

the additional costs may be passed on to producers. However, these costs are offset by the benefits derived by the operation of the marketing order.

In addition, the Committee's meeting was widely publicized throughout the Colorado Area No. 3 potato industry and all interested persons were invited to attend the meeting and participate in Committee deliberations on all issues. Like all Committee meetings, the May 8, 2008, meeting was a public meeting and all entities, both large and small, were able to express views on this issue.

This rule imposes no additional reporting or recordkeeping requirements on either small or large Colorado Area No. 3 potato handlers. As with all Federal marketing order programs, reports and forms are periodically reviewed to reduce information requirements and duplication by industry and public sector agencies.

AMS is committed to complying with the E-Government Act, to promote the use of the Internet and other information technologies to provide increased opportunities for citizen access to Government information and services, and for other purposes.

As noted in the initial regulatory flexibility analysis, USDA has not identified any relevant Federal rules that duplicate, overlap, or conflict with this rule.

A proposed rule concerning this action was published in the **Federal Register** on July 25, 2008 (73 FR 43375). Copies of the proposed rule were also mailed or sent via facsimile to all handlers. Finally, the proposal was made available through the Internet by USDA and the Office of the Federal Register. A 15-day comment period ending August 11, 2008, was provided for interested persons to respond to the proposal. No comments were received.

A small business guide on complying with fruit, vegetable, and specialty crop marketing agreements and orders may be viewed at: <http://www.ams.usda.gov/AMSv1.0/ams.fetchTemplateData.do?template=TemplateN&page=MarketingOrdersSmallBusinessGuide>. Any questions about the compliance guide should be sent to Jay Guerber at the previously mentioned address in the **FOR FURTHER INFORMATION CONTACT** section.

After consideration of all relevant material presented, including the information and recommendation submitted by the Committee and other available information, it is hereby found that this rule, as hereinafter set forth will tend to effectuate the declared policy of the Act.

Pursuant to 5 U.S.C. 553, it is also found and determined that good cause

exists for not postponing the effective date of this rule until 30 days after publication in the **Federal Register** because: (1) The 2008–2009 fiscal period began on July 1, 2008, and the marketing order requires that the rate of assessment for each fiscal period apply to all assessable potatoes handled during such fiscal period; (2) the northern Colorado potato shipping season began in July; (3) the Committee needs to have sufficient funds to pay for expenses which are incurred on a continuous basis; and (4) handlers are aware of this action which was recommended by the Committee at a public meeting and is similar to other assessment rate actions issued in past years. Also, a 15-day comment period was provided for in the proposed rule.

#### List of Subjects in 7 CFR Part 948

Marketing agreements, Potatoes, Reporting and recordkeeping requirements.

■ For the reasons set forth in the preamble, 7 CFR part 948 is amended as follows:

#### PART 948—IRISH POTATOES GROWN IN COLORADO

■ 1. The authority citation for 7 CFR part 948 continues to read as follows:

**Authority:** 7 U.S.C. 601–674.

■ 2. In Part 948, the suspension of § 948.215 is lifted.

Dated: September 4, 2008.

**Lloyd C. Day,**

*Administrator, Agricultural Marketing Service.*

[FR Doc. E8–20853 Filed 9–8–08; 8:45 am]

**BILLING CODE 3410–02–P**

#### DEPARTMENT OF AGRICULTURE

##### Animal and Plant Health Inspection Service

##### 9 CFR Parts 71, 83, and 93

[Docket No. APHIS–2007–0038]

RIN 0579–AC74

##### Viral Hemorrhagic Septicemia; Interstate Movement and Import Restrictions on Certain Live Fish

**AGENCY:** Animal and Plant Health Inspection Service, USDA.

**ACTION:** Interim rule and request for comments.

**SUMMARY:** We are establishing regulations to restrict the interstate movement and importation into the United States of live fish that are susceptible to viral hemorrhagic

septicemia, a highly contagious disease of certain fresh and saltwater fish. In 2005 and 2006, viral hemorrhagic septicemia was detected in freshwater fish in several of the Great Lakes and related tributaries. The disease has been responsible for several large-scale die-offs of wild fish in the Great Lakes region. This action is necessary to prevent further introductions into, and dissemination within, the United States of viral hemorrhagic septicemia.

**DATES:** *Effective date:* This interim rule is effective November 10, 2008.

*Comment dates:* Comments on the interim rule are due on or before November 10, 2008. Comments on the environmental assessment are due on or before October 9, 2008.

**ADDRESSES:** You may submit comments by either of the following methods:

• *Federal eRulemaking Portal:* Go to <http://www.regulations.gov/fdmspublic/component/main?main=DocketDetail&d=APHIS-2007-0038> to submit or view comments and to view supporting and related materials available electronically.

• *Postal Mail/Commercial Delivery:* Please send two copies of your comment to Docket No. APHIS–2007–0038, Regulatory Analysis and Development, PPD, APHIS, Station 3A–03.8, 4700 River Road Unit 118, Riverdale, MD 20737–1238. Please state that your comment refers to Docket No. APHIS–2007–0038.

*Reading Room:* You may read any comments that we receive on this docket in our reading room. The reading room is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue, SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 690–2817 before coming.

*Other Information:* Additional information about APHIS and its programs is available on the Internet at <http://www.aphis.usda.gov>.

**FOR FURTHER INFORMATION CONTACT:** Dr. P. Gary Egrie, Senior Staff Veterinary Medical Officer, National Center for Animal Health Programs, VS, APHIS, 4700 River Road Unit 46, Riverdale, MD 20737–1231; (301) 734–0695; or Dr. Peter L. Merrill, Senior Staff Veterinarian, National Center for Import and Export, VS, APHIS, 4700 River Road Unit 39, Riverdale, MD 20737–1231; (301) 734–8364.

**SUPPLEMENTARY INFORMATION:**

## Background

Viral hemorrhagic septicemia (VHS) is a highly contagious disease of certain fresh and saltwater fish, caused by a rhabdovirus. It is listed as a notifiable disease by the World Organization for Animal Health (OIE). The pathogen produces variable clinical signs in fish including lethargy, skin darkening, exophthalmia, pale gills, a distended abdomen, and external and internal hemorrhaging. The development of the disease in infected fish can result in substantial mortality. Other infected fish may not show any clinical signs or die, but may be lifelong carriers and shed the virus.

Four genotypes of VHS virus have been identified, and appear to be distributed geographically. Genotypes I, II, and III are mainly found in Europe or Asia and are highly pathogenic to rainbow trout. The fourth genotype, referred to as North American type IV, has been found in wild fish from the East and West coasts of North America periodically since 1988. This genotype is less virulent to commercially important fish stocks than the European/Asian VHS virus genotypes because it results in less morbidity and mortality than those genotypes.

In 2005 and 2006, VHS outbreaks were reported in wild fish from the Great Lakes in both Canada and the United States. The mortality associated with numerous individual outbreaks ranged from just a few fish to many thousands per outbreak.

The 2005 and 2006 VHS outbreaks were the first freshwater isolations of VHS virus in the United States. The strain of VHS virus isolated from all of these outbreaks, while similar to North American type IV found in saltwater, has been shown to be genetically distinct from other known strains of VHS virus, and is apparently capable of causing substantial morbidity and mortality in many native species of fish. It is currently believed that the saltwater-adapted type IV strain mutated into a strain that is affecting new host fish species in new environments in both Canada and the United States. The extent of VHS viral distribution is not yet known; however, reported epizootics attributable to VHS since 2005 have been limited to wild fish from the Great Lakes watershed.

The emerging strain (tentatively called North American type IV(b) to differentiate it from what will likely be renamed type IV(a)) has caused a number of mass mortalities in wild fish populations, ranging up to many thousands of fish. Some outbreaks were reported to occur at temperatures that

had not been previously associated with the development of VHS disease. Virus growth is generally inhibited when water temperatures are above 15 °C; however, this VHS virus appears to have a much wider temperature range. According to research conducted at the U.S. Geological Survey, type IV(b), in vitro, grows best at 15 °C and up to 20 °C where growth begins to decline. Type IV(b) viral growth was inhibited at 25 °C. Additionally, all the species of fish in the 2005 and 2006 North American outbreaks had not previously been known to be susceptible to VHS infection and/or disease. The list of fish species susceptible to VHS, as determined by the Animal and Plant Health Inspection Service (APHIS), currently includes 28 separate species. These species include baitfish, recreationally important fish, and food fish such as salmonids and catfish.

## Federal Order

The Animal Health Protection Act (AHPA) authorizes the Secretary of Agriculture to prohibit or restrict the importation or movement in interstate commerce of any animal, article, or means of conveyance if the Secretary determines that the prohibition or restriction is necessary to prevent the introduction or dissemination of any pest or disease of livestock into or within the United States.

In response to recent outbreaks of VHS in wild fish populations in the Great Lakes, the Administrator determined that it was necessary, in order to prevent the spread of VHS into aquaculture facilities, to prohibit or restrict the interstate movement and importation of VHS-regulated species of live fish. Accordingly, on October 24, 2006, APHIS issued a Federal Order prohibiting the importation of VHS-susceptible species of live fish from two Canadian provinces (Ontario and Quebec) into the United States and the interstate movement of the same species of live fish from the eight States bordering the Great Lakes (Illinois, Indiana, Michigan, Minnesota, New York, Ohio, Pennsylvania, and Wisconsin).

At the time the Federal Order was issued, only three States (Michigan, New York, and Ohio) had been affected by VHS within the jurisdictional borders of their States. Epidemiologic considerations such as the commonality of the Great Lakes watershed influenced APHIS' decision to include all of the States within the Great Lakes watershed as "affected" or "at-risk."

In October 2006, APHIS held a 2-day meeting with Federal, State, Tribal, and industry representatives to discuss VHS

and the Federal Order, and to obtain information regarding State regulations and diagnostic testing programs related to VHS. During this meeting, APHIS received several recommendations from participants regarding modifications to the Federal Order that could be made to alleviate impacts on industry and related businesses in the Great Lakes region while still protecting against the spread of VHS.

APHIS also met with the Department of Fisheries and Oceans Canada (DFO) and the Canadian Food Inspection Agency (CFIA) in November 2006. At that time, Canada provided APHIS with information about its VHS testing program and requested that APHIS amend the Federal Order to allow the importation of fish that Canada certifies as VHS-free.

Based on the information gathered at these meetings, on November 14, 2006, APHIS modified the Federal Order to allow VHS-susceptible species of live salmonid fish from the affected Canadian provinces to be imported into the United States if the shipment meets the regulations of the U.S. Fish and Wildlife Service (FWS) in 50 CFR 16.13(a)(3) and 16.13(b). The FWS regulations in 50 CFR 16.13(a)(3) provide that live or dead unviscerated salmonid fish are prohibited entry into the United States for any purpose except by direct shipment accompanied by a certification that: (1) The fish lots from which the shipments originated have been sampled; (2) viral assays have been conducted on the samples according to methods specified in the regulations; and (3) certain pathogens, including the virus causing VHS, have not been detected in the fish stocks from which the samples were taken. The FWS regulations further provide that live salmonid fish can be imported into the United States only with the written approval of the Director of FWS. The regulations in 50 CFR 16.13(b) set out the information that must be included in the certification statement required in § 16.13(a)(3).

The modified Federal Order also established conditions under which VHS-susceptible species of live fish could be moved from the eight States bordering the Great Lakes. Specifically, the Order provided that VHS-susceptible live fish may be moved interstate for slaughter if the fish are: (1) Intended for human consumption; (2) transported to a State-inspected slaughter facility that discharges waste water into a municipal sewage system that includes waste water disinfection, or disposes of waste water in a non-discharging settling pond or a settling pond that disinfects according to State

and Federal requirements, and renders or composites offal, including carcasses; and (3) accompanied by a valid VS Form 1–27 issued by an APHIS area office if not tested for VHS.

The Order also provided that VHS-susceptible fish may be moved interstate to research and diagnostic laboratories provided the fish are: (1) Accompanied by a valid VS Form 1–27 issued by an APHIS area office stating that the fish are destined for a research or diagnostic laboratory that has been approved by a State, Tribal, or Federal competent authority for aquatic animal health and (2) received at a laboratory where waste fluids and carcasses are considered medical waste and disposed of according to State and Federal requirements. Finally, the Order provided that VHS-susceptible fish may be moved interstate for purposes other than slaughter, research, or diagnostics provided the fish are transported with documentation from the appropriate State, Tribal, or Federal competent authority for aquatic animal health stating that the fish have tested negative for VHS virus under specific national and international standards.

In January 2007, APHIS hosted public meetings in Lakewood, CO; Memphis, TN; Romulus, MI; and Coraopolis, PA. The purpose of the meetings was to present current information about the outbreaks of VHS and actions taken to prevent its spread, and to give interested stakeholders an opportunity to present data and views concerning the possible regulation of VHS by the Agency.

On May 4, 2007, APHIS modified the Federal Order to allow for the catch-and-release of VHS-susceptible regulated fish in waters that cross State and international boundaries. These activities include recreational fishing, tournaments, competitions, fishing derbies, or other types of contests where individuals catch, compare, and release live VHS-susceptible fish. However, catch-and-release fishing activities do not include the movement of VHS-susceptible fish intended to be used as live bait. Catch and release fishing activities are considered low risk for spreading VHS virus because fish are caught and released within the same body of water and within a limited geographic area over a limited time period. In contrast, the use of live bait is considered high risk for spreading VHS virus because the bait is used for fishing in multiple bodies of water over a broader geographic area.

On November 8, 2007, APHIS modified the Federal Order by revising the list of VHS-susceptible species. We removed 12 species and added 2 new freshwater fish species that are

susceptible to VHS. We also clarified the scientific names of several species. Currently, there are 28 separate species of fish listed.

The original October 2006 Federal Order listed 37 species of VHS-susceptible fish, including all species listed by the OIE as susceptible to all known strains of VHS. The updated list includes only those species found in freshwater environments in the United States and Canada that have been infected by VHS under natural (i.e., nonexperimental) conditions of exposure and from which VHS virus has been isolated by cell culture, with confirmation of strain identity through molecular detection. Anadromous fish species<sup>1</sup> that have migrated into freshwater and from which VHS strain type IV(a) is isolated are excluded.

Finally, on April 2, 2008, APHIS modified the Federal Order to allow VHS-susceptible species of live non-salmonid fish from affected Canadian provinces to be imported into the United States for direct slaughter if accompanied by an APHIS permit.

The Federal Order was issued in response to the rapid spread of VHS in the Great Lakes region and was designed to prevent the introduction of VHS into aquaculture facilities by controlling the movement of VHS-susceptible fish species while APHIS gathered more information about the disease and developed a regulatory program that would allow the interstate movement and importation of VHS-susceptible fish under certain conditions. Taking into consideration the information provided by States, Tribes, and other interested stakeholders, APHIS has now developed a regulatory framework for the interstate movement and importation of VHS-susceptible fish species.

In the Federal Order, we used the terms “VHS-susceptible species” and “VHS-affected or at-risk States or regions;” however, for the purposes of these regulations we will use the terms “VHS-regulated species” and “VHS-regulated areas or regions.”

Accordingly, we are amending the interstate movement regulations in title 9, subchapter C, by adding a new part 83, “Viral Hemorrhagic Septicemia” (§§ 83.1 through 83.7). We are also amending 9 CFR part 71 to provide that fish affected with VHS may be moved interstate in accordance with part 83. Finally, we are amending the animal import regulations in 9 CFR part 93, subpart I, “Aquatic Animal Species” (§§ 93.900 through 93.916). The new

<sup>1</sup> We define *anadromous fish* as fish that are born and spawn in freshwater, but which spend part of their lifecycle in saltwater.

interstate movement and importation requirements are discussed in detail below.

As stated previously in this document, the AHPA authorizes the Secretary of Agriculture to prohibit or restrict the importation or movement in interstate commerce of any animal, article, or means of conveyance if the Secretary determines that the prohibition or restriction is necessary to prevent the introduction or dissemination of any pest or disease of livestock into or within the United States. Ballast water (i.e., water with its suspended matter taken on board a ship to control trim, list, draught, stability, or stresses of a ship) can be taken onto a ship in its port of origin and discharged into the water body of the ship’s destination port, making it a potential pathway for VHS virus. APHIS has neither the regulatory authority nor the technical expertise to safely regulate ballast water discharge. Therefore, we do not address ballast water in this interim rule. APHIS will assist the U.S. Coast Guard, which has clear regulatory authority for ballast water, in their development of ballast water discharge standards.

#### Definitions (§§ 83.1 and 93.900)

In §§ 83.1 and 93.900, we define the terms used in the regulations. In § 83.1, we set out the following standard terms and definitions, which are found throughout title 9, subchapter C: *Accredited veterinarian, Administrator, Animal and Plant Health Inspection Service (APHIS), APHIS representative, Department, interstate, moved (movement), person, State, and State animal health official*. These terms and their definitions are set out in the regulatory text at the end of this document.

In both §§ 83.1 and 93.900, we define terms that are specific to VHS and aquatic animals. These terms are *anadromous fish, catch-and-release fishing, cultured fish, secure water source, VHS virus, and viral hemorrhagic septicemia (VHS)*. These terms are defined as follows:

*Anadromous fish.* Fish that are born and spawn in freshwater, but which spend part of their lifecycle in saltwater.

*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.

*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.

*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.

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

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

Due to slight differences in terminology and program requirements, some VHS-specific terms are defined differently in §§ 83.1 and 93.900. These terms are *approved laboratory*, *competent authority*, *VHS-regulated area*, *VHS-regulated region*, and *VHS-regulated fish*.

In § 83.1, *approved laboratory* is defined as a laboratory authorized by a State, Tribal, or Federal competent authority for aquatic animal health to perform assays for the detection of VHS virus while, in § 93.900, *approved laboratory* is defined as a laboratory authorized by the competent authority of a country for aquatic animal health to perform assays for the detection of VHS virus.

In § 83.1, we define *competent authority* as the State, Tribal, or Federal entity with the legal responsibility for ensuring or supervising the implementation of aquatic animal health measures. This definition is similar to the current definition for *competent authority* in § 93.900, which refers to the national veterinary services or other authority of a country responsible for aquatic animal health.

In § 83.1, *VHS-regulated area* is defined as any State or portion of a State listed in accordance with § 83.4. Section 93.900 defines *VHS-regulated region* as any region listed in accordance with § 93.910.

In § 83.1, we define *VHS-regulated fish* as any fish species listed in accordance with § 83.4 while, in § 93.900, we define *VHS-regulated fish* as any fish species listed in accordance with § 93.910.

Finally, in § 83.1, we define the term *Interstate Certificate of Inspection (ICI)*. This term is specific to the interstate movement requirements in part 83 and is defined as an official document issued by an accredited veterinarian or a State, 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.

#### Interstate Movement

##### *General Restrictions; Conditions of Movement (§§ 83.2 and 83.3)*

Section 83.2 provides that live VHS-regulated fish may not be moved interstate from a VHS-regulated area except in compliance with part 83. Section 83.3 sets forth the conditions under which live VHS-regulated fish may be moved interstate.

Paragraph (a) of § 83.3 provides that, apart from the exceptions provided in paragraphs (b) through (e) of that 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.

Paragraph (b) of § 83.3 provides that live VHS-regulated fish may be moved interstate directly to a slaughtering establishment provided the fish are transported in a sealed conveyance and accompanied by a VS Form 1–27. The VS Form 1–27 is available through APHIS' Veterinary Services offices, and can be issued by a State, Tribal, Federal, or accredited veterinarian. The fish must be moved to a slaughtering establishment that 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. In addition, any water used to transport the fish must be disposed of 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. These requirements are necessary to ensure that water waste discharged to the environment (or to a public waterway) does not contain any viable VHS virus. Offal, including carcasses, from the slaughtering establishment must be either rendered or composted.

Paragraph (c) of this section extends these same provisions to fish moved for research or diagnostic purposes.

Paragraph (d) specifies that live VHS-regulated fish may be moved interstate during catch-and-release fishing.

Finally, paragraph (e) provides that the Administrator may, on a case-by-case basis, permit the interstate movement of fish whose movement is not otherwise provided for in part 83, under such conditions as the Administrator may prescribe in each case to prevent the introduction and dissemination of VHS.

##### *VHS-Regulated Fish and VHS-Regulated Areas (§ 83.4)*

Paragraph (a) of § 83.4 provides that 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 under this rule because this strain appears to be less pathogenic than type IV(b). Type IV(a) has been in the United States since at least 1988 and has not resulted in large-scale fish mortalities across a broad range of species such as those that were associated with the outbreaks of type IV(b) in the Great Lakes.

Paragraph (a) further provides that, when APHIS determines that a species meets the criteria of this paragraph and should be added to the list of VHS-regulated fish, APHIS will publish a notice in the **Federal Register** announcing that determination.

Paragraph (b) of this section provides that 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 to be at risk of having VHS based on criteria such as inadequate surveillance or movement requirements, or other epidemiologic information.

Paragraph (b) further provides that, if the Administrator determines that a State or portion of a State meets the criteria for a VHS-regulated area, 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.

Paragraph (c) provides that these lists of VHS-regulated fish and VHS-regulated areas will be maintained on the APHIS aquaculture Web site at [http://www.aphis.usda.gov/animal\\_health/animal\\_dis\\_spec/aquaculture](http://www.aphis.usda.gov/animal_health/animal_dis_spec/aquaculture). The purpose of maintaining the lists on the Web site is to maintain the most accurate, up-to-date list possible in a location where affected parties can easily view recent changes. The Web site list should be particularly useful when a new area is added to the list, which occurs immediately after APHIS receives and confirms reports of a new outbreak. Changes to lists maintained in the regulations typically take several weeks, so maintaining the lists on the Web site will allow APHIS to communicate new developments and take prompt action as soon as it confirms an outbreak or identifies a new species of fish affected by VHS.

Paragraph (c) also includes an address from which the lists of VHS-regulated fish and VHS-regulated areas may be obtained from APHIS.

As of this rule's effective date, the following fish species and areas are regulated because of VHS:

*VHS-Regulated Areas*

Illinois, Indiana, Michigan, Minnesota, New York, Ohio, Pennsylvania, Wisconsin.

**VHS-REGULATED FISH SPECIES**

Black crappie .....	<i>Pomoxis nigromaculatus.</i>
Bluegill .....	<i>Lepomis macrochirus.</i>
Bluntnose minnow.	<i>Pimephales notatus.</i>
Brown bullhead ..	<i>Ameiurus nebulosus.</i>
Brown trout .....	<i>Salmo trutta.</i>
Burbot .....	<i>Lota lota.</i>
Channel catfish ..	<i>Ictalurus punctatus.</i>
Chinook salmon	<i>Oncorhynchus tshawytscha.</i>
Emerald shiner ...	<i>Notropis atherinoides.</i>
Freshwater drum	<i>Aplodinotus grunniens.</i>
Gizzard shad .....	<i>Dorosoma cepedianum.</i>
Lake whitefish ....	<i>Coregonus clupeaformis.</i>
Largemouth bass	<i>Micropterus salmoides.</i>
Muskellunge .....	<i>Esox masquinongy.</i>
Northern pike .....	<i>Esox lucius.</i>
Pumpkinseed .....	<i>Lepomis gibbosus.</i>
Rainbow trout .....	<i>Oncorhynchus mykiss.</i>
Rock bass .....	<i>Ambloplites rupestris.</i>
Round goby .....	<i>Neogobius melanostomus.</i>
Shorthead redhorse.	<i>Moxostoma macrolepidotum.</i>
Silver redhorse ...	<i>Moxostoma anisurum.</i>

**VHS-REGULATED FISH SPECIES—  
Continued**

Smallmouth bass	<i>Micropterus dolomieu.</i>
Spottail shiner ....	<i>Notropis hudsonius.</i>
Trout-Perch .....	<i>Percopsis omiscomaycus.</i>
Walleye .....	<i>Sander vitreus.</i>
White bass .....	<i>Morone chrysops.</i>
White perch .....	<i>Morone americana.</i>
Yellow perch .....	<i>Perca flavescens.</i>

This interim rule does not provide a process by which APHIS will remove areas from the list of VHS-regulated areas if the area petitions APHIS for a reassessment of its disease status. As discussed in more detail below under the heading "Related Issues on Which APHIS is Seeking Comment," we particularly invite comments on which specific factors APHIS should consider before removing an area from the list of VHS-regulated areas.

*Interstate Certificate of Inspection (ICI) (§ 83.5)*

Paragraph (a) of § 83.5 requires that live VHS-regulated fish moved interstate in accordance with § 83.3(a) be accompanied by an ICI issued by an accredited veterinarian or a State, Tribal, or Federal competent authority for aquatic animal health. This paragraph further provides that an ICI will be valid for 30 days from the date of issuance.

Paragraph (b) of this section requires that the ICI 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 found to be free of any clinical signs of disease consistent with VHS, and (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.

In addition, the section specifies that the ICI must contain the following information:

- The name, address, and phone number of the owner or owner's agent.
- The name, address, and phone number of the facility in which the fish originated.
- The name, address, and phone number of the person or facility who will receive the fish; or the State or other regulatory authority responsible for oversight of the environment in which the fish will be introduced.
- The name, address, and phone number of the shipping or transportation company.
- The species and number of the fish.
- The lot (or other) identification of the shipment.
- The name, address, and phone number of the approved laboratory that

performed the testing required by § 83.6 and the number of fish tested, the assay(s) used for testing, and the test results.

- The date the certificate was issued.
- The type of water source according to § 83.6(c).

Requiring the issuance of an ICI will ensure that appropriate testing procedures were applied as well as allow for traceback should an inspector encounter a problem with or have questions about a shipment.

*Testing Requirements (§ 83.6)*

Paragraph (a) of § 83.6 provides that a facility can demonstrate freedom from VHS through negative testing results provided by an approved laboratory. Paragraph (a) also specifies that such testing must:

- Be conducted with a testing sample size that provides for a 95 percent confidence level of detecting a 2 percent prevalence of infection in the facility.
- Include virus isolation or other assay 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.
- Use proportional numbers of each VHS-regulated fish species which might be present in the facility.
- 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.

Facilities with a history of negative testing results for VHS are assumed to have a lower risk of spreading VHS; therefore, we will decrease the number of fish required to be tested for such facilities. Specifically, paragraph (a)(1) of § 83.6 also provides that 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 for a 95 percent confidence level of detecting a 5 percent prevalence of infection in the facility. 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 fish facility. Such facilities must be on a secure water source, and testing must be conducted twice a year, with at least 3 months between tests. These facilities must also 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.

Because this is an emerging disease, APHIS may update the list of VHS-regulated fish species as our knowledge of species susceptibility increases. Paragraph (b) explains how facilities can maintain VHS-free status when new species are added to the list of VHS-regulated fish species. Specifically, paragraph (b) provides that, when a new species is added to the list of VHS-regulated fish, a facility that has been determined to be free of VHS must conduct additional testing on the newly listed species, if present in the facility, and the fish must be free of VHS virus in order for the facility to retain its free status. Paragraph (b) further provides that 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 fish facility in order to return the facility to the same health status that existed prior to the new listing of the VHS-regulated species.

Paragraph (c) of this section specifies that the test results for fish maintained on a secure water source will be valid for 6 months from the date of sample collection provided 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. This will help to ensure that fish qualified to move interstate by virtue of a health certification program retain that qualification for a reasonable length of time while not compromising the health status of those fish through the introduction of additional fish of unknown or lesser VHS status, or introduction of VHS virus through the water source.

#### *Shipping Containers; Cleaning and Disinfection (§ 83.7)*

Paragraph (a) of § 83.7 requires that all live VHS-regulated fish that are to be moved interstate in accordance with § 83.3(a) must be moved in new containers or containers that have been cleaned and disinfected to neutralize any VHS virus to which the shipping containers may have been exposed. Cleaning and disinfection must be monitored by the accredited veterinarian or State, Tribal, or Federal competent authority for aquatic animal health who issues the ICI. The cleaning and disinfection protocols used must be referenced in the ICI or in a separate cleaning and disinfection certificate accompanying the shipment.

#### **Import Restrictions**

##### *General Restrictions; Exceptions (§ 93.910)*

As previously discussed, the Federal Order, as amended, allows VHS-susceptible species of live salmonid fish from the affected Canadian provinces to be imported into the United States if the shipment meets the FWS regulations in 50 CFR 16.13(a)(3) and 16.13(b). This interim rule will continue to allow live salmonid VHS-regulated fish to be imported into the United States from VHS-regulated regions in accordance with the FWS regulations. In addition, this rule establishes conditions under which live non-salmonid VHS-regulated fish species may be imported into the United States from VHS-regulated regions.

Specifically, paragraph (a) of § 93.910 provides that no live VHS-regulated species of fish may be imported into the United States from VHS-regulated regions except in accordance with subpart I or the regulations of the FWS in 50 CFR 16.13(a)(3) and 16.13(b). This paragraph further provides that no such live VHS-regulated fish may be moved from the port of entry after arrival until released by an APHIS representative or FWS official. In addition, this paragraph specifies that the Administrator may, upon request in specific cases, allow the importation of live VHS-regulated fish into the United States under conditions other than those specifically set forth in the subpart when the Administrator determines that such movement will not result in the further introduction of VHS into the United States.

Paragraph (b) of § 93.910 provides that 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 competent authority to be adequate to detect VHS virus, with confirmation of strain identity through genetic sequencing. As stated previously, anadromous fish that have migrated into freshwater and from which VHS strain type IV(a) has been isolated are not considered VHS-regulated fish under this rule. Paragraph (b) further provides that, when APHIS determines that a species meets the criteria of this paragraph and should be added to the list of VHS-regulated fish, APHIS will publish a notice in the **Federal Register** announcing that determination.

Paragraph (c) of this section provides that APHIS will list as a VHS-regulated region any region in which VHS virus

has been officially reported to the OIE by the country's competent authority for aquatic animal health from any fish species in a water source that is not a secure water source, or which the Administrator determines to be at risk of having VHS based on criteria such as inadequate surveillance, less restrictive import requirements, or other epidemiologic information.

Paragraph (c) further provides that, if the Administrator determines that a region meets the criteria for a VHS-regulated region, APHIS will publish a notice of its decision in the **Federal Register** and take comments from the public. The designation as a VHS-regulated region 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 region will remain in effect.

Paragraph (d) provides that these lists will be maintained on the APHIS aquaculture Web site at [http://www.aphis.usda.gov/animal\\_health/animal\\_dis\\_spec/aquaculture](http://www.aphis.usda.gov/animal_health/animal_dis_spec/aquaculture). This paragraph further provides an address from which the lists of VHS-regulated fish and VHS-regulated regions may be obtained from APHIS.

As of this rule's effective date, only two Canadian Provinces (Ontario and Quebec) are listed as VHS-regulated regions. The current list of VHS-regulated fish species is set out above under the heading "VHS-regulated fish and VHS-regulated areas (§ 83.4)."

This interim rule does not provide a process by which APHIS will remove regions from the list of VHS-regulated regions if the area petitions APHIS for a reassessment of its disease status. As discussed in more detail below under the heading "Related Issues on Which APHIS Is Seeking Comment," we particularly invite comments on which specific factors APHIS should consider before removing an area from the list of VHS-regulated regions.

Paragraph (e) of § 93.910 provides that other provisions of part 93 relating to the importation of live VHS-regulated fish shall not apply to shipments of such fish imported from VHS-regulated regions if they are imported in accordance with the FWS regulations in 50 CFR 16.13. As previously discussed, the FWS regulations pertain to live salmonid fish species to be imported into the United States. This paragraph makes it clear that live salmonid VHS-regulated fish to be imported into the United States from VHS-regulated regions will be exempt from the other provisions in part 93 provided that the

fish are imported in accordance with the FWS regulations.

Paragraph (f) of this section provides that other provisions of part 93 relating to the importation of live VHS-regulated fish shall not apply to shipments of such fish in transit through the United States, if an import permit has been obtained under § 93.912 and all conditions of the permit are observed, and if the live VHS-regulated fish species are handled as follows:

- They are maintained under continuous confinement while in transit through the United States aboard an aircraft, ocean vessel, or other means of conveyance; or if they are unloaded in the course of such transit, they are placed in a holding facility that is provided by the carrier or its agent and has been approved by the Administrator as adequate to prevent the spread within the United States of any finfish pathogen; they are maintained there under continuous confinement until loaded aboard a means of conveyance for transportation from the United States; and they are maintained under continuous confinement aboard such means of conveyance until it leaves the United States.

- They are moved in accordance with any additional conditions prescribed in the permit that the Administrator has determined to be necessary to ensure that the fish do not introduce VHS into the United States.

For a holding facility to be approved by the Administrator, the following conditions must be met:

- The holding facility must be sufficiently isolated to prevent direct or indirect contact of the live fish it contains with any other live VHS-regulated fish species in the United States.

- The holding facility must be constructed to provide adequate protection against environmental conditions and so that it can be adequately cleaned, washed, and disinfected.

- Provision must be made for disposal of fish carcasses, shipping water, effluent, waste, and any associated shipping materials in a manner that will prevent dissemination of disease.

- Provision must be made for adequate sources of feed and water and for attendants for the care and feeding of fish in the facility.

- The holding facility must comply with all applicable local, State, and Federal requirements for environmental quality.

- The holding facility must comply with any additional requirements that the Administrator may impose on a

particular shipment in order to prevent the dissemination of VHS virus.

Paragraph (g) provides that the provisions of the subpart relating to the importation of live VHS-regulated fish shall not apply to fish moved into the United States from VHS-regulated regions during catch-and-release fishing.

*Ports Designated for the Importation of Live VHS-Regulated Fish Species (§ 93.911)*

Section 93.911 designates ports through which live VHS-regulated fish from VHS-regulated regions may be imported into the United States without an import permit. To relieve some of the paperwork burden associated with import permits, we will allow VHS-regulated fish species that have been tested in accordance with § 93.913(b) and found to be free of VHS virus to be imported through certain Canadian border ports without an import permit. We consider those ports to have adequate facilities and inspectors to perform the necessary inspections of shipments of live fish without advance notification of the arrival of a shipment that is associated with the application for and issuance of an import permit. As described later in this document in the section titled "Declaration and other documents (§ 93.914)," all importers must submit a declaration to Customs. The information included in the declaration will parallel the information required in an import permit, except that importers must indicate the route of travel in an import permit. APHIS asks for notice of a shipment's route of travel in order to prevent transits of animals through countries subject to import restrictions because of certain animal disease risks. We typically do not require this information for shipments coming through land border ports because it is unlikely that a shipment entering the United States at a land border port would have traveled through any other countries.

Paragraph (a) provides that VHS-regulated fish species may be imported into the following Canadian border ports without an import permit: Eastport, ID; Houlton and Jackman, ME; Detroit, Port Huron, and Sault Ste. Marie, MI; Baudette, MN; Opheim, Raymond, and Sweetgrass, MT; Alexandria Bay, Buffalo, and Champlain, NY; Dunseith, Pembina, and Portal, ND; Derby Line and Highgate Springs, VT; and Oroville and Sumas, WA.

Paragraph (b) provides that live VHS-regulated fish may be imported into the United States with an import permit through the following ports: Anchorage, AK; Los Angeles and San Francisco, CA;

Miami and Tampa, FL; Atlanta, GA; Honolulu, HI; Chicago, IL; Boston, MA; Newark, NJ; Jamaica and Newburgh, NY; Portland, OR; Memphis, TN, Dallas-Ft. Worth, TX; Seattle, WA; and San Juan, PR.

Paragraph (c) of this section also provides for other ports to be designated by the Administrator in specific cases with the concurrence of the Secretary of the Department of Homeland Security.

*Import Permits (§ 93.912)*

Paragraph (a) of § 93.912 requires that live VHS-regulated fish imported from VHS-regulated regions through a limited port listed in § 93.911(b) be accompanied by an import permit issued by APHIS and must be imported within 30 days of the proposed arrival date stated in the import permit.

Paragraph (b) provides the address and APHIS Web site from which prospective importers may request import permit applications and to which completed applications should be sent. An application for an import permit must be submitted for each shipment of live VHS-regulated fish.

Paragraph (c) of this section specifies the information that must be included on an import permit application. It states that the application must include the name and address of the exporter; the proposed date of shipment to the United States; the name and address of the importer; the species and number of live VHS-regulated fish to be imported into the United States; the purpose of the importation; the port of embarkation; the mode of transportation; the route of travel, including all carrier stops en route; the port of entry in the United States; the proposed date of arrival in the United States; and the name and address of the person to whom the live VHS-regulated fish will be delivered in the United States.

APHIS needs this information to determine whether the live fish are eligible for importation, to respond to an applicant, to identify the shipment at the port of entry, to ensure that inspectors and facilities are available for inspection in the United States, and to contact appropriate persons if any questions arise concerning the importation.

Finally, paragraph (d) explains what happens after we receive and review the permit application. This paragraph provides that, if following our review, we determine that the live VHS-regulated fish are eligible for importation, we will issue an import permit. This paragraph also specifies that an import permit does not guarantee that any live fish will be



allowed entry into the United States; the VHS-regulated fish will be allowed to enter the United States only if they meet all applicable requirements of the regulations.

#### *Health Certificate (§ 93.913)*

Paragraph (a) of § 93.913 requires that all live VHS-regulated fish that are imported from VHS-regulated regions for other than immediate slaughter or research or laboratory use be accompanied by a health certificate. The health certificate must be in English or contain an English translation and must be issued by a full-time salaried veterinarian of the national government of the exporting country, or issued by a certifying official and endorsed by the competent authority of that country. The health certificate will be valid for 30 days from the date of issuance.

In addition, the health certificate must state that the shipment was inspected by the veterinarian or certifying official who issued the certificate within 72 hours prior to shipment, and found to be free of any clinical signs of disease consistent with VHS; and the live fish covered by the health certificate originated in a region or facility that has demonstrated freedom from VHS through testing in accordance with paragraphs (b) and (c) of § 93.913.

Paragraph (b) provides that a facility can demonstrate freedom from VHS through negative testing results by a pathogen detection laboratory approved for VHS viral assays by the competent authority. All viral testing must meet the following conditions:

- Be conducted with a testing sample size that provides for a 95 percent confidence level of detecting a 2 percent prevalence of infection in the facility.
- Include virus isolation or other assays authorized by the competent authority, 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.

- Test proportional numbers of each VHS-regulated fish species which might be present in a shipment, if applicable.

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

As stated previously in this document, facilities with a history of negative testing results for VHS are assumed to have a lower risk of spreading VHS; therefore, we will decrease the number of fish that are required to be tested for such facilities. Specifically, paragraph (b) of this

section also allows facilities with cultured fish of VHS-regulated species which can document a 2-year negative testing history for VHS virus to conduct testing at a sampling level to provide a 95 percent confidence level of detecting a 5 percent prevalence of infection in the facility and facilities with cultured fish of VHS-regulated species which can document a 4-year negative testing history for VHS virus to conduct testing at a sampling level to provide a 95 percent confidence level of detecting a 10 percent prevalence of infection in the fish facility. Such facilities must be on a secure water source, and testing must be conducted twice a year, with at least 3 months between tests. The facilities must also 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.

Paragraph (c) explains how facilities can maintain VHS-free status when new species are added to the list of VHS-regulated fish species. Specifically, paragraph (c) provides that when a new species is added to the list of VHS-regulated fish, a facility that has been determined to be free of VHS 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 in order for the facility to retain its free status. Paragraph (c) further provides that 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 fish facility.

Paragraph (d) of this section requires that, except as provided in § 93.910(e) through (g), all live fish be shipped in new containers or containers that have been cleaned and disinfected to neutralize any VHS virus to which the shipping containers may have been exposed. Cleaning and disinfection of shipping containers must take place under the supervision of the veterinarian or certifying official who issues the health certificate, and be sufficient to neutralize any VHS virus to which shipping containers may have been exposed. Cleaning and disinfection protocols must be referenced in the health certificate or in a separate cleaning and disinfection certificate accompanying the shipment to the U.S. port of entry.

#### *Declaration and Other Documents (§ 93.914)*

Section § 93.914 requires the importer or his or her agent to submit the following documents to the appropriate

Customs and Border Protection officer for use by the port veterinarians:

- All permits, certificates, or other documentation required under §§ 93.912 and 93.913; and
- Two copies of a declaration that lists the port of entry; the name and address of the importer; the name and address of the broker; the origin of the live fish; the number, species, and the purpose of the importation; the name of the person to whom the fish will be delivered; and the location of the place to which such delivery will be made. This information will allow for the traceback of shipments should any problems occur subsequent to entry into the United States.

#### *Inspection at the Port of Entry (§ 93.915)*

Section 93.915 sets forth requirements for port of entry inspections of shipments of live fish. Paragraph (a) provides that the shipments of live VHS-regulated fish must be presented for inspection at a port of entry designated under § 93.911. This paragraph also provides that the port veterinarian must be notified at least 72 hours in advance of the arrival of the shipment in the United States for live fish of VHS-regulated species being imported through a limited port listed in § 93.911(c). It also provides that any shipment that does not meet the requirements of this subpart will be refused entry (e.g., lacking appropriate permits, declarations, and/or health certificates or exhibiting clinical signs consistent with VHS).

Paragraph (b) states that shipments refused entry must be exported within a time fixed in each case by the Administrator, and in accordance with other provisions he or she may require in each case for their handling, or the shipment will be disposed of as the Administrator may direct.

#### *Special Provisions (§ 93.916)*

Section 93.916 sets forth requirements for importation for slaughter or for research or laboratory purposes.

Paragraph (a) provides that live VHS-regulated fish from VHS-regulated regions may be imported directly for slaughter under the following conditions:

- An import permit has been obtained under § 93.912 and all conditions of the permit are observed.
- An APHIS representative at the port seals the means of conveyance with official seals.

- The shipment is moved directly from the port of entry to a slaughtering establishment that 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. Offal, including carcasses, from the slaughtering establishment is either rendered or composted.

- An APHIS representative unseals the vehicle upon arrival at the slaughtering establishment.

- 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. Paragraph (b) of this section provides that live non-salmonid VHS-regulated fish may be imported from a VHS-regulated region for research or laboratory use under the following conditions:

- An import permit has been obtained under § 93.912 and all conditions of the permit are observed.

- The laboratory or research facility disposes of effluent 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.

- Carcasses must be rendered or composted.

- 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.

These measures will ensure that VHS virus that may be present in such fish is effectively neutralized or that the fish are rendered incapable of infecting fish in other waters of the United States.

#### **Related Issues on Which APHIS Is Seeking Comment**

There are two additional issues related to VHS for which we are seeking public comment. This interim rule does not make any of the possible changes discussed below, because there are no immediate risks associated with them that would justify immediate action. However, we believe the following changes would improve the effectiveness of our programs to prevent

the introduction of VHS and other fish pathogens and may include such changes in a subsequent rulemaking.

As discussed above, the new lists of VHS-regulated areas and VHS-regulated regions will be maintained on the APHIS Web site, not in the regulations. We do not however, provide criteria for removing an area or region from those lists. At present, VHS occurs only in wild fish populations in the United States and Canada, making the disease difficult to contain and eradicate. For that reason, we do not believe any areas or regions that are currently on the lists of VHS-regulated areas or VHS-regulated regions will be eligible for removal from those lists in the immediate future. Further, APHIS is still considering what information we would use in reassessing an area's or region's disease status and would find public input valuable. Specifically, APHIS seeks comments on what factors should be considered when removing areas and regions from the lists of VHS-regulated areas and VHS-regulated regions.

We recognize that gametes are a potential pathway for the spread of VHS due to the ability of the virus to survive in ovarian fluid. While the disinfection of salmonid eggs is common practice, no standardized protocols exist for disinfecting non-salmonid eggs. Further, there is not sufficient documented scientific evidence to support regulated egg treatment protocols for non-salmonid eggs. APHIS seeks comment on what types of egg disinfection protocols, if any, should be considered for VHS-regulated non-salmonid species.

#### **User Fees**

APHIS user fees for processing permit applications and for inspecting animals at the port of entry will apply. The user fees are set forth in 9 CFR part 130. User fees for processing applications for permits to import certain animals and animal products are listed in the table in § 130.4. User fees for inspection at the port of entry and laboratory and facility inspections are the hourly rates set forth in § 130.30.

#### **Emergency Action**

The Administrator of the Animal and Plant Health Inspection Service has determined that there is good cause for publishing this interim rule without prior opportunity for public comment. Immediate action is necessary to prevent the introduction of VHS into aquaculture facilities by controlling the movement of live fish at risk of harboring VHS virus. Despite its current VHS-free status for farmed fish, the

United States remains unprotected from continuing introductions of VHS-infected non-salmonid fish imported from Canada, since there are a number of exporters of VHS-regulated fish species in VHS-regulated areas in Canada, and pretesting of these fish is not currently required. Additionally, although VHS outbreaks have so far been limited to States within the Great Lakes watershed, there are no standardized restrictions in place other than those specified in the FWS regulations in title 50 and the existing APHIS Federal Order to prevent the further spread of VHS into new watersheds or areas by the transfer of live salmonid or non-salmonid VHS-regulated species. Therefore, it is necessary to implement regulations that will restrict such movements in as timely a manner as possible.

We will consider comments we receive during the comment periods for this interim rule and the environmental assessment (see **DATES** above). After the comment period closes, we will publish another document in the **Federal Register** to notify the public of our decision regarding the environmental assessment. We will also publish a document in the **Federal Register** that will include a discussion of any comments we receive and any amendments we are making to the rule.

#### **Executive Order 12866 and Regulatory Flexibility Act**

This rule has been reviewed under Executive Order 12866. The rule has been determined to be not significant for the purposes of Executive Order 12866 and, therefore, has not been reviewed by the Office of Management and Budget.

We have prepared an economic analysis for this interim rule. It provides an initial regulatory flexibility analysis, which considers the potential economic effects of this proposed rule on small entities, as required by the Regulatory Flexibility Act, as well as a cost-benefit analysis. The economic analysis is summarized below. The full economic analysis may be viewed on the Regulations.gov Web site (see **ADDRESSES** at the beginning of this document for instructions for accessing Regulations.gov). You may request paper copies of the economic analysis by calling or writing to the person listed under **FOR FURTHER INFORMATION CONTACT**. Please refer to Docket No. APHIS-2007-0038 when requesting copies. The economic analysis is also available for review in our reading room (information on the location and hours of the reading room is listed under the heading **ADDRESSES** at the beginning of this document).

Based upon available data and expected effects, we believe that the benefits of the interim rule, in terms of disease prevention, will justify the costs associated with restricting the movement of live fish. Costs associated with the interim rule will likely be difficult to distinguish from those already imposed by the amended Federal Order. Also, several of the States that will be regulated by the interim rule have regulations in place that compare closely with the interim rule. Net impacts of the interim rule therefore may be relatively small.

We first consider potential costs of the rule for producers, allied industries, and State, Federal, and Tribal authorities. Possible benefits of the rule in terms of preventing the spread of VHS virus are then examined. Third, alternatives to the rule are presented. Lastly, we address expected impacts for small entities.

#### *Summary of Cost-Benefit Analysis*

The interim rule will place restrictions on the importation and interstate movement of live VHS-regulated fish species from States within the Great Lakes Region where this disease has been confirmed. The potential impacts of the interim rule are not known, given the lack of information on aquaculture operations and commercial fisheries in the regulated areas. Additionally, little is known about the potential impacts on allied fishing industries and on hatcheries operating under Federal, State, or Tribal authority.

Benefits of the rule will accrue from preventing the spread of an emerging strain of VHS virus to aquaculture facilities beyond the regulated States. Five of these States have comprehensive regulations in place to curb the spread of the virus. Impacts of the interim rule are likely to be largely already realized because of the amended Federal Order, and may be additionally diminished in the five States that have adopted movement restrictions consistent with the interim rule.

#### *Expected Costs of the Interim Rule*

One industry that may be impacted is the wild-caught segment of the baitfish industry, to the extent that the requirements of the interim rule are more restrictive than the amended Federal Order and the regulations of the various States. However, we foresee any incremental changes to be minimal. A testing and certification protocol by which movement will be allowed under the rule is unlikely to be feasible for this segment of the industry. In addition to aquaculture and commercial fisheries,

allied fishing industries such as bait shops and marinas may also be affected by the interim rule. Bait shops that sell VHS-regulated species may face tighter supplies on top of the certification requirement for sales to unregulated States.

State, Federal, and Tribal authorities may also be affected by the interim rule. Within the 8 regulated States, there are 7 Federal, 69 State, and at least 13 Tribal hatcheries. These hatcheries produce and stock fish in streams, rivers, and lakes throughout the eight States and possibly in surrounding States. The interim rule may limit production and stocking by the agencies, and therefore the availability of broodstock in the regulated States and possibly other States, depending on the species stocked. Affected States may also face a decline in the number of fishing licenses sold due to reduced stocking and a limited availability of bait.

Overall, regulated aquaculture facilities and commercial fisheries will bear the costs of testing, cleaning, and disinfection of containers, and fees associated with inspections and the issuance of permits. However, given the regulatory response to VHS to date by five of the eight regulated States, the impact of the interim rule may be muted. Many of the regulations in place in Michigan, New York, Ohio, Pennsylvania, and Wisconsin are closely aligned with the requirements in the interim rule and in some cases may be even more restrictive. In some instances, effects of the interim rule are already realized because of rules implemented at the State level. Additionally, the rule will codify restrictions and procedures already in place under the amended Federal Order. Net impacts of the interim rule are expected to be small because of the existing State regulations and the Federal Order.

#### *Expected Benefits of the Interim Rule*

The interim rule is expected to benefit aquaculture facilities. The rule is intended to curtail the introduction of the VHS virus into areas outside of the Great Lakes Region. Mississippi dominates catfish farming in the United States. Alabama and Arkansas also have fairly large sales of cultured catfish. Additionally, Arkansas boasts the largest sales of cultured baitfish, accounting for 53 percent of baitfish aquaculture according to the 2005 Census of Aquaculture. Preventing VHS from spreading to these areas will help preserve the catfish and baitfish industries, valued at almost \$440 million.

#### *Alternatives to the Interim Rule*

APHIS considered three alternatives for the interim rule. The first alternative considered by the Agency would entail regulations much broader in scope than the provisions of the May 4, 2007, amended Federal Order. This alternative would restrict interstate movement of VHS-regulated species for all States where any VHS virus strain is detected, and would restrict importation of VHS-regulated species from all VHS-regulated countries, including countries in Europe, and also would regulate additional commodities. APHIS determined the interim rule will be less costly and provide the same level of protection as this alternative, based on current knowledge of the status of the two strains of VHS virus, type IV(a) and type IV(b), in the United States and Canada. VHS virus strain type IV(a) is not known to exist anywhere other than in marine environments and, thus, is unlikely to be found in the Great Lakes Region.

A second alternative considered by the Agency would be to regulate areas based on Hydrologic Unit Code (HUC) level 2, or regional, definitions. APHIS determined that regulating areas known to have VHS virus type IV(b) based on the HUC 2 definition could pose an undue burden on entities within these areas far removed from the specific location of the VHS virus type IV(b) confirmation.

Finally, APHIS considered a “no action” alternative. In this instance, APHIS would not implement regulations covering the interstate movement of VHS-regulated fish from VHS-regulated areas or the importation of VHS-regulated fish from VHS-regulated regions. Under this alternative, State agencies and Federal agencies other than APHIS would assume responsibility for preventing the spread of the VHS virus. Compliance with the various regulations could be burdensome for aquaculture producers and others who move fish interstate or internationally.

#### *Summary of the Initial Regulatory Flexibility Analysis*

In accordance with the Regulatory Flexibility Act, we examined the potential economic effects the interim rule will have on small entities. The interim rule may affect aquaculture facilities, commercial harvesters, marinas, and other allied fishing industries in Illinois, Indiana, Michigan, Minnesota, New York, Ohio, Pennsylvania, and Wisconsin. Although information concerning many of these industries is sparse, it is likely that most

of the entities within these industries are small as defined by the Small Business Administration (SBA) guidelines.

While it is likely that the majority of firms affected by the interim rule will be small, the magnitude of the impacts is unclear given the lack of data.

Aquaculture facilities in States not regulated for VHS will benefit from the interim rule because the likelihood that fish in these facilities will be exposed to this disease will be reduced. Facilities located in Illinois, Indiana, Michigan, Minnesota, New York, Ohio, Pennsylvania, and Wisconsin will face costs related to testing if they raise VHS-regulated species for interstate movement. In States that have enacted their own regulations to prevent the potential spread of VHS, impacts on aquaculture facilities and commercial fishing operations as a result of this interim rule are likely to be dampened.

The interim rule will impose some additional reporting, recordkeeping, and other compliance requirements. Live VHS-regulated species of fish may be imported and moved live from regulated Provinces and States. Movement requires testing and certification as described in the interim rule. Firms wishing to move live fish will be responsible for ensuring that the fish originate from a facility that has been tested and found to be free of VHS virus. Additionally, these firms will also be responsible for obtaining the permits needed to transport fish interstate, as well as paying the user fees associated with inspection of shipments.

#### **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 rule has been reviewed under Executive Order 12988, Civil Justice Reform. This rule: (1) Preempts all State and local laws and regulations that are in conflict with this rule; (2) has no retroactive effect; and (3) does not require administrative proceedings before parties may file suit in court challenging this rule.

#### **National Environmental Policy Act**

To provide the public with documentation of APHIS' review and analysis of any potential environmental impacts associated with this interim rule, we have prepared an environmental assessment. The

environmental assessment was prepared in accordance with: (1) The National Environmental Policy Act of 1969 (NEPA), as amended (42 U.S.C. 4321 *et seq.*), (2) regulations of the Council on Environmental Quality for implementing the procedural provisions of NEPA (40 CFR parts 1500–1508), (3) USDA regulations implementing NEPA (7 CFR part 1b), and (4) APHIS' NEPA Implementing Procedures (7 CFR part 372). The environmental assessment provides a basis for our determination that implementation of this interim rule will not have a significant impact on the quality of the human environment.

We will accept comments on the environmental assessment for 30 days. To comment, follow the instructions under **ADDRESSES** at the beginning of this document. The environmental assessment may be viewed on the Regulations.gov Web site or in our reading room. (Instructions for accessing Regulations.gov and information on the location and hours of the reading room are provided under the heading **ADDRESSES** at the beginning of this interim rule.) In addition, copies may be obtained by writing to the individual listed under **FOR FURTHER INFORMATION CONTACT**.

#### **Paperwork Reduction Act**

In accordance with section 3507(j) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the information collection and recordkeeping requirements included in this interim rule have been submitted for emergency approval to the Office of Management and Budget (OMB). OMB has assigned control number 0579–0340 to the information collection and recordkeeping requirements.

We plan to request continuation of that approval for 3 years. Please send written comments on the 3-year approval request to the following addresses: (1) Office of Information and Regulatory Affairs, OMB, Attention: Desk Officer for APHIS, Washington, DC 20503; and (2) Docket No. APHIS–2007–0038, Regulatory Analysis and Development, PPD, APHIS, Station 3A–03.8, 4700 River Road, Unit 118, Riverdale, MD 20737–1238. Please state that your comments refer to Docket No. APHIS–2007–0038 and send your comments within 60 days of publication of this rule.

This interim rule establishes regulations to restrict the interstate movement and importation into the United States of live fish that are susceptible to VHS. In order to be moved interstate, live VHS-regulated fish must originate from a facility that has been found free of VHS virus

through testing specified in the regulations and be accompanied by an ICI issued by an accredited veterinarian or a State, Tribal, or Federal competent authority for aquatic animal health.

Live VHS-regulated fish to be imported into the United States may need to be accompanied by a permit and must be accompanied by a declaration and by a health certificate that states that the live fish originated in a region or facility that has demonstrated freedom from VHS through testing in accordance with the regulations. The fish must be shipped in new containers or containers that have been cleaned and disinfected to neutralize any VHS virus to which the shipping containers may have been exposed. The cleaning and disinfection protocols must be referenced in the health certificate or in a separate cleaning and disinfection certificate accompanying the shipment to the U.S. port of entry. Finally, live fish imported for slaughter or for research or diagnostic purposes must, among other things, be accompanied by a VS Form I–27, which will be issued by the port veterinarian.

We are soliciting comments from the public (as well as affected agencies) concerning our information collection and recordkeeping requirements. These comments will help us:

(1) Evaluate whether the information collection is necessary for the proper performance of our agency's functions, including whether the information will have practical utility;

(2) Evaluate the accuracy of our estimate of the burden of the information collection, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the information collection on those who are to respond (such as through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology; e.g., permitting electronic submission of responses).

*Estimate of burden:* Public reporting burden for this collection of information is estimated to average 0.2681871 hours per response.

*Respondents:* Accredited veterinarians, importers and exporters of VHS-regulated live fish, shippers moving VHS-regulated live fish interstate, and States.

*Estimated annual number of respondents:* 515.

*Estimated annual number of responses per respondent:* 16.601941.

*Estimated annual number of responses:* 8,550.

*Estimated total annual burden on respondents:* 2,293. (Due to averaging, the total annual burden hours may not equal the product of the annual number of responses multiplied by the reporting burden per response.)

Copies of this information collection can be obtained from Mrs. Celeste Sickles, APHIS' Information Collection Coordinator, at (301) 851-2908.

### E-Government Act Compliance

The Animal and Plant Health Inspection Service is committed to compliance with the E-Government Act to promote the use of the Internet and other information technologies, to provide increased opportunities for citizen access to Government information and services, and for other purposes. For information pertinent to E-Government Act compliance related to this interim rule, please contact Mrs. Celeste Sickles, APHIS' Information Collection Coordinator, at (301) 851-2908.

### List of Subjects

#### 9 CFR Part 71

Animal diseases, Livestock, Poultry and poultry products, Quarantine, Reporting and recordkeeping requirements, Transportation.

#### 9 CFR Part 83

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

#### 9 CFR Part 93

Animal diseases, Imports, Livestock, Poultry and poultry products, Quarantine, Reporting and recordkeeping requirements.

■ Accordingly, we are amending 9 CFR chapter I as follows:

### PART 71—GENERAL PROVISIONS

■ 1. The authority citation for part 71 continues to read as follows:

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

■ 2. Section 71.3 is amended as follows:

■ a. In paragraph (a), in the list of diseases which are endemic to the United States, by adding the words "viral hemorrhagic septicemia," after "chlamydiosis,".

■ b. By adding a new paragraph (c)(5) to read as set forth below.

#### § 71.3 Interstate movement of diseased animals and poultry generally prohibited.

\* \* \* \* \*

(c)(5) Fish affected with viral hemorrhagic septicemia may be moved interstate in accordance with part 83 of this subchapter.

\* \* \* \* \*

■ 3. A new part 83 is added to read as follows:

### PART 83—VIRAL HEMORRHAGIC SEPTICEMIA

Sec.

83.1 Definitions.

83.2 General restrictions.

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

83.4 VHS-regulated fish and VHS-regulated areas.

83.5 Interstate Certificate of Inspection (ICI).

83.6 Testing requirements.

83.7 Shipping containers; cleaning and disinfection.

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

#### § 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 saltwater.

**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, 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.

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

**§ 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 requirements, 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](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 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]

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

PART 93—IMPORTATION OF CERTAIN ANIMALS, BIRDS, FISH, AND POULTRY, AND CERTAIN ANIMAL, BIRD, AND POULTRY PRODUCTS; REQUIREMENTS FOR MEANS OF CONVEYANCE AND SHIPPING CONTAINERS

■ 4. The authority citation for part 93 continues to read as follows:

Authority: 7 U.S.C. 1622 and 8301-8317; 21 U.S.C. 136 and 136a; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.4.

■ 5. Section 93.900 is amended by adding the following definitions in alphabetical order to read as set forth below.

§ 93.900 Definitions.

\* \* \* \* \*

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

\* \* \* \* \*

Approved laboratory. A laboratory authorized by the competent authority of a country 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.

\* \* \* \* \*

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.

\* \* \* \* \*

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.

\* \* \* \* \*

VHS-regulated fish. Any fish species listed in accordance with § 93.910.

VHS-regulated region. Any region listed in accordance with § 93.910.

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

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

§§ 93.901 through 93.906 [Undesignated heading added]

■ 6. Subpart I is amended by adding an undesignated center heading, "General Provisions for SVC-Regulated Fish Species", preceding § 93.901.

§§ 93.907 through 93.909 [Reserved]

■ 7. Sections 93.907 through 93.909 are added and reserved.

■ 8. An undesignated center heading and new §§ 93.910 through 93.916 are added to subpart I after the newly reserved §§ 93.907 through 93.909 to read as follows:

General Provisions for VHS-Regulated Fish Species

§ 93.910 General restrictions; exceptions.

(a) No live VHS-regulated species of fish may be imported into the United States from VHS-regulated regions except in accordance with this subpart or the regulations of the U.S. Fish and Wildlife Service (FWS) in 50 CFR 16.13(a)(3) and 16.13(b), nor may such live VHS-regulated fish be moved from the port of entry after arrival until released by an APHIS representative or FWS official; Provided, that the Administrator may, upon request in specific cases, allow the importation of live VHS-regulated fish into the United States under conditions other than those specifically set forth in this subpart

when the Administrator determines that such movement will not result in the further introduction of VHS into the United States.

(b)(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 competent authority to be adequate to detect VHS virus, with confirmation of strain identity through genetic sequencing. Anadromous fish species 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 (b)(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.

(c)(1) APHIS will list as a VHS-regulated region any region in which VHS virus has been officially reported to the World Health Organization for Animal Health by the country's competent authority for aquatic animal health from any fish species in a water source that is not a secure water source, or which the Administrator determines to be at risk of having VHS based on criteria such as inadequate surveillance, less restrictive import requirements, or other epidemiologic information.

(2) If the Administrator determines that a region meets the criteria in paragraph (c)(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 region 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 region will remain in effect.

(d) APHIS maintains the lists of VHS-regulated fish and VHS-regulated regions on the APHIS aquaculture Web site at [http://www.aphis.usda.gov/animal\\_health/animal\\_dis\\_spec/aquaculture](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.

(e) Other provisions of this subpart relating to the importation of live VHS-regulated fish shall not apply to shipments of such fish imported from

VHS-regulated regions if they are imported in accordance with the FWS regulations in 50 CFR 16.13.

(f) Other provisions of this subpart relating to the importation of live VHS-regulated fish shall not apply to shipments of such fish in transit through the United States, if an import permit has been obtained under § 93.912 and all conditions of the permit are observed, and if the live VHS-regulated fish species are handled as follows:

(1) They are maintained under continuous confinement while in transit through the United States aboard an aircraft, ocean vessel, or other means of conveyance; or, if they are unloaded in the course of such transit, they are placed in a holding facility that is provided by the carrier or its agent and has been approved by the Administrator as adequate to prevent the spread within the United States of any finfish disease; they are maintained there under continuous confinement until loaded aboard a means of conveyance for transportation from the United States; and they are maintained under continuous confinement aboard such means of conveyance until it leaves the United States.

(2) They are moved in accordance with any additional conditions prescribed in the permit that the Administrator has determined to be necessary to ensure that the fish do not introduce VHS into the United States.

(3) For a holding facility to be approved by the Administrator, the following conditions must be met:

(i) The holding facility must be sufficiently isolated to prevent direct or indirect contact of the live fish it contains with any other live VHS-regulated fish species in the United States.

(ii) The holding facility must be constructed to provide adequate protection against environmental conditions and so that it can be adequately cleaned, washed, and disinfected.

(iii) Provision must be made for disposal of fish carcasses, shipping water, effluent, waste, and any associated shipping materials in a manner that will prevent dissemination of disease.

(iv) Provision must be made for adequate sources of feed and water and for attendants for the care and feeding of fish in the facility.

(v) The holding facility must comply with all applicable local, State, and Federal requirements for environmental quality.

(vi) The holding facility must comply with any additional requirements that the Administrator may impose on a

particular shipment in order to prevent the dissemination of disease.

(g) Other provisions of this subpart relating to the importation of live VHS-regulated fish shall not apply to fish moved into the United States from VHS-regulated regions during catch-and-release fishing.

#### **§ 93.911 Ports designated for the importation of live VHS-regulated fish species.**

(a) Live VHS-regulated fish from VHS-regulated regions may be imported into the United States without an import permit through the following Canadian border ports: Eastport, ID; Houlton and Jackman, ME; Detroit, Port Huron, and Sault Ste. Marie, MI; Baudette, MN; Opheim, Raymond, and Sweetgrass, MT; Alexandria Bay, Buffalo, and Champlain, NY; Dunseith, Pembina, and Portal, ND; Derby Line and Highgate Springs, VT; and Oroville and Sumas, WA.

(b) Live VHS-regulated fish may be imported into the United States with an import permit through the following ports: Anchorage, AK; Los Angeles and San Francisco, CA; Miami and Tampa, FL; Atlanta, GA; Honolulu, HI; Chicago, IL; Boston, MA; Newark, NJ; Jamaica and Newburgh, NY; Portland, OR; Memphis, TN; Dallas-Ft. Worth, TX; Seattle, WA; and San Juan, PR.

(c) *Designation of other ports.* Other ports may be designated by the Administrator in specific cases with the concurrence of the Secretary of the Department of Homeland Security.

#### **§ 93.912 Import permits.**

(a) Live VHS-regulated fish imported from VHS-regulated regions through a limited port as described in § 93.911(b) must be accompanied by an import permit issued by APHIS and must be imported within 30 days of the proposed arrival date stated in the import permit.

(b) An application for an import permit must be submitted for each shipment of live VHS-regulated fish to the Animal and Plant Health Inspection Service, Veterinary Services, National Center for Import and Export, 4700 River Road Unit 38, Riverdale, MD 20737-1231. Application forms for import permits may be obtained from this address. Applications may also be obtained from the following APHIS Web site: <http://www.aphis.usda.gov/vs/ncie/pdf/vs17-129.pdf>.

(c) A completed application must include the following information:

(1) The name and address of the person intending to export live VHS-regulated fish to the United States;

(2) The proposed date of shipment to the United States;



(3) The name and address of the person intending to import live VHS-regulated fish into the United States;

(4) The species and number of live VHS-regulated fish to be imported into the United States;

(5) The purpose of the importation;

(6) The port of embarkation;

(7) The mode of transportation;

(8) The route of travel, including all carrier stops en route;

(9) The port of entry in the United States;

(10) The proposed date of arrival in the United States; and

(11) The name and address of the person to whom the live VHS-regulated fish will be delivered in the United States.

(d) If APHIS determines that the live VHS-regulated fish from VHS-regulated regions are eligible for importation, APHIS will issue an import permit indicating the applicable conditions for importation. An import permit does not guarantee that any live VHS-regulated fish will be allowed entry into the United States; the VHS-regulated fish will be allowed to enter the United States only if they meet all applicable requirements of the permit and regulations.

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

#### **§ 93.913 Health certificate.**

(a) *General.* All live VHS-regulated fish that are imported from VHS-regulated regions for other than immediate slaughter or research or laboratory use must be accompanied by a health certificate issued by a full-time salaried veterinarian of the national government of the exporting country, or issued by a certifying official and endorsed by the competent authority of that country. The health certificate must be written in English or contain an English translation. The health certificate will be valid for 30 days from the date of issuance. The health certificate for the live VHS-regulated fish must state that:

(1) The live fish were inspected by the veterinarian or certifying official who issued the certificate within 72 hours prior to shipment, and were found to be free of any clinical signs of disease consistent with VHS; and

(2) The live fish covered by the health certificate originated in a region or facility that has demonstrated freedom from VHS through testing in accordance with paragraphs (b) and (c) of this section.

(b) *Testing.* A facility can demonstrate freedom from VHS through negative testing results by a pathogen detection laboratory approved for VHS viral

assays by the competent authority of that country. Testing must meet the following conditions:

(1) Testing must be conducted with a testing 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) Tests must include virus isolation or other assays authorized by the competent authority, 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) Proportional numbers of each VHS-regulated fish species which might be present in a shipment must be used for testing, if applicable.

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

(c) 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 (b) 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 fish facility.

(d) *Shipping containers.* Except as provided in § 93.910(e)–(g), all live fish that are to be shipped to the United States must be shipped in new containers or in containers that have been cleaned and disinfected.

(1) Cleaning and disinfection of shipping containers must be monitored by the veterinarian or certifying official who issues the health certificate.

(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 health certificate or in a separate cleaning and disinfection certificate accompanying the shipment to the U.S. port of entry.

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

#### **§ 93.914 Declaration and other documents.**

(a) For live VHS-regulated fish offered for importation under this subpart, the importer or his or her agent must submit the following documents to the appropriate Customs and Border Protection officer for use by the port veterinarians:

(1) All permits, certificates, or other documentation required under §§ 93.912 and 93.913; and

(2) Two copies of a declaration that lists the port of entry; the name and address of the importer; the name and address of the broker; the origin of the live fish; the number, species, and the purpose of the importation; the name of the person to whom the fish will be delivered; and the location of the place to which such delivery will be made.

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

#### **§ 93.915 Inspection at the port of entry.**

(a) Shipments of live VHS-regulated fish must be presented for inspection at a port of entry designated under § 93.911. For live fish entering through a limited port listed in § 93.911(c), the APHIS port veterinarian must be notified at least 72 hours in advance of the arrival in the United States of the shipment. Any shipment that does not meet the requirements of this subpart will be refused entry.

(b) Shipments refused entry must be exported within a time fixed in each case by the Administrator, and in accordance with other provisions he or she may require in each case for their handling, or the shipment will be disposed of as the Administrator may direct.

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

**§ 93.916 Special provisions.**

(a) *Slaughter.* Live VHS-regulated fish from VHS-regulated regions may be imported directly for slaughter under the following conditions:

(1) An import permit has been obtained under § 93.912 and all conditions of the permit are observed.

(2) An APHIS representative at the port seals the means of conveyance with official seals.

(3) The shipment is moved directly from the port of entry to a slaughtering establishment that 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) An APHIS representative will unseal the vehicle upon arrival at the slaughtering establishment.

(5) 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.

(b) *Research or laboratory use.* Live VHS-regulated fish may be imported from a VHS-regulated region for research or laboratory use under the following conditions:

(1) An import permit has been obtained under § 93.912 and all conditions of the permit are observed.

(2) The laboratory or research facility disposes of effluent 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.

(3) Carcasses must be 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.

Done in Washington, DC, this 4th day of September 2008.

**Kevin Shea,**

*Acting Administrator, Animal and Plant Health Inspection Service.*

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**DEPARTMENT OF AGRICULTURE****Food Safety and Inspection Service****9 CFR Parts 317, 381, and 442**

**[Docket No. FSIS-2008-0015]**

**RIN # 0583-AD17**

**Determining Net Weight Compliance for Meat and Poultry Products**

**AGENCY:** Food Safety and Inspection Service, USDA.

**ACTION:** Final rule.

**SUMMARY:** The Food Safety and Inspection Service (FSIS) is amending its regulations to reference the most recent version of the National Institute of Standards and Technology (NIST) Handbook 133 that contains standards for determining the reasonable variations allowed for the declared net weight on labels of immediate containers of meat and poultry products; the procedures to be used to determine the net weight and net weight compliance of meat and poultry products; and related definitions. The Agency is also consolidating the separate net weight regulations for meat and poultry products in a new CFR part, applicable to both meat and poultry products.

This final rule does not incorporate by reference sections in Handbook 133 that concern the "wet tare" method for determining net weight. The "wet tare" method does not include free-flowing liquid as part of the product but as part of the tare weight. The Agency regards any solutions that are added to meat or poultry to be part of the product and considers free-flowing liquids to be an integral component of these products, and therefore uses the "dry tare", not the "wet tare" method.

**DATES:** *Effective Date:* This regulation is effective October 9, 2008. The incorporation by reference of the NIST Handbook 133, Fourth Edition, is approved by the Director of the Federal Register as of October 9, 2008.

**FOR FURTHER INFORMATION CONTACT:**

Charles Gioglio, Director, Labeling and Program Delivery Division, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250-3700; (202) 205-0010.

**SUPPLEMENTARY INFORMATION:****Background**

FSIS administers the Federal Meat Inspection Act (FMIA) (21 U.S.C. 601-695), the Poultry Products Inspection Act (PPIA) (21 U.S.C. 451-470), and the regulations that implement these Acts. The FMIA and the PPIA require that packages of meat and poultry products bear an accurate statement of the quantity of their contents in terms of weight, measure, or numerical count (21 U.S.C. 601(n)(5) and 453(b)(5)). The FMIA and PPIA also provide the Secretary of Agriculture with the authority to prescribe standards of fill of containers for such articles (21 U.S.C. 607(c)(2), 457(b)(2)) that are not inconsistent with any such standards established under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301-392). In implementing regulations, FSIS has elected to adopt the relevant NIST standards established for determining compliance with the net weight contents statement of packaged goods that are enumerated in NIST Handbook 133. Consequently, FSIS has incorporated by reference certain NIST standards in the Federal meat and poultry inspection regulations.

NIST was established by Congress in 1988 to assist industry in the development of technology to improve product quality, to modernize manufacturing processes, to ensure product reliability, and to facilitate rapid commercialization of products based on new scientific discoveries. NIST's basic functions include developing, maintaining, and retaining custody of the national standards of measurement and providing the means and methods for comparing standards used in science, engineering, manufacturing, commerce, industry, and education with the standards adopted or recognized by the Federal Government.

NIST Handbook 133 is a procedural guide for compliance testing of net content statements on packaged goods. FSIS has elected to make mandatory the NIST standards in Handbook 133 regarding the determination of the reasonable variations allowed from the declared net weight on labels of immediate containers of meat and poultry products, the procedures to be used to determine net weight and net weight compliance for meat and poultry products, and related definitions.

Consequently, FSIS currently incorporates by reference the NIST standards from Handbook 133 in its meat and poultry regulations. The Agency first incorporated NIST Handbook 133 by reference in