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U.S. Department of Agriculture
Animal and Plant Health Inspection Service
Regulatory Analysis and Development
PPD, APHIS, Station 3A-03.8
4700 River Road Unit 118
Riverdale, MD 20737-1238

RE: Docket No. APHIS-2007-0038; Viral Hemorrhagic Septicemia, Interstate Movement and Import Restrictions on Certain Live Fish Interim Rule

Dear Sir or Madam:

I am writing on behalf of the American Veterinary Medical Association (AVMA), established in 1863 and the largest veterinary medical association in the world. As a not-for-profit association established to advance the science and art of veterinary medicine, AVMA is the recognized national voice for the veterinary profession. The association's more than 76,000 members comprise approximately 86% of U.S. veterinarians, all of whom are involved in a myriad of areas of veterinary medical practice including private, corporate, academic, industrial, governmental, military, and public health services.

The AVMA appreciates that APHIS desires to promulgate regulations to control the spread of viral hemorrhagic septicemia (VHS) in a number of finfish species imported into the United States and through interstate movement. However, the AVMA has concerns with the proposed interim rule as published in the *Federal Register* of September 9, 2008.

As announced in the *Federal Register* of October 28, 2008, the AVMA agrees with delaying the effective date of the interim rule. This action will allow APHIS to consider all comments and make adjustments to the interim rule in order to implement regulations that are effective, practical, and affordable. It is important that APHIS considers the interests of all stakeholders, including commercial farmed finfish industries, that the interim rule preserves the economic viability of the aquaculture industry without significantly increasing the risk of moving VHS into aquaculture or to other geographic regions. Since national regulations affect the promulgation of state regulations, and because the U.S. aquaculture industries have not yet been able to adopt universal procedures used in livestock industries to prevent the spread of diseases, the AVMA suggests that implementation of the interim rule may need to be postponed beyond January 9, 2009. The AVMA believes it is important for APHIS to hold educational and discussion meetings to allow greater exploration and concurrence on these issues.

The AVMA offers the following comments for APHIS to consider in promulgating effective, practical, and economical regulations for the control of VHS.

General Comments

The AVMA appreciates that, for a variety of reasons, existing state and federal regulations designed to restrict the movement of diseased finfish and other aquatic animals are very disparate and may not be effective. We further recognize the primary goal of this interim rule is to assure that animals infected with VHS are not moved. As proposed, this is accomplished through the issuance of a Certificate of Inspection by a competent individual who accepts the responsibility for the health status of the fish, and with approval and oversight of the state or federal government agency with responsibility over the source populations in question. It is clearly recognized that while the proposed interim rule applies primarily to VHS in the Great Lakes states, the approaches taken are likely to be applied by all states. Indeed, we are already seeing states outside the Great Lakes region promulgate regulations to prevent the incursion of VHS and other aquatic animal diseases from this region and other states. Therefore, the processes and procedures developed within this interim rule for VHS are likely to be applied to other finfish and aquatic animals.

For many decades terrestrial animals, particularly livestock, demonstrated to be free of specific diseases have been moved (even from regions affected by a disease) in large numbers without disrupting commerce. The same principles that allow for safe terrestrial animal commerce must be applied to aquaculture. Compared to other commercial livestock industries, the U.S. commercial aquaculture industry is relatively small. Cumbersome, expensive and disparate regulations will not adequately serve the aquatic animal industries or the government agencies with oversight of aquatic animal disease.

Consequently, the AVMA believes it is imperative that the proposed interim rule be developed based on sound scientific principles and appropriate risk analysis; be designed as a model for other aquatic animal regulations; that the final processes and procedures incorporated into the Code of Federal Regulations will be easily harmonized with local, interstate and international regulations and approaches; and, that the approaches address aquaculture industry concerns.

The AVMA also recognizes that APHIS has primary responsibility for aquatic livestock (commercial aquaculture/farmed fish) and we applaud the agency for assisting and funding the Great Lakes states to develop VHS surveillance programs. We note that almost all of these efforts have gone towards VHS surveillance in wild populations, which fall within the U.S. Fish and Wildlife Services jurisdiction. These data can be used to help establish risk from open water sources. APHIS' collaboration with the U.S. Fish and Wildlife Service and state natural resources agencies is critical to the development of similar harmonized programs for wild finfish and for other diseases. We hope that these agencies will provide additional resources to this effort.

Biosecurity for Aquatic Animals

Biosecurity programs should serve as the basis for farms to be certified and audited to be VHS free. The most practical, economic and effective approach is for aquaculture facilities to develop and implement a written biosecurity plan with the assistance and oversight of a veterinarian or another competent official. An effective biosecurity plan should include: determining that the aquaculture facility is free of VHS; site-specific procedures and protocols for assessing and mitigating the critical control points for preventing VHS entry; contingencies for the control and eradication should VHS be discovered; and auditable record keeping requirements. Isolation of fish populations that have been shown to be free of VHS, cleaning and disinfection, and other procedures should be included in this plan.

The AVMA believes this approach of auditing the implementation and maintenance of a biosecurity plan by a veterinarian or another competent official would facilitate the rapid and uncomplicated issuing of Interstate Certificates of Inspection (ICI) and endorsement by the competent authority any time fish are to be moved.

Epidemiological Approaches for Determining Finfish are Free of Disease

The AVMA believes that surveillance, monitoring and disease-freedom certification programs should be based on epidemiological units (zones, compartments and facilities – farms) not state political boundaries. This approach is consistent with the World Organization for Animal Health's (OIE) approach for identifying zones, compartments and facilities (as epidemiological units) that are free of disease; an approach that is fully supported by the United States as a member of OIE. The AVMA therefore believes that:

- Watersheds (possibly defined by Hydrologic Unit Codes), rather than state political lines should be used as a means of regulating aquatic animal diseases. However, we recognize that further epidemiological data needs to be obtained to support regulation by watersheds, that the process can be time consuming, and will require support and cooperation of state competent authorities.
- Once wild epidemiological units are determined to be free of VHS, unprotected water sources can be regarded the same as protected water sources in terms of risk of disease transmission.

The AVMA is also aware that currently no privately owned commercial aquaculture operations have been identified as being infected with VHS. The AVMA therefore encourage APHIS to work with states and collaborate financially to support expansion of VHS surveillance and monitoring efforts in commercial aquaculture operations in order to confirm that fish farms are free of VHS. Once VHS freedom is verified and accepted by the competent authorities having jurisdiction over these operations, compartments or zones, we believe that Interstate Certificates of Inspection (ICI) can be issued rapidly and without additional diagnostic testing, provided operation-specific biosecurity plans (see below) are maintained, audited and verified by the attending accredited veterinarian or another competent official.

Veterinary and Non-veterinary Aquatic Animal Workforce

The AVMA believes there needs to be an adequate workforce to support and implement the interim rule. Currently AVMA estimates approximately 2,000-2,500 U.S. veterinarians are involved in aquatic veterinary medicine in one way or another, including private clinical practitioners and those that work in diagnostic laboratories, government, academia, industry, or other facets of animal health. Some of these veterinarians and disease diagnostic laboratories that provide aquatic animal diagnostic services can be located at www.AquaVetMed.info, a website administered by the AVMA in partnership with other collaborators. The AVMA recognizes that currently these online resources have limitations and the AVMA is examining options for their improvement. Furthermore, the AVMA believes that current efforts to develop aquatic modules under the direction of APHIS will support the National Veterinary Accreditation Program (NVAP) and will strengthen the aquatic veterinary workforce.

Additionally, 60-70 non-veterinarians (primarily AFS-FHS certified fish health inspectors and certified fish pathologists) could potentially be available to help the aquaculture industry comply with eventual regulations. However, there are challenges in using these non-veterinarians in veterinarian-regulatory roles.

The AVMA believes there is a lack of clarity in describing “officials” and “authorities” involved with VHS regulatory functions. We strongly encourage APHIS to clearly distinguish “competent officials” (e.g.

accredited veterinarians, and non-accredited veterinarians and non-veterinarians employed by an agency and designated as a state animal health official) from “competent authority” (a government agency with full knowledge, understanding and authority over disease of finfish). It is important that all parties understand that any “competent officials” must recognize and accept the legal responsibility for inspecting animals (evaluating possible clinical signs in populations), interpreting laboratory diagnostic results, and issuing Interstate Certificates of Inspection (ICI)s. The AVMA also notes that:

- Most non-veterinary personnel are employed by state or federal agencies to perform in-house laboratory work and are unavailable to assist on-farm.
- Government agencies have few funds to support the use of government employees to perform all VHS regulatory work and ultimately government-industry cost-sharing will need attention.

Certificates of Inspection

The AVMA believes that Certificates of Inspection attesting to the health of aquatic animals and used for certifying their disease status for intrastate, interstate and international movement, should only be issued by appropriate government-employed veterinarians, or USDA-accredited veterinarians. However, the AVMA recognizes that, given the current aquatic veterinary workforce numbers, it may not be feasible in the short term for all such certificates to be issued by veterinarians. While supporting the integration of all veterinarian and non-veterinarian resources to achieve disease-free certification (as captured in the AVMA policy on certificates of inspection for aquatic animals below), if non-veterinarians are given the authority to issue Interstate Certificates of Inspection (ICI) they must be held to the same legal standards as accredited veterinarians.

Issuing Certificates of Inspection for Aquatic Animals

The AVMA recognizes the importance and encourages the development of uniform criteria for certificates of inspection attesting to the health of aquatic animals that can be used for certifying their disease status for intrastate, interstate and international movement.

Issuance of certificates of inspection attesting to the health of aquatic animals requires a veterinarian’s clinical evaluation of the animals, interpretation of diagnostic assays, and the veterinarian signing declarations that require knowledge of all factors used to determine the disease status of the animals. Therefore, the AVMA’s position is that certificates of inspection attesting to the health of aquatic animals only be issued by federal or accredited veterinarians.

The AVMA recognizes that the involvement of non-veterinarians in producing information such as diagnostic assay results is necessary for issuing these certificates and encourages systems that integrate veterinary and non-veterinary participation in these important roles. The AVMA will therefore actively work with local, state and federal agencies, aquaculture industry representatives, and others to ensure the optimal roles of all personnel in the development and issuance of such certificates.

Interstate Certificates of Inspection (ICI) need clear identification of certain items to ensure uniform content within the Certificate of Inspection (ICI) for use by all states, including the following:

- Adequate information for an importing state to verify the source and destination; tests used and results; verifying statements of veterinarian (or state non-veterinarian designee); and endorsement by the “competent authority.”
- The proposed interim rule does not include the name and contact information of the veterinarian (or state non-veterinarian designee) issuing and signing the document. The name and contact information of the signer should be required on the Interstate Certificate of Inspection (ICI). Absence of such information makes it nearly impossible to contact the signing individual.

The AVMA strongly encourages interstate harmonization of requirements for movement of aquatic animals, with the eventual goal of APHIS developing a model Interstate Certificate of Inspection for possible use by all states and territories. Before proceeding however, APHIS should seek stakeholder input for its optimal structure and use.

Testing Requirements

The AVMA shares the National Aquaculture Association's (NAA) concerns regarding diagnostic sampling requirements and believes there are logistical constraints to compliance and associated costs could be prohibitive.

The current U.S. protocol for identifying VHS utilizes cell culture and PCR and can take up to 28 days to produce results. The interim rule proposes a 30 day window for diagnostic test result validity in operations having unsecured water sources. Test results will likely be invalid by the time the farm, attending veterinarian or government agency receives them. In addition, the interim rule requires diagnostic samples to be taken when water temperatures are between 50-72 degrees F. Because of seasonal temperature variation in many areas this becomes very problematic and diagnostic sampling of some finfish species in some aquaculture operations may be impractical at the temperature range specified by the rule. Furthermore, there is no current science that determines or supports a specific period of time (30 days) for validity of the test results. In the absence of such evidence, the AVMA proposes that other options be considered that can mitigate risks of VHS while removing logistical barriers and balancing economic impact.

The AVMA also proposes that, in the absence of an audited biosecurity plan demonstrating VHS freedom, the following should be used to determine if a population of fish intended to be moved are free of VHS:

- Operations with open water sources (not already determined to be free of VHS) should be tested twice a year, whereas operations with secure, closed or VHS-free water sources should be tested once a year when water temperatures are permissible for detection of VHS (50-72 degrees F);
- Negative diagnostic laboratory test results should be determined to be valid from the date of test results (rather than sample collection);
- Populations of fish that have been sampled for diagnostic testing and are intended for shipment should be isolated from untested populations at the origin; and,
- Provided that biosecurity plans are implemented and these populations are not exposed to potential sources of VHS, the issuance of ICIs should be valid for 6 months.

Laboratory Diagnostics

Because of the logistic challenges with the current testing, the AVMA supports the recent USAHA resolution:

The United States Animal Health Association (USAHA) requests that the United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS), Veterinary Services (VS) evaluate and validate the Canadian (all strains) and/or Cornell (strain IVb) polymerase chain reaction (PCR) assay for the detection of viral hemorrhagic septicemia (VHSv). The test will be used to monitor the spread of VHSv in wild fish and to satisfy VHSv interstate movement requirements for regulated species of fish as determined by USDA-APHIS-VS.

The AVMA therefore suggests that if APHIS were to evaluate, validate and determine that rapid PCR assays meet the "fitness of purpose" for determining fish are not infected with VHS virus outside the 50-72 degrees F limitation, this would further facilitate rapid determination of VHS freedom. Our suggestion

presumes that infected fish held outside the 50-72 degrees F limitation are indeed infected, but are not actively replicating the virus.

Visual Inspection and Disinfection Requirements

The AVMA believes that the requirement of a visual inspection within 72 hours of shipment does not provide any added benefit to biosecurity programs or in minimizing disease transmission. The AVMA also believes that the visual inspection requirement prior to shipment poses several challenges including the lack of specific pathognomonic clinical signs/lesions for VHS and currently the veterinary and non-veterinary workforce is inadequate to meet the demands of the industry if required to complete a visual inspection 72 hours prior to every shipment. The AVMA therefore recommends that the 72 hour rule be removed and offers an alternative to this 72 hour rule, namely that aquaculture facility should develop an effective biosecurity program that can be periodically audited to verify that a VHS-free facility has procedures in place to prevent exposure to VHS.

Similarly, given workforce limitations, economics, and logistics, the monitoring of the cleaning and disinfection of transport containers (which is inevitably done immediately before or after shipment) by an accredited veterinarian or competent official is impractical. Furthermore we know of no government agency-approved cleaning and disinfection procedures nor products that have been shown to adequately remove VHS contamination. The AVMA believe that once these are developed, it is more appropriate to require them to be included in an operation's biosecurity program than in regulations.

Consequently, the AVMA proposes removing this requirement from the interim rule. However, if APHIS does not exercise this option, the AVMA believes it is more practical and appropriate for cleaning and disinfection of transport containers to be certified by the producer or hauler. This certification could be either attested to in the Certificate of Inspection or an accompanying affidavit.

In conclusion, the AVMA urges for ongoing discussion and delay of the effective date of the interim rule. This action will allow APHIS to consider all comments and make adjustments to the interim rule in order to implement regulations that are effective, practical, and affordable. It is important that the interim rule preserves the economic viability of the aquaculture industry without significantly increasing the risk of moving VHS into aquaculture or to other geographic regions.

The AVMA thanks APHIS for the opportunity to offer comments.

Sincerely,



for

W. Ron DeHaven DVM, MBA
Executive Vice President