

SUPPORTING STATEMENT - OMB NO. 0579-XXXX
VIRAL HEMORRHAGIC SEPTICEMIA; INTERSTATE MOVEMENT AND
IMPORT RESTRICTIONS ON CERTAIN LIVE FISH

March 2008

A. Justification

1. Explain the circumstances that make the collection of information necessary. Identify any legal or administrative requirements that necessitate the collection. Attach a copy of the appropriate section of each statute and regulation mandating or authorizing the collection of information.

The Animal Health Protection Act (AHPA) of 2002 is the primary Federal law governing the protection of animal health. The law gives the Secretary of Agriculture broad authority to detect, control, or eradicate pests or diseases of livestock or poultry. The Secretary may also prohibit or restrict import or export of any animal or related material if necessary to prevent the spread of any livestock or poultry pest or disease.

The AHPA is contained in Title X, Subtitle E, Sections 10401-18 of P.L. 107-171, May 13, 2002, the Farm Security and Rural Investment Act of 2002.

Disease prevention is the most effective method for maintaining a healthy animal population and enhancing the U.S. Department of Agriculture's (USDA) Animal and Plant Health Inspection Service's (APHIS) ability to allow U.S. animal producers to compete in the world market of animal and animal product trade.

APHIS regulations in title 9 of the *Code of Federal Regulations* (9 CFR), part 93 govern the importation of certain species of fish to prevent the introduction or spread of specific pests and diseases of aquacultured fish within the United States.

APHIS is establishing regulations to prevent the introduction of VHS into U.S. aquaculture facilities by controlling the movement of certain live fish species at risk of harboring viral hemorrhagic septicemia (VHS) virus, a highly contagious disease of certain fresh and saltwater fish. VHS is listed as a notifiable disease by the World Organization for Animal Health. 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.

In 2005 and 2006, VHS was detected in freshwater wild 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. APHIS' proposed regulations in parts 83 and 93 of the CFR are necessary to prevent further introductions into, and dissemination within, the United States of VHS. Accordingly, APHIS is requiring the use of the following information collection activities: Completion of an Interstate Certificate of Inspection, VS form 1-27, Cleaning and Disinfection Certificate, Import Permit Application, and Health Certificate; a 72-hour Notification; and Recordkeeping for Testing Requirements.

APHIS is asking OMB to approve, for 6 months, the use of this information collection activity in connection with its efforts to prevent the spread of pests and diseases of aquaculture within the United States.

2. Indicate how, by whom, how frequently, and for what purpose the information is to be used. Except for a new collection, indicate the actual use the agency has made of the information received from the current collection.

Interstate Certificate of Inspection (ICI)

Live VHS-regulated fish moved interstate 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. The ICI must state that the live fish were inspected by the accredited veterinarian or a State Tribal, or Federal competent authority within 72 hours prior to shipment, and were found to be free of any clinical signs of disease consistent with VHS. In addition, the ICI must state that the live fish covered by the ICI originated in an area or facility that has demonstrated freedom from VHS. The ICI must also include the species and number of the fish, the lot identification of shipment, and the name, address, and phone number of the owner or owner's agent; the facility in which the fish originated; the person or facility who will receive the fish, or State or other regulatory authority responsible for oversight of the environment in which the fish will be introduced; the shipping or transportation company; and the approved laboratory that performed the testing required. 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 questions about a shipment. The ICI will originate with the owner of the fish in the State in which the fish are located, and the ICI will be transferred and remain with the receiver of the fish. A form is being developed that will ask the same information, but will be an option in lieu of preparing a narrative.

Permit for Movement of Restricted Animals (VS Form 1-27)

Live VHS-regulated fish can be moved interstate, untested, to a research, diagnostic laboratory, or slaughter facility if discharges from these facilities go to a municipal sewage treatment plant with chemical disinfection, and if the shipment is accompanied by a VS Form 1-27 issued by an accredited veterinarian or a person authorized by a State, Tribal, or Federal competent authority for aquatic animal health.

Cleaning and Disinfection Certificate

All live VHS-regulated species of fish that are to be moved interstate must be moved in new containers or in containers that have been cleaned and disinfected. The cleaning and disinfection protocols must be referenced in the ICI or in a separate cleaning and disinfection certificate accompanying the shipment and completed by an accredited veterinarian or State, Tribal, or Federal competent authority for aquatic animal health. Requiring the issuance of Cleaning and Disinfection Certificate will ensure that appropriate cleaning and disinfection procedures were applied as well as allow for traceback should an inspector encounter a problem with or questions about a shipment.

Application for Import or In Transit Permit (Form VS 17-129)

U.S. importers of live VHS-regulated fish must complete and submit to APHIS, an application for an import permit for each shipment unless the live fish are imported through Los Angeles, CA, Miami, FL, Newburgh (JFK) NY, or certain Canadian land border ports. The application must include the following information: names and addresses of the exporter to the United States, person to whom the live fish will be delivered, and the person intending to import the live fish; proposed date of shipment; species and number of the fish to be imported; purpose of importation; port of embarkation; mode of transportation; route of travel; and port of entry into the United States. APHIS needs the Import Permit Application to determine whether the live VHS-regulated fish are eligible for importation, to respond to an applicant, to identify the shipment at the specific ports 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.

Health Certificate

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 must state that 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. In addition, the certificate must state that the live fish covered by the health certificate originated in a region or facility that has demonstrated freedom from VHS through testing. Facilities with a 2-year or greater history of negative testing results for VHS will be assumed to have a lower risk of spreading the disease; therefore, APHIS will decrease the number of fish required to be tested for such facilities which decreases public burden.

72-Hour Notification

Shipments of live VHS-regulated fish must be presented for inspection at a port of entry. For live fish entering through certain limited ports listed in APHIS' regulations, the importer must notify the APHIS port veterinarian at least 72-hours in advance of the arrival in the United States of the shipment. This notification is necessary to ensure APHIS is prepared for the arrival of 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

Recordkeeping for Testing Requirements

Testing records to support an aquaculture facility's claim of disease freedom from VHS virus must be maintained for a maximum of 4 years. This recordkeeping will provide APHIS with historical documentation to determine the risk of spreading VHS from a given facility.

3. Describe whether, and to what extent, the collection of information involves the use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses, and the basis for the decision for adopting this means of collection. Also describe any consideration of using information technology to reduce burden.

Interstate Certificate of Inspection: This document is not available through an automated system since no single template exists for an ICI. The information that must be included in an ICI is listed in the regulation, but the format can vary.

VS form 1-27: The VS 1-27 is a multiple-carbon type form and is available only through individual VS Area Offices; therefore, it is not suitable for electronic submission.

Cleaning and Disinfection Certificate: This document is not available through an automated system since no single template exists for a cleaning and disinfection certificate. Statements regarding cleaning and disinfection can be included in health certificates or in an ICI. The information that must be included in the cleaning and disinfection certificate is listed in the regulation, but the format can vary.

Import Permit Application (VS 17-129): Form VS 17-129 (and instructions) will be available on the APHIS Web site, by mail, or fax from Riverdale, MD VS Headquarters; or at VS Area Offices.

Health Certificate: This document is not available through an automated system since no single template exists for a health certificate. The information that must be included in the health certificate is listed in the regulation, but the format can vary.

72-hour Notification: Prior notification to the port veterinarian may be made by phone, fax or email.

4. Describe efforts to identify duplication. Show specifically why any similar information already available cannot be used or modified for use for the purpose described in item 2 above.

The information APHIS collects in connection with this program is not available from any other source. APHIS is the only Agency responsible for preventing the interstate spread of animal diseases.

5. If the collection of information impacts small businesses or other small entities, describe any methods used to minimize burden.

The information APHIS must collect in connection with this program is the absolute minimum needed to help protect the United States against the spread of VHS. Although information concerning many of the affected industries is sparse, it is estimated that 90 percent of the respondent entities within these industries are small as defined by the Small Business Administration guidelines.

6. Describe the consequence to Federal program or policy activities if the collection is not conducted or is conducted less frequently, as well as any technical or legal obstacles to reducing burden.

If the information was collected less frequently or not collected at all, it would significantly cripple APHIS' ability to prevent the introduction of VHS into U.S. aquaculture facilities by controlling the movement of live fish at risk of harboring VHS virus.

7. Explain any special circumstances that require the collection to be conducted in a manner inconsistent with the general information collection guidelines in 5 CFR 1320.5.

The information collection is conducted in a manner consistent with the guidelines established in 5 CFR 1320.5.

8. Describe efforts to consult with persons outside the Agency to obtain their views on the availability of data, frequency of collection, the clarity of instructions and recordkeeping, disclosure, or reporting form, and on the data elements to be recorded, disclosed, or reported. If applicable, provide a copy and identify the date and page number of publication in the Federal Register of the agency's notice, soliciting comments on the information collection prior to submission to OMB.

APHIS' interim rule (Docket No. APHIS-2007-0038) *Viral Hemorrhagic Septicemia; Interstate Movement and Import Restrictions on Certain Live Fish* will describe its information gathering requirements, and also provide a 60-day comment period. During this time, interested members of the public will have the opportunity to provide APHIS

with their input concerning the usefulness, legitimacy, and merit of the information collection activities APHIS is proposing.

In 2008, APHIS has engaged in productive consultations with the following individuals in connection with the information collection requirements associated with this program:

Mr. Gary Whelan
Michigan Department of Natural Resources
Fisheries Division
Box 30466
Lansing, MI 48909
(517) 373-6948

Dr. Myron Kebus
Wisconsin Department of Agriculture, Trade & Consumer Protection
Division of Animal Health
P.O. Box 8911
Madison, WI 53708-8911
(608) 224-4876

Dr. Tony Forshey
Ohio Department of Agriculture
8995 E. Main St.
Reynoldsburg, OH 43068
(614) 728-6220

9. Explain any decision to provide any payment or gift to respondents, other than remuneration of contractors or grantees.

This information collection activity involves no payments or gifts to respondents.

10. Describe any assurance of confidentiality provided to respondents and the basis for the assurance in statute, regulation, or agency policy.

No additional assurance of confidentiality is provided with this information collection. However, the confidentiality of information is protected under 5 U.S.C. 552a.

11. Provide additional justification for any questions of a sensitive nature, such as sexual behavior or attitudes, religious beliefs, and other matters that are commonly considered private. This justification should include the reasons why the agency considers the questions necessary, the specific uses to be made of the information,

the explanation to be given to persons from whom the information is requested, and any steps to be taken to obtain their consent.

This information collection activity will ask no questions of a personal or sensitive nature.

12. Provide estimates of the hour burden of the collection of information. Indicate the number of respondents, frequency of response, annual hour burden, and an explanation of how the burden was estimated.

- **Indicate the number of respondents, frequency of response, annual hour burden, and an explanation of how the burden was estimated. If this request for approval covers more than one form, provide separate hour burden estimates for each form and aggregate the hour burdens in Item 13 of OMB Form 83-I.**

See APHIS Form 71. Burden estimates were developed from discussions with accredited veterinarians, importers and exporters of live VHS-regulated fish, and States.

- **Provide estimates of annualized cost to respondents for the hour burdens for collections of information, identifying and using appropriate wage rate categories.**

Respondents are accredited veterinarians, importers and exporters of live VHS-regulated fish, and States. APHIS estimates the total annualized cost to these respondents to be \$65,373.701. APHIS arrived at this figure by multiplying the hours of estimated response time (2,191.05 hours) by the estimated average hourly wage of the above respondents (\$29.8367). APHIS determined the estimated hourly wage from the U.S. Department of Labor, Bureau of Labor Statistics Report - National Compensation Survey: Occupational Wages in the United States, July 2006. See <http://www.bls.gov/oes/current/oes291131.htm>

13. Provide estimates of the total annual cost burden to respondents or recordkeepers resulting from the collection of information (do not include the cost of any hour burden shown in items 12 and 14). The cost estimates should be split into two components: (a) a total capital and start-up cost component annualized over its expected useful life; and (b) a total operation and maintenance and purchase of services component.

There is zero annual cost burden associated with capital and start-up costs, operation and maintenance expenditures, and purchase of services.

14. Provide estimates of annualized cost to the Federal government. Provide a description of the method used to estimate cost and any other expense that would not have been incurred without this collection of information.

See APHIS Form 79. The annualized cost to the Federal government is estimated at \$26,682.

15. Explain the reasons for any program changes or adjustments reported in Items 13 or 14 of the OMB Form 83-1.

This is a new collection.

16. For collections of information whose results are planned to be published, outline plans for tabulation and publication.

APHIS has no plans to publish information collected in connection with this program.

17. If seeking approval to not display the expiration date for OMB approval of the information collection, explain the reasons that display would be inappropriate.

If forms were to be discarded because of an outdated OMB expiration date, but were otherwise usable, higher printing costs would be incurred by the Federal Government. Therefore, APHIS is seeking approval to not display the OMB expiration date on the forms.

18. Explain each exception to the certification statement identified in the "Certification for Paperwork Reduction Act."

APHIS can certify compliance with all provisions.

B. Collections of Information Employing Statistical Methods

Statistical methods are not employed in this information collection activity.