting means of conveyance.
- 85.13 Cleaning and disinfecting livestock markets and other facilities.

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.