

SUPPORTING STATEMENT
Approval of Laboratories for
Conducting Aquatic Animal Tests for Export Health Certificates
OMB-579-XXXX

A. Justification

April 2014

1. Explain the circumstances that make the collection of information necessary. Identify any legal or administrative requirements that necessitate the collection.

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 ability of U.S. producers to compete in the global market of animal and animal product trade.

The regulations of the Animal and Plant Health Inspection Service (APHIS) do not require APHIS approval or certification for laboratories conducting tests for the export of aquaculture animals. However, as a condition of entry, some countries require testing results from a laboratory approved by the competent authority, in this case APHIS. State, university, and private laboratories can voluntarily seek approval of individual diagnostic methods. APHIS does this as a service to U.S. exporters who ship aquaculture animals to countries requiring this certification.

APHIS evaluates diagnostic methods of aquatic animal pathogens listed by the World Organization for Animal Health (OIE) according to international standards in the OIE diagnostic manual and other supporting scientific literature. The list of laboratories approved to conduct diagnostic testing in support of export health certification of aquatic species is available at http://www.aphis.usda.gov/animal_health/lab_info_services/downloads/ApprovedLabs_Aquaculture.pdf. Following APHIS approval, laboratories are inspected by APHIS every other year to maintain their approval.

The information collection activities involved are:

1. Notification for Intent to Request Approval
2. Application for APHIS Approval

3. Protocol Statement
4. Submission of Sample Copies of Diagnostic Reports
5. Recordkeeping of Sample Copies of Diagnostic Reports
6. Quality Assurance/Control Plans
7. Recordkeeping of Quality Assurance/Control Plans
8. Notification of Proposed Changes to Assay Protocols
9. Recordkeeping: Supporting Assay Documentation
10. Request for Removal of Approved Status

Because APHIS collects information from the requesting laboratories to certify them for export activities, APHIS is asking OMB to approve, for 3 years, its use of the associated information collection activities.

2. Indicate how, by whom, 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 will use the following information activities to certify laboratories for aquaculture export activities.

Notification for Intent to Request Approval

The laboratory must inform APHIS via telephone or email of its intent to request approval. This initial contact notifies the National Veterinary Services Laboratory (NVSL) through the Area Veterinarian in Charge (AVIC) that the laboratory is initiating the process. This is necessary because there are two components to acquiring APHIS approval — NVSL's review of the technical information and the AVIC's site inspection.

Application for APHIS Approval

Laboratories voluntarily requesting approval submit an application on their letterhead to APHIS. The application must contain:

- The laboratory's name, physical location, and mailing address
- The names of the legally responsible official and the laboratory director
- A description of the laboratory facilities and equipment used in performing pathogen detection assays
- A list of specific diagnostic assays for which the laboratory has requested approval
- Test protocols
- A list of individuals performing the tests, including their names, professions, and technical qualifications
- A statement confirming that the laboratory has met proper storage conditions

Laboratories go through the full approval process only once; their protocols are reevaluated biennially. The approval process includes an inspection by the AVIC, during which the AVIC reviews with laboratory staff information provided in the application.

Protocol Statement

Laboratories must develop protocol statements that outline their standard operating procedures and ensure compliance with OIE testing requirements. A protocol statement must be provided for each assay the laboratory submits for approval. The laboratory must provide the statement in writing to the AVIC, who forwards it to NVSL technical staff. NVSL staff review the document for compliance with OIE-published protocols as listed in the current Manual of Diagnostic Tests for Aquatic Animals.

Submission of Sample Copies of Diagnostic Reports

Laboratories produce diagnostic reports. To obtain APHIS approval for certification, laboratories must give APHIS a copy of these reports.

Recordkeeping of Sample Copies of Diagnostic Reports

Laboratories must maintain records of the sample copies of diagnostic reports for 2 years. APHIS uses these records to compare the actual reports with the templates the laboratory has submitted for use.

Quality Assurance/Control Plans

Laboratories produce and maintain appropriate quality assurance and quality control plans. To obtain APHIS approval for certification, laboratories must give APHIS a copy of these plans.

Recordkeeping of Quality Assurance/Control Plans

Laboratories must maintain copies of their quality control and assurance plans for 5 years. Recordkeeping is critical to ensure swift and accurate animal health investigations.

Notification of Proposed Changes to Assay Protocols

Laboratories must submit to the AVIC, in advance and in writing, any proposed changes to assay protocols. The AVIC will in turn submit the proposed changes to the NVSL. Laboratories that generate results based on modified protocols that have not received written approval from NVSL risk losing approval status. For export health certification, laboratories cannot generate results using non-OIE-compatible protocols. Consequently, APHIS must approve any proposed changes before the laboratory incorporates those changes. Without APHIS' prior approval, APHIS would be unable to determine if the Agency can endorse the test results.

Recordkeeping: Supporting Assay Documentation

To verify a laboratory's compliance with APHIS-approved protocols, which are in accordance with OIE recommendations, APHIS may request supporting pathogen detection and identification assay documentation for test results that support specific export health certification endorsed through the VS Area Office. The laboratory should keep this documentation for 5 years.

Request for Removal of Approved Status

Laboratories voluntarily requesting removal of approved status do so in writing to the AVIC. This will make APHIS aware of a laboratory's status for actual capacity or willingness to conduct the activities APHIS has approved.

3. Describe whether, and to what extent, the collection of information involves the use of automated, electronic, mechanical, 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.

The Notification for Intent to Request Approval can be emailed or called into APHIS.

The following activities can be submitted via hard copy or email:

- Application for APHIS Approval
- Protocol Statement
- Submission of Sample Copies of Diagnostic Reports
- Quality Assurance/Control Plans
- Notification of Proposed Changes to Assay Protocols
- Request for Removal of Approved Status

APHIS does not provide documents to the respondents to be completed.

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 is exclusive to its mission of providing export certification services.

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

APHIS considers none of the respondents to be small businesses. In addition, the information APHIS collects in connection with this program is the absolute minimum needed to ensure that laboratories comply with APHIS-approved aquatic animal pathogen detection procedures.

6. Describe the consequences 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 APHIS cannot collect this information, it cannot approve the laboratory assays that support exports from U.S. producers. This could prevent U.S. producers from exporting aquaculture animals and products to countries that specifically require APHIS-approved laboratories to certify they have performed aquatic animal pathogen detection procedures. An increasing number of foreign trading partners require this. If APHIS cannot collect this information, it could significantly hinder U.S. animal and animal product trade.

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;**
- **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;**

APHIS requires that laboratories keep record for 5 years to ensure that animals can be traced in the event of a disease outbreak.

- **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, frequency of collection, the clarity of instructions and recordkeeping, disclosure, or reporting from, 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 held productive consultations with the following individuals concerning the information collection activities associated with this certification:

Bill Keleher
Micro Technologies, d/b/a Kennebec River Biosciences
41 Maine St.
Richmond, ME 04357
207-737-2637

Ralph Elston
Aqua Technics Inc.
455 West Bell St.
Sequim, WA 98382
360-681-3122

Kevin Snekvik
Washington Animal Disease Diagnostic Laboratory
College of Veterinary Medicine
Washington State University
P.O. Box 647034
Pullman, WA 99164-7034
509-335-9696

On Tuesday, December 31, 2013, (pages 79656-79657), APHIS published in the Federal Register, a 60-day notice seeking public comments on its plans to request approval of a new information collection. No comments from the public 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. 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 and attitudes, religious beliefs, and others that are considered private. This justification should include the reasons why the agency considers the questions necessary.

This information collection activity asks 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 83-1.

See APHIS Form 71. Burden estimates were developed from discussions with State, university, and private laboratory personnel.

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 respondents to be \$600,871. APHIS arrived at this figure by multiplying the hours of estimated response time (18,336 hours) by the estimated average hourly wage of the above respondents (\$32.77).

The average hourly rate is derived from the U.S Department of Labor; Bureau of Labor Statistics March 2012 Report – National Compensation Survey: Occupational Employment and Wages, May 2011. See <http://www.bls.gov/oes/#tables>. The rate is the average hourly rate given for animal scientists.

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 estimated 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.

The annualized cost to the Federal Government is estimated at \$15,360.
(See APHIS Form 79.)

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

	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	495	0	0	0	495	0
Annual Time Burden (Hr)	18,336	0	0	0	18,336	0
Annual Cost Burden (\$)	0	0	0	0	0	0

This is a new information collection resulting in 18,336 burden hours.

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 of OMB approval of the information collection, explain the reasons that display would be inappropriate.

There are no forms associated with this information collection.

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

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

B. Collections of Information Employing Statistical Methods.

Statistical methods are not used in this information collection.