SUPPORTING STATEMENT - OMB NO. 0579-0301
Spring Viremia of Carp Interim Rule Information Collection

January 19, 2007

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 U.S. Department of Agriculture's (USDA) Animal and Plant Health Inspection Service (APHIS) is responsible for the development and administration of regulations intended to protect the health of U.S. farmed fish populations. APHIS is adding 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' Veterinary Services (VS) 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.

This necessitates the use of several information collection activities, including application by U.S. importers for an import permit for SVC-susceptible fish species, or for diagnostic samples containing viable SVC virus. APHIS will also require that importers obtain a health certificate from the exporting facility indicating that the exporting country, zone, or aquaculture establishment is in compliance with OIE guidelines to demonstrate freedom from SVC.

APHIS is asking Office of Management and Budget (OMB) to approve, for 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)

Information will be collected through two mechanisms for live animal imports: VS 17-129 import permits (including applications) issued by APHIS; and health certificates issued by the Competent Authority of the exporting country. Import permits will be required of all private and commercial importers of live SVC-susceptible finfish species or their gametes. The information contained in these permit applications will be collected by APHIS permit staff at the National Center for Import and Export (NCIE), 4700 River Rd., Unit 38, Riverdale, MD 20737, and will be 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 will 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 will also be collected and reviewed by VS inspectors at the time of importation. It is estimated that in the first year, 12,010 import permit applications for SVC-susceptible finfish and their gametes will be issued to entities requesting them.

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. Applications for these permits may be obtained from APHIS staff at the NCIE, 4700 River Rd., Unit 40, Riverdale, MD 20737. Information contained in the application will be reviewed by NCIE permits staff to ensure that importers requesting such samples are approved to handle them in a Biosafety Level 2 facility. An estimated 10 permit applications per year are anticipated for diagnostic specimens containing viable SVC virus.

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

Information for Form VS 17-136 will be collected from shipping invoices, manifests, or from the public if applicable (for example, fish imported as personal baggage). The form will allow 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 will be retained by port veterinarians as proof of notification and follow-through.

Health Certificates

Health certificates issued by the exporting country's Competent Authority will be 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 9 CFR Section 93, Part I, subsections 901 through 907. It is estimated that in the first year 12,010 health certificates will be required of these parties.

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.

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/vs/ncie/pdf/vs17-129.pdf. Forms may be downloaded, mailed, or faxed by APHIS to interested parties, but may currently be submitted to APHIS only through mailing or faxing.

It has been determined that VS 17-136 is not practical for automation under GEPA 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, needed 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. 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/vs/ncie/pdf/vs16-3.pdf. This form may be submitted to VS Permits staff electronically, or downloaded and mailed or faxed to APHIS by interested parties.

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.

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.

No special circumstances exist that would require this collection of information to be conducted in a manner inconsistent 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.

In 2006 APHIS engaged in consultations with the following groups or individuals in connection with the information collection requirements:

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

Art Rawlins
Florida Tropical Fish Farms Assoc.
P.O. Drawer 1519

Winter Haven, FL 33862
(914) 293-5710

Sandy Yosha, DVM
Christina Animal Hospital
6165 S. Florida Avenue
Lakeland, FL 33813
(914) 646-9619

On Wednesday, August 30, 2006, pages 51429-51437, APHIS published an interim rule and request for comments in the Federal Register. The rule stated its plans to request continuation of a 3-year renewal for this information collection, and also provided a 60-day comments period. During that time, APHIS received 18 comments from interested members of the public. None of these comments dealt with information collection issues.

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 $119,380. APHIS arrived at this figure by multiplying the hours of estimated response time (5,969) by the estimated average hourly wage of the above respondents ($20.00).

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 $237,001.07. (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.

There is no change in total burden from the interim rule for this 3-year information collection but the annual responses increased by 12,010 because the recordkeepers are now accounted for in that category.

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.

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.

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.