July 2020

SUPPORTING STATEMENT
IMPORTS OF LIVE FISH, FERTILIZED EGGS, AND GAMETES FROM TILAPIA LAKE VIRUS (TILV)-SUSCEPTIBLE SPECIES
OMB Control No. 0579-0473

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.

The U.S. aquaculture industry experienced an outbreak of Tilapia Lake Virus (TiLV) in March 2019. The virus can cause high mortality in susceptible fish. Signs of the disease include cloudy or bulging eyes; skin lesions such as darkening, bruising, or ulcers; protruding gills, and abdominal swelling. Fish may move slowly and stop eating. There are currently no treatments or vaccines for the disease.

APHIS determined that the introduction and establishment of TiLV poses a serious threat to U.S. agriculture. An APHIS Preliminary Risk Assessment and Analysis of U.S. Imports and Exports of Live Tilapia, Eggs, and Milt determined the risk posed to relevant industries by the introduction of TiLV via imported tilapia fingerlings (young fish) or the shipping water carrying them as "high." The assessment also determined a high likelihood that tilapia infected with TiLV will be imported into the United States because the United States currently lacks import regulations certifying tilapia as healthy and disease free; also, there is insufficient global TiLV surveillance and detection. More than 15 countries are considered to be "affected" by TiLV, while many more are considered to be "at risk."

After APHIS determined the United States needed restrictions to prevent the introduction and establishment of TiLV and address the animal health and economic risks associated with imports of live fish, fertilized eggs, and gametes from TiLV-susceptible species, it issued a Federal Order placing certain requirements on importers of these commodities. Importers now must obtain an import permit, submit a health certificate, and undergo an inspection before bringing susceptible commodities into the United States. The APHIS Federal Order import requirements apply uniformly to all live fish, fertilized eggs, and gametes from Tilapia Lake Virus (TiLV)-susceptible species imported into the United States from all countries.

APHIS is asking the Office of Management and Budget (OMB) to approve for 3 years continued use of these information collection activities in connection with its efforts to prevent introduction of TiLV into 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.

APHIS uses the following activities to collect information necessary to prevent introduction of TiLV into the United States:

Application for Import or In-Transit Permit (for Live Animals, Animal Semen, Animal Embryos, Birds, Poultry, and Hatching Eggs) (VS Form 17-129); (Business)
Businesses or importers seeking to import live fish, fertilized eggs, and gametes from TiLV-susceptible species into the United States must complete an application (VS 17-129) to attain the permit (VS Form 17-135) allowing import of these commodities. The importer must provide his/her name, address, and telephone number as well as the name and address of the shipper in the country of origin. The importer must list the port of embarkation, the country from which the live fish, fertilized eggs, and/or gametes are to be shipped, and the mode of transportation. He/she must also describe the type, number, and identification of the animals to be exported. The importer must further list the origin, intended date and location of arrival, routes of travel, and destination of the animals. APHIS uses the permit applications to track, identify, and monitor animals entering the United States.

Veterinary Health Certificate for the Import of Tilapia into the United States; (Business)
Businesses or importers seeking to import live fish, fertilized eggs, and gametes from TiLV-susceptible species into the United States must provide an official health certificate issued and endorsed by an official veterinarian of the country of origin's competent authority. The certificate must accompany the shipment to the port of entry. The health certificate provides the following information:

- The name and address of the consignor.
- The name and address of the consignee.
- The country of origin.
- The port of embarkation.
- The means of transportation.
- The route of travel (country of origin +/- country or countries of transit).
- The designated U.S. port of entry.
- The date of veterinary inspection in the country of origin.
- The total quantity of animals.
- The total number of packages/containers.
- The intended use of the animals (i.e., breeding, culture/grow out, research, human consumption)

The official veterinarian of the exporting country's competent authority must certify the following statements:

- Either:

  - Tilapia from this population to be exported tested negative for TiLV within thirty (30) days prior to export per the World Organization for Animal Health (OIE) or a laboratory testing method reviewed and approved by APHIS prior to export. Sampling procedures used an assumed pathogen prevalence of two (2) percent, with a corresponding confidence level of ninety-five (95) percent.

  - Samples were collected by an official veterinarian or other certifying official representing the competent authority.

  Or:

  - The facility of origin participates in an ongoing TiLV monitoring program for species susceptible to TiLV, by testing negative twice annually for a minimum of two (2) consecutive years, with at least three (3) months between tests; and

  - The facility sampled populations using an assumed pathogen prevalence of two (2) percent, with a corresponding confidence level of ninety-five (95) percent, and found negative for TiLV; and

  - Samples were collected by an official veterinarian or other certifying official representing the competent authority, and tested per the OIE or a laboratory testing method reviewed and approved by APHIS prior to export.

- No OIE-listed disease(s) affecting tilapia was/were reported at the premises of origin within sixty (60) days prior to export.

- The tilapia originated in the exporting country or were legally imported and verified to be of equal health status before entering the population for export.

- The tilapia were inspected by an official veterinarian of the exporting country's competent authority within seventy-two (72) hours prior to export, and showed no clinical signs of disease.

- All shipping containers are new, or have been properly cleaned and disinfected prior to use to ensure removal of organic material and mitigation of diseases of concern the species is susceptible to.

- The shipment will ship directly to the United States with no stops en route other than those provided for on the APHIS import permit.

- After the animal inspection, the health certificate is valid for seventy-two (72) hours prior to export.

Inspection; (Business; State, Local, or Tribal Government)

On arrival at the designated port of entry, the importer, or the importer's agent, must present the original official health certificate and the original APHIS import permit for the live fish, fertilized eggs, and/or gametes to a VS port official. The port official will inspect the shipping containers and the live fish, fertilized eggs, and/or gametes to ensure the accuracy of the information contained in the permit and health certificate. The importer, or the importer's agent, must notify the VS port official 72 hours in advance of the shipment's expected arrival to expedite the shipment's inspection and clearance. The shipment may not be removed until the port official determines that the shipment meets import requirements and releases the shipment.

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.

Electronic and automated submission methods are minimal, although APHIS accepts electronic permit applications and issues import permits electronically via ePermits. Owners and contractors must provide original signature to the documents. In some situations electronic signatures may be allowed and submitted via 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 that APHIS collects in connection with this initiative is not available from any other source. APHIS is the only Federal agency responsible for preventing, detecting, controlling, and eliminating animal diseases from the United States.

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

APHIS estimates there are no small entities involved with this information collection. The information collected is the absolute minimum needed to prevent the spread of TiLV.

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.

Collecting this information less frequently or failing to collect it would make it impossible for APHIS to contain and prevent TiLV outbreaks in the United States.

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, such as:

- **requiring respondents to report information to the agency more often than quarterly;**
- **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 3 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.**

This 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 engaged in productive consultations with the following individuals in connection with the information collection requirements associated with these requirements. APHIS contacted these respondents by email and phone to discuss the information APHIS collects to administer its new import requirements. We discussed with them how we and they obtain the necessary data and how frequently; how much data is available; the convenience and clarity of reporting formats

and other collection instruments; and the clarity of, and necessity for, any recordkeeping requirements. The respondents stated via email or phone that they had no concerns with any of these items and had no further recommendations.

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On April 21, 2020, a 60-day notice was published in the Federal Register for public comment on this information collection request renewal (85 FR 22124). No comments were received.

9. Explain any decision to provide any payment or gift to respondents, other than reenumeration 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.

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 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 these respondents to be $4,223. APHIS arrived at this figure by multiplying the hours of estimated response time (96 hours) by the estimated average hourly wage of the below respondents ($30.78), and then multiplying the result by 1.429 to capture benefit costs.

  Estimated hourly wages for the respondents were determined from the U.S. Department of Labor; Bureau of Labor Statistics Occupational Employment Statistics May 2019 Occupation Profiles Report (http://www.bls.gov/current/oes_stru.htm).

  [13-1020] Buyers and Purchasing Agents ($33.50)
  [19-1011] Animal Scientists ($32.96)
  [29-1131] Veterinarians ($50.39)
  [45-2011] Agricultural Inspectors ($22.67)
  [45-2093] Farmer ($14.37)

  According to DOL BLS news release USDL-20-0451 released March 19, 2020, employee benefits account for 30 percent of employee costs, and wages account for the remaining 70 percent. Mathematically, total costs can be calculated as a function of wages using a multiplier of 1.429.

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.

No annual cost burden is associated with capital and startup 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 $6,231.

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

The activities in this request reflect 114 responses and 96 hours of burden. There are no changes from the estimates in the previous submission.

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 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.

VS Forms 17-129 is used in multiple information collections with differing expiration dates. It is not practical to include an OMB approval expiration date on the form. APHIS is seeking approval not to display the date on this form.

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

APHIS can certify compliance with all provisions under the Act.

B. Collections of Information Employing Statistical Methods

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