



APHIS Restrictions on Interstate Movement of Fish in the Great Lakes Region

October 2008

On September 9, 2008, the Animal and Plant Health Inspection Service (APHIS), an agency within the U.S. Department of Agriculture, issued regulations restricting the import and interstate transport of live fish susceptible to viral hemorrhagic septicemia (VHS) within the Great Lakes region. (73 Fed. Reg. 52173). VHS is a highly contagious fish disease once thought to be limited to farmed rainbow trout in Europe. VHS, however, has been detected in a variety of saltwater species, both wild and cultured, in the Atlantic and Pacific Oceans. In 2005 – 2006, the outbreak of a new strain of VHS resulted in mass mortality of freshwater fish in the Great Lakes region. By the end of 2007, this new strain, VHSV Genotype IVb, had been isolated from over 25 finfish species in Lake Michigan, Lake Huron, Lake St. Clair, Lake Erie, Lake Ontario, the Saint Lawrence River, and inland lakes in New York, Michigan, and Wisconsin. (USGS Fact Sheet, *Detection of Viral Hemorrhagic Septicemia Virus* (July 12, 2007)).

APHIS has the authority to prohibit or restrict the “the importation or entry of any animal, article, or means of conveyance, or use of any means of conveyance or facility, if the Secretary determines that the prohibition or restriction is necessary to prevent the introduction into or dissemination within the United States of any pest or disease of livestock.” (7 U.S.C. §8303(a)(1)). APHIS may also prohibit the movement of any animal if necessary to prevent the introduction or dissemination of a livestock disease or pest. (7 U.S.C. § 8303(a)(2)).

Important Procedural Note

Public comments on the rule are due by November 10, 2008, on which date the rule becomes effective. This type of rulemaking is sometimes referred to as interim-final rulemaking. APHIS has issued the rule pursuant to the Administrative Procedures Act’s (APA) “good cause” exception. Notice and comment is not required “when the agency for good cause finds (and incorporates the finding and a brief statement of reasons therefore in the rules issued) that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest.” (5 U.S.C. § 553(b)(B)). APHIS claims that “immediate action is necessary to prevent the introduction of VHS into aquaculture facilities.” (73 Fed. Reg. 52181).

Although APHIS is accepting public comments, it is under no legal obligation to consider those comments. Further, APHIS is not required to engage in further process (i.e., issue a final rule) after adopting a rule pursuant to the good cause exception. Most agencies that issue interim-final rules, however, do complete the rulemaking process by issuing a final rule. Unless the final rule independently qualifies for an APA exception, it must be preceded by public notice and comment. However, “the invitation for comments that accompanied the interim-final rule generally satisfies the APA’s public participation requirements” applicable to final rules. (Michael Asimow, *Interim-Final Rules: Making Haste Slowly*, 51 ADMIN. L. REV. 703, 722 (1999)). Any comments submitted on the interim rule, therefore, may be considered comments on the future final rule.

Interstate Transport Restrictions

After November 10, live VHS-regulated fish may only be moved interstate from a VHS-regulated area if the fish originates from a facility that has been found free of VHS 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. APHIS intends to maintain the official lists of VHS-regulated fish and areas on its website at http://www.aphis.usda.gov/animal_health/animal_dis_spec/aquaculture/. The VHS-regulated areas currently include Illinois, Indiana, Michigan, Minnesota, New York, Ohio, Pennsylvania, and Wisconsin. All live fish must be moved in new containers or in containers that have been cleaned and disinfected in a manner sufficient to neutralize any VHS. The cleaning and disinfection must be monitored by the entity that issues the ICI.

The ICI must state that the fish were inspected within 72 hours prior to shipment and found free of any clinical signs of disease and originate in an area or facility that has demonstrated freedom from VHS. A facility can demonstrate freedom from VHS through negative testing results provided by an approved laboratory. Testing must:

- Be conducted with a sample size that provides for a 95% confidence level of detecting a 2% prevalence of infection in the facility;
- Include virus isolation or other assays authorized by the Administrator, using appropriate cell lines to detect the VHS virus, if present;
- Use proportional numbers of each VHS-regulated fish species which might be present in the facility; and
- Be conducted at water temperatures between 50 °F and 72 °F, or at other times or under environmental conditions when VHS is most likely to be detected.

For VHS-regulated fish maintained on a secure water source, test results will be valid for six months from the date of sample collection provided that no fish of a lesser or unknown health status are introduced into the facility. A secure water source is “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.” Test results for fish held on a non-secure water source will be valid for thirty days.

Facilities which can document a two-year history of negative testing can conduct testing at a sampling level to provide a 95% confidence level of detecting a 5% prevalence of infection in the facility. Facilities with a four-year negative history can conduct testing at a sampling level to provide a 95% confidence level of detecting a 10% prevalence of infection in the facility. These facilities must be on a secure water source.

When new species are added to the list, facilities must conduct additional testing on that species if present to maintain their “VHS-free” status. Such testing must be conducted on each newly listed species with a sample size that provides for a 95% confidence level of detecting a 2% prevalence of infection in the facility.

Practical Effect of Testing Requirements

According to APHIS’ factsheet, Q&A: VHS Interim Rule, an ICI for fish from non-secure water sources can be issued as soon as test results are available, up to thirty days from sample collection. The ICI is valid for thirty days. In theory, then, producers on non-secure water sources have up to sixty days from the date of sample collection to move the animals.

The reality of existing testing methods, however, suggests that producers will have much less flexibility. Currently, a laboratory needs twenty-eight days to conduct a valid VHS test. In the

best-case scenario, a facility could sample its fish on September 1 and ship the sample to the laboratory overnight. If the laboratory could begin cell culture on September 2, the results would be available on September 29. Facilities would have only one day to obtain the ICI. The ICI would be valid during the month of October. Each shipment of fish in October under that ICI would need to be inspected by a veterinarian 72 hours in advance.

Two Exceptions

The regulations contain two exceptions. First, live VHS-regulated fish may be moved interstate for research or diagnostic purposes or directly to a slaughtering establishment if the fish are accompanied by the appropriate forms and transported in sealed conveyances to a facility or slaughtering establishment that renders or composts the offal and discharges its waste water to a non-discharging settling pond or a municipal sewage system or settling pond that disinfects sufficiently to neutralize any VHS virus. Water used to transport the fish must be disposed in a similar manner.

Second, live VHS-regulated fish may also be moved interstate during catch-and-release fishing. Catch and release fishing is defined as “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 definition, however, excludes VHS-regulated fish used, or intended to be used, as live bait.

Import Restrictions

The interim rule permits the importation of live VHS-regulated fish into the United States from VHS-regulated regions in accordance with U.S. Fish and Wildlife Service (FWS) regulations (50 CFR § 16.13(a)(3) and § 16.13(b)). APHIS intends to list as VHS-regulated regions “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.” Currently, Ontario and Quebec are listed as VHS-regulated regions.

Depending on the point of entry, importers may need to obtain import permits. APHIS has identified twenty Canadian border ports that it considers to have adequate facilities and inspectors to handle live shipments of fish without advance notice. Import permits, however, are required to import live VHS-regulated fish through seventeen U.S. ports. The designated ports will be listed at 9 C.F.R. § 93.911. Unless imported for immediate slaughter or research/laboratory use, all imported fish 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. No live fish may be moved from the port of entry after arrival until released by an APHIS representative or FWS official.

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