

UNITED STATES ANIMAL HEALTH ASSOCIATION - 2008 RESOLUTION

RESOLUTION NUMBER: 9 **APPROVED**

SOURCE: USAHA/AAVLD JOINT COMMITTEE ON AQUACULTURE

SUBJECT MATTER: USE AND INTERPRETATION OF POLYMERASE CHAIN REACTION (PCR) RESULTS FOR VIRAL HEMORRHAGIC SEPTICEMIA VIRUS (VHSV)

BACKGROUND INFORMATION:

Viral hemorrhagic septicemia virus (VHSV), an emerging fish pathogen, has led to unprecedented regulatory action by the United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS), Veterinary Services (VS) to prevent the transfer to/from aquaculture. Given the nature of the aquaculture industry, the risk of spread is great and surveillance is necessary. In response, the USDA funded a \$2.5 million, multi-state VHSV surveillance program (2007-present) and has also required susceptible fish moving interstate from any Great Lakes state to be tested for the VHSV. In addition, some states have begun to require VHSV testing for intrastate movement. Current laboratory testing protocols require virus isolation as the gold-standard. Compared to available molecular methods, the drawbacks to this technique include increased cost of labor and turn around time, and lower sensitivity. Two quantitative polymerase chain reaction (PCR) assays have been developed for the detection of VHSV, including one for all known strains (Canadian VHSV assay) and one specifically for the Great Lakes strain IVb (Cornell VHSV assay). Laboratory trials have shown these assays to be 1,000 to 10,000 times more sensitive than virus isolation and reduces the turn-around time from 28 days to one day. In addition, demonstrating confidence in the Cornell VHSV assay, over 6,000 samples have been tested without a PCR false positive. The Canadian assay is currently undergoing complete World Organization for Animal Health (OIE) validation (expected completion 2009), but already is being used as the gold standard in the Canadian VHSV surveillance program.

The use of PCR for surveillance is not a novel idea and is widely accepted for other animal pathogens in the United States. Programs currently using PCR include avian influenza, classical swine fever, bacterial meningitis, Johne's disease, bovine spongiform encephalopathy, and others. For these surveillance programs, PCR positive results indicate this is a population in need of further study. Additional testing of the original material or population to confirm the PCR result is required to eliminate the possibility of a false positive result. Depending on the pathogen, these methods may include isolating the bacteria or virus, serological tests, or additional PCR tests. During confirmatory testing, movement of the animals is controlled based on the regulatory status of the disease and demonstration of clinical signs. For example, movement restrictions for low-path avian influenza are minimal based on an initial PCR positive in apparently healthy poultry, since this disease would be clinically apparent. This same standard can

not be applied to all animals, including fish, where the VHSv has been shown to be present asymptotically. To prevent the unknowing spread of VHSv, it would be appropriate to monitor or restrict the movement of fish undergoing additional testing. Using these PCR assays for VHSv surveillance and farm inspections would benefit all parties involved. In particular, regulatory agencies and private aquaculturists demand the most sensitive, accurate and fastest test available to prevent the potential spread of the VHSv.

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 virus (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.

RESPONSE:

USDA, APHIS, Veterinary Services

The U.S. Department of Agriculture, Animal and Plant Health Inspection Service, Veterinary Services (VS) recognizes the United States Animal Health Association's concerns about viral hemorrhagic septicemia (VHS). As mentioned in the resolution, there are multiple real time (RT) polymerase chain reaction (PCR) assays, both published and unpublished, at various stages of validation. VS' National Veterinary Services Laboratories (NVSL) is willing to critically evaluate validation studies on any molecular assay developed for the detection and/or identification of VHS. VS is prepared to accept RT-PCR assay results in place of traditional cell culture assays once validation data have been reviewed and results are supported by NVSL.