SUPPORTING STATEMENT
OMB NO. 0579-0301
SPRING VIREMIA OF CARP; IMPORT RESTRICTIONS ON CERTAIN LIVE FISH, FERTILIZED EGGS, AND GAMETES

EXPLANATION FOR CHANGE OF TITLE: The title of this collection changed to provide a clearer understanding of the import requirements and restrictions for Spring Viremia of Carp (SVC).

A. JUSTIFICATION **June 2013**

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 United States 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 developing and administering regulations intended to protect the health of the United States farmed fish populations. APHIS has import restrictions at title 9, *Code of Federal Regulations* (9 CFR) 93.900 for certain species of finfish 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 United States 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.

Three SVC outbreaks have been reported in privately held fish facilities in the United States since 2002, necessitating eradication of affected populations at these locations. APHIS determined 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 developed the import requirements for SVC-susceptible fish species.

The effective implementation of SVC regulations necessitates the use of several information collection activities, including the completion of VS Form 17-129 (Fish Import Permit Application); presentation of a health certificate; completion of VS Form 16-3 (Diagnostic Specimen Import Permit

Application), VS Form 17-136 (Refusal of Entry and Order to Dispose of Fish), and VS Form 17-29 (Application for Import or In Transit Permit (Animals, Animal Semen, Animal Embryos, Birds, Poultry, or Hatching Eggs)); presentation of a cleaning and disinfection certificate, and 72-hour notification of arrival (to ensure that an APHIS veterinary medical officer is available to visually inspect the shipment on arrival), as well as recordkeeping requirements.

APHIS is asking Office of Management and Budget (OMB) to approve, for an additional 3 years, its use of these information collection activities in connection with its efforts to continually improve the health and quality of the United States farmed fish populations, and to increase the potential for export of United States 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.

APHIS uses the following information activities to develop the import requirements to prevent the outbreak of Spring Viremia of Carp (SVC) for susceptible finfish or -gametes.

Fish Import Permit Application (VS 17-129) (Business)

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 are provided by the United States importers, collected by APHIS, and reviewed by APHIS national aquaculture program coordinators. Program coordinators determine that imported consignments of live SVC-susceptible finfish and their gametes meet acceptable criteria for importation. Among other criteria, the fish must originate from SVC-free territories. Supplemental information includes 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 (Business)

Health certificates issued by the exporting country's competent authority are collected and reviewed by APHIS 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) (Business)

Importers of diagnostic specimens containing the 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. Supplemental information includes the names of the exporter and importer; the means of conveyance to the United States; the port of entry; description of material, such as type and use of animal; treatment of material before import; and appropriate disposal of material.

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

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 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 options for disposing of refused consignments, 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 (Business)

Records of purchases, sales, or transfers, and the identity and disposition of all SVC-susceptible finfish or gamete lots that are handled must be maintained for 3 years by importers. Records are kept so that if a disease outbreak occurs in imported fish, APHIS can trace the origin of the fish. The records also help APHIS meet trading partners' audit expectations.

Application for Import or In Transit Permit (VS Form 17-29) (Business)

Imported fish must be accompanied by a Customs declaration under APHIS import requirements. Those requirements can be found at 93.914. They include accompaniment by a health certificate from the exporting country's competent authority demonstrating freedom from SVC according to specified testing and a visual inspection 72-hours before export. Animals are also expected to be transported in new containers or containers properly cleaned and disinfected to avoid transfer of SVC. This form is completed by importers and is submitted to the Customs and Border Protection (CBP) officer. APHIS reviews the information included in the documents but does not process these documents. APHIS and CBP use this form to identify the quantity of fish, livestock, semen, or embryos. This form also lists the final destination of the commodity. This information is important for traceback purposes in the event of disease outbreak and for statistical analysis.

Cleaning and Disinfection Certificate (Foreign Government)

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 United States port of entry.

72-Hour Notification (Business)

The importer must notify the port veterinarian 72 hours in advance of the shipment's arrival into the United States to schedule an appointment for shipment inspection. This includes inspection of documents and a visual inspection of the fish. Upon arrival in the United States, the shipment is inspected by an APHIS veterinary medical officer to ensure the necessary documentation is presented and the animals are healthy.

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 the APHIS National Center for Import and Export (NCIE) Web site at: http://www.aphis.usda.gov/animal_health/permits. The fillable forms may be downloaded, mailed, or faxed by APHIS to interested parties. Applications can also be submitted online via the e-Permitting system.

Health Certificates and Cleaning and Disinfection Certificates - need to accompany imported shipments of SVC-susceptible finfish or their gametes and 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 candidates for electronic submission. They are not anticipated to present an undue burden for importers of SVC-susceptible species of finfish or their gametes.

VS Form 17-136 – There are few transactions necessitating this form; therefore, APHIS has determined that it is not practical to automate this form. Obtaining and submitting this form is not anticipated to be an undue burden for importers of SVC-susceptible species of finfish or their gametes.

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

VS Form 17-29 (Declaration of Importation) - is available to importers and exporters electronically on the NCIE Web site at: http://www.aphis.usda.gov/import_export/forms.shtml. The 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 and may be filled out and presented there in person. These forms cannot currently be submitted through ePermits; as importers and exporters customarily present them with the shipment. APHIS has no plans for electronic submission.

72-Hour Notification - 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 activities in this collection are APHIS' only source for this information. It 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 collects is the minimum needed to protect United States 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 known to be susceptible to SVC from imports of finfish or their gametes infected with the SVC virus. This could spread infection among United States farmed fish, damaging fish populations and causing economic harm to the United States farmed fish market.

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.

- **requiring respondents to report information to the agency more often than quarterly;**

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 is accomplished through a phone call to the port veterinarian. Ports must have a 72-hour notice to ensure the port veterinarian is available to visually inspect documentation and the fish at the first port of entry. The inspection ensures import requirements are being met and the animals are not introducing the SVC virus into the United States.

- **requiring respondents to prepare a written response to a collection of information in fewer than 30 days after receipt of it;**
- **requiring respondents to submit more than an original and two copies of any document;**
- **requiring respondents to retain records, other than health, medical, government contract, grant-in-aid, or tax records for more than three years;**
- **in connection with a statistical survey, that is not designed to produce valid and reliable results that can be generalized to the universe of study;**
- **requiring the use of a statistical data classification that has not been reviewed and approved by OMB;**
- **that includes a pledge of confidentiality that is not supported by authority established in statute or regulation, that is not supported by disclosure and data security policies that are consistent with the pledge, or which unnecessarily impedes sharing of data with other agencies for compatible confidential use; or**
- **requiring respondents to submit proprietary trade secret, or other confidential information unless the agency can demonstrate that it has instituted procedures to protect the information's confidentiality to the extent permitted by law.**

No other special circumstances exist that would require this collection to be conducted in a manner inconsistent with the general information collection guidelines 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 2013 APHIS engaged in consultations with the following groups or individuals in connection with the information collection requirements associated with this collection:

Mr. Tom Beat
Sun Pet LTD
3765 Zip Industrial Blvd.
Atlanta, GA 30354
(404) 761-7360

Ms. Maria Staples
Transship Discounts Ltd.
157-01 Rockaway Blvd.
Jamaica, NY 11434
(718) 252-5000

Dr. Cem Giray
Kennebec River Biosciences
41 Main Street
Richmond, ME 04357
(207) 737-2637 (ext. 207)

On Wednesday, February 27, 2013, pages 13301-13302, 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. During that time, APHIS received one comment from an interested member of the public. This comment did not deal with information collection issues. The person wanted to ban the import of all animals from any country because it was her belief that these animals brought problems into the United States.

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

This collection makes 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. Any and all information obtained in this collection shall not be disclosed except in accordance with 5 U.S.C. 552a.

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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 collection 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 CBP 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 APHIS Form 71 for hour burden estimates. $22.81 is the hourly rate derived from the U.S. Department of Labor, Bureau of Labor Statistics May 2012 Report – Occupational Employment and Wages in the United States. See http://www.bls.gov/news.release/pdf/ocwage.pdf.

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

Total cost to respondents was estimated by multiplying their average hourly wage ($22.81) by the total number of hours (1,017) needed to complete the work. $22.81 X 1,017= $23,197.77.

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 costs, maintenance costs, and purchase of services in connection with this program.

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 $50,832. (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.

ICR Summary of Burden:

N	Requested	Program Change Due to New Statute	Program Change Due to Agency Discretion	Change Due to Adjustment in Agency Estimate	Change Due to Potential Violation of the PRA	Previously Approved
Annual Number of Responses	5,371	0	0	-14,257	0	19,628
Annual Time Burden (Hr)	1,017	0	0	-1,001	0	2,018
Annual Cost Burden ($)	0	0	0	0	0	0

There is an adjusted decrease of -375 respondents, -14,257 annual responses, and -1,001 total burden hours.

These decreases are due to less respondents and a downturn in the economy.

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 it collects in connection with this activity.

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.

The health certificate and cleaning and disinfection certificate are forms by the exporting countries and are not eligible for OMB expiration dates.

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.