

SUPPORTING STATEMENT - OMB NO. 0579-0301
Spring Viremia of Carp Import Restrictions

July 2009

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 the health of animals under the U.S. Department of Agriculture's (USDA) Animal and Plant Health Inspection Service (APHIS) regulatory authority. 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 to maintain a healthy animal population and to enhance the nation's ability to globally compete in the trade of animals and animal products. APHIS is responsible for the development and administration of regulations intended to protect the health of U.S. farmed fish populations. APHIS added import restrictions for certain species of finfish that are susceptible to spring viremia of carp disease (SVC). SVC is considered a foreign animal disease reportable to USDA and is also a World Organization for Animal Health (OIE)-reportable disease. Fish species currently considered susceptible to SVC include: Common carp (*Cyprinus carpio*), grass carp (*Ctenopharyngodon idellus*), silver carp (*Hypophthalmichthys molitrix*), bighead carp (*Aristichthys nobilis*), crucian carp (*Carassius carassius*), goldfish (*Carassius auratus*), tench (*Tinca tinca*), and sheatfish (*Silurus glanis*). These susceptible species include koi carp and goldfish, both of which are of economic importance to the U.S. aquaculture industry and to individual fish hobbyists. Experimental infection has also been demonstrated in a number of other fish species, some of which represent important public resources or recreational assets to the United States.

There have been three SVC outbreaks reported in privately held fish facilities in the United States since 2002, necessitating eradication of affected populations at three locations. APHIS has determined that there was a substantial and causal link between these outbreaks and the unregulated importation of SVC-susceptible fish species to the United States from countries where SVC is known to exist. As a result of this determination, APHIS has developed import requirements for SVC-susceptible fish species.

The effective implementation of the SVC rule necessitates the use of several information collection activities, including the completion of VS forms 17-129, 17-29, 16-3, and 17-136; a health certificate and/or cleaning and disinfection certificate; 72-hour notification of arrival, and recordkeeping requirements.

APHIS is asking Office of Management and Budget (OMB) to approve, for an additional 3 years, its use of these information collections in connection with its efforts to continually improve the health and quality of U.S. farmed fish populations, and to increase the potential for export of U.S.-produced fish and gametes.

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.

Fish Import Permit Application (VS 17-129)

Import permits are required of all private and commercial importers of live SVC-susceptible finfish species or their gametes. The information contained in these permit applications is collected by APHIS, and reviewed in conjunction with APHIS National Aquaculture Program Coordinators for determination that imported consignments of live SVC-susceptible finfish and their gametes meet acceptable criteria for importation, which include originating from SVC-free territories. Supplemental information include the names of the exporter and importer; names and addresses of the exporting and importing facilities, if different; the species being imported; the port of entry; the shipping and arrival dates; the means of conveyance to the United States; the route of travel, including all carrier stops; and the location where the finfish or their gametes will be kept. Copies of issued permits are also collected and reviewed by VS inspectors at the time of importation.

Health Certificates

Health certificates issued by the exporting country's competent authority are collected and reviewed by VS staff at the port of entry to determine that imported consignments of live SVC-susceptible finfish and their gametes meet the minimally acceptable health status criteria contained in the CFR.

Diagnostic Specimen Import Permit Application (VS 16-3)

Importers of diagnostic specimens containing viable SVC virus must apply for a VS 16-3 import permit. Information contained in the application will be reviewed by APHIS to ensure that importers requesting such samples are approved to handle them in a Biosafety Level 2 facility.

Refusal of Entry and Order to Dispose of Fish (VS 17-136)

Information for Form VS 17-136 is collected from shipping invoices, manifests, or from the public if applicable (for example, fish imported as personal baggage). The form allows port veterinarians to notify shippers or intended recipients of SVC-susceptible species of fish that consignments have been refused entry to the United States under a number of possible refusal criteria. These refusal criteria include incomplete, incorrect, or misleading import documentation, such as USDA-issued import permits, or health certificates from exporting countries. The form also details and provides documentation for the options with which such refused consignments will be disposed of, including re-export or destruction at the owner's expense. Copies of issued permits are retained by port veterinarians as proof of notification and follow-through.

Recordkeeping

Records of purchases, sales or transfers, and the identity/disposition of all SVC-susceptible finfish or gamete lots that are handled, must be maintained for a period of 3 years by importers in a manner in accordance with the SVC interim rule's stipulations. Records are kept in case a disease outbreak occurs in imported fish, APHIS can trace back the origin of the fish. Additionally, it enables APHIS to meet trading partners audit expectations.

Application for Import or In Transit Permit (Animals, Animal Semen, Animal Embryos, Birds, Poultry, or Hatching Eggs) (VS Form 17-29)

Imported fish must be accompanied by a Customs Declaration under APHIS' import requirements. This form is completed by importers and is submitted to the Customs and Border Protection officer. APHIS reviews the information included in the documents but does not process these documents. USDA APHIS as well as Customs and Border Protection use this form for identifying the number/quantity of fish, livestock, semen or embryos. This form also provides the final destination of the commodity. This information is important for trace back purposes in the event of disease outbreak and for statistical analysis.

Cleaning and Disinfection Certificate

The exporting country's competent authority must document that cleaning and disinfection of shipment containers are sufficient to neutralize any SVC virus to which shipping containers may have been exposed. This documentation can be captured on the health certificate or in a separate cleaning and disinfection certificate. The cleaning and disinfection certificate accompanies the shipment to the U.S. port of entry.

72-Hour Notification

The importer of the shipment must notify the port veterinarian 72 hours in advance of the shipment's arrival in the United States to schedule an appointment for shipment inspection.

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.

Form VS 17-129 (Application for Import Permit) is available to importers and exporters on USDA-NCIE's Web site at: http://www.aphis.usda.gov/animal_health/permits. The 17-129 (fillable) Forms may be downloaded, mailed, or faxed by APHIS to interested parties. Currently this form may be submitted to APHIS through mailing or faxing. About one percent of the total amount of the forms received might be submitted through email.

It has been determined that VS 17-136 is not practical for automation due to the relatively low number of transactions involving these forms, but the burden of obtaining and submitting this form is not anticipated to present an undue burden for importers of SVC-susceptible species of finfish or their gametes.

Health certificates and cleaning and disinfection certificates need to accompany imported shipments of SVC-susceptible finfish or their gametes must be coordinated with exporting producers. These documents must be signed by the competent authority of the exporting country. The need for original signatures makes these documents unsuitable candidate for electronic submission. They are not anticipated to present an undue burden for importers of SVC-susceptible species of finfish or their gametes.

Importers of diagnostic specimens containing viable SVC virus may use Form VS 16-3, available on USDA-NCIE's Web site at: http://www.aphis.usda.gov/animal_health/permits. This form may be submitted to VS Permits staff electronically, or downloaded and mailed or faxed to APHIS by interested parties.

Form VS 17-29 (Declaration of Importation) is available to importers and exporters electronically on USDA-NCIE's Web site at: http://www.aphis.usda.gov/import_export/forms.shtml. The 17-29 (fillable)

forms may be downloaded, and presented to Customs officials in person or submitted in advance to accompany the consignment to the port of arrival. These forms are also available at ports of entry to the United States adm may be filled out and presented there in person.

The 72-hour notification activity is accomplished through a phone call to the port veterinarian.

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.

APHIS is the only Federal agency currently responsible for preventing the introduction or interstate spread of SVC in farmed fish populations. The information APHIS is collecting is its only source for the information and is not being collected through other forms or reports, or by other agencies.

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

Fifty percent of the importers are considered small businesses. However, the information APHIS is collecting through import permit applications and health certificates is the minimum needed to protect U.S. farmed fish populations from SVC.

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 were collected less frequently or not collected, APHIS would be unable to effectively protect farmed fish populations that are known to be susceptible to SVC from imports of finfish or their gametes infected with SVC 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.

72-Hour Notification

The importer of the shipment must notify the port veterinarian 72 hours in advance of the shipment's arrival in the United States to schedule an appointment for shipment inspection. The 72-hour notification activity is accomplished through a phone call to the port veterinarian.

There are no other special circumstances associated with this information collection.

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.

In 2009, APHIS engaged in consultations with the following groups or individuals in connection with the information collection requirements associated with this regulation:

Andy Goodwin, PhD.
Arkansas Diagnostic Laboratory
1200 N. University Drive
Pine Bluffs, AR 71601
(870) 575-8137

Ms. Sandy Moore
Florida Tropical Fish Farms Assoc.
P.O. Drawer 1519
Winter Haven, FL 33862
(863) 293-5710
(813) 677-9196

Mr. Peter Hsu
California Goldfish World
18199 Valley Blvd.
La Puente, CA 91744
(626) 374-3283

On Monday, November 16, 2009, page 58937, APHIS published in the Federal Register, a 60-day notice seeking public comments on its plans to request a **3-year renewal** of this collection of information. No comments from the public were received.

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

There are no payments or gifts to respondents being contemplated at this time.

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.

Information collections associated with these regulations 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.

Burden estimates were developed from reviews of Customs and Border Protection historical records of imported shipments of ornamental fish species, as well as from discussions with stakeholder groups (fish farmers, brokers, and other importers, and personnel at aquatic pathogen detection laboratories). (See Form 71)

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

APHIS estimates the total annualized cost to the above respondents to be \$48,694.34. APHIS arrived at this figure by multiplying the total burden hours (2,018) by the estimated average hourly wage of the above respondents (\$24.13). The salary estimates was determined by the National employment and wage data from the Occupational Employment Statistics survey by occupation, May 2008.

13. Provide estimates of the total annual cost burden to respondents or record keepers 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, operation and maintenance, 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.

An estimate of the annual cost to the Federal Government is \$47,992.00. (See APHIS Form 79)

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

The figures used in the previously approved collection were estimates of the imports expected as a result of the interim rule for SVC import restrictions. APHIS now has a better account for the number of respondents and number of responses being collected because of more accurate information provided from data systems. This has resulted in an adjusted decrease of the number of respondents from 12,010 to 462 and a decrease in the number of responses from 36,010 to 19,628 from the previous collection; thereby, causing the total burden hours to decrease by -4347.

There is a program change of +396 hours. The program change is due to the addition of the Customs Declaration for Import or In Transit Permit (VS Form 17-29), The Cleaning and Disinfection Certificate, and the 72-Hour Notification requirement. These items were inadvertently omitted in the previous submission.

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

Collections of information are not anticipated to be published.

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.

Forms 17-129; 17-29; and 16-3 are used in multiple collections; therefore, it is not practical to include an OMB expiration date because of the various expiration dates for each collection. APHIS is seeking approval to not display the OMB expiration dates on these forms.

Form 17-136 will show the expiration date.

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

APHIS is able to certify compliance with all the provisions under the Act.

B. Collections of Information Employing Statistical Methods

No statistical methods are associated with the information collection activities used in this program.