July 2021

SUPPORTING STATEMENT
Approval of Laboratories for Conducting Aquatic Animal Tests
for Export Health Certificates
OMB NO. 0579-0429

A. Justification

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. It 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. Animal and Plant Health Inspection Service (APHIS) regulations do not require APHIS approval or certification for laboratories conducting disease 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 to test for specific diseases. APHIS provides laboratory approval as a service to U.S. exporters who ship aquaculture animals to countries requiring this certification.

APHIS evaluates diagnostic methods for detecting aquatic animal pathogens listed by the World Organization for Animal Health (OIE) in the OIE diagnostic manual and other supporting scientific literature. The laboratories currently approved to conduct diagnostic testing in support of export health certification of aquatic species are listed below:

- University of Arizona Aquaculture Pathology Laboratory
- University of Arkansas Pine Bluff-Lonoke Fish Health Inspection Laboratory
- Bronson Animal Disease Diagnostic Laboratory
- Kennebec River Biosciences
- South Dakota State University Animal Disease Research and Diagnostic Laboratory
- New Jersey Division of Animal Health, Animal Health Diagnostic Laboratory
- Aqua Technics Inc.
- Washington Animal Disease Diagnostic Laboratory, College of Veterinary Medicine

A detailed listing of these laboratories is also available at http://www.aphis.usda.gov/animal_health/lab_info_services/downloads/ApprovedLabs_Aquaculture.pdf.

Once approved, laboratories are inspected, and protocols reevaluated by APHIS every 2 years to maintain their approval.

APHIS is asking OMB to renew the approval of the associated information collection activities for 3 years to ensure that APHIS may certify certain laboratories that conduct aquatic animal testing for export 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 of Intent to Request Approval; (Business) (State)
The laboratory must inform APHIS via telephone or email of its intent to request approval.

Application for APHIS Approval; (Business) (State)
Laboratories voluntarily requesting approval submit an application on their letterhead to the APHIS Veterinary Services (VS) office for the State where the laboratory is located. 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.

The applications are reviewed by the VS office prior to scheduling the initial inspection/site visit.

Protocol; (Business) (State)
The laboratory must provide a written protocol for each assay submitted for approval to the Port or Service Center Director, who forwards it to the NVSL. NVSL staff review the document for equivalency with OIE-published protocols as listed in the current Manual of Diagnostic Tests for Aquatic Animals.

Submission of Sample Copies of Diagnostic Reports; (Business) (State)
Laboratories produce diagnostic reports. To obtain APHIS approval for certification, laboratories give APHIS an example copy of these reports. APHIS usually receives the reports from exporters seeking to use the laboratories to certify products for export.

Recordkeeping of Sample Copies of Diagnostic Reports; (Business) (State)
Laboratories generally maintain records of the sample copies of diagnostic reports for 2 years. APHIS does not require this retention, although it uses these records to compare the actual reports with the templates (examples) the laboratory has submitted for use.

Quality Assurance/Control Plans; (Business) (State)
Laboratories must 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; (Business) (State)
Laboratories generally maintain copies of their quality control and assurance plans for up to 5 years. While not required, recordkeeping is critical to ensure swift and accurate animal health investigations.

Notification of Proposed Changes to Assay Protocols; (Business) (State)
Laboratories must submit to the Port or Service Center Director, in advance and in writing, any proposed changes to assay protocols. The Director in turn submits 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; (Business) (State)
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 Service Center or Port Services Office. Laboratories may keep this documentation for up to 5 years, although they are not required to do so.

Request for Removal of Approved Status; (Business) (State)
Laboratories voluntarily requesting removal of approved status do so in writing to the Port or Service Center Director. This alerts APHIS 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 may be emailed or telephoned into APHIS.

The following activities may be submitted via mail or email:

- Application for APHIS Approval
- Protocol
- 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; therefore, there are no official APHIS forms. APHIS has no plans to implement an electronic database for this information as the number of annual responses is small.

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 APHIS collects in connection with this program is not available from any other source. APHIS is the only Agency responsible for preventing the introduction of exotic animal diseases into the United States.

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 did not collect this information, U.S. producers would be prevented from exporting aquaculture animals and products to countries that specifically require APHIS-approved laboratories to certify they have performed aquatic animal pathogen detection procedures. A significant number of foreign trading partners require this testing. If APHIS did not collect this information, it could greatly 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 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.**

No 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 contacted the following respondents by email and phone to discuss the information APHIS collects to administer its equipment import regulations. Discussed were how the data was collected 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 had no concerns with any of these items and had no further recommendations.

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On January 8, 2021, APHIS published in the Federal Register (86 FR 1476) a 60-day notice seeking public comment on its plans to request a 3-year renewal of this collection of information. No comments were received

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

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 $81,390. APHIS arrived at this figure by multiplying the estimated hours of burden (1,462 hours) by the estimated average hourly wage of the above respondents ($38.42) and then multiplying the result then multiplying the result by 1.449 to capture benefit costs.

The average hourly rates used to calculate the estimate are for animal scientists ($35.84, SOCC 19-1011); life science technicians ($27.32, SOCC 19-4099); and veterinarians ($52.09, SOCC 29-1131). The rates were obtained from the U.S. Bureau of Labor Statistics website https://www.bls.gov/oes/current/oes_stru.htm.

According to DOL BLS news release USDL-21-0437 released March 18, 2021, employee benefits account for 31 percent of employee costs, and wages account for the remaining 69 percent. Mathematically, total costs can be calculated as a function of wages using a multiplier of 1.449.

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.

See APHIS Form 79. The annualized cost to the Federal Government is estimated at $49,993.

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	416		78	(1,867)		2,205
Annual Time Burden (Hr)	1,462		101	(60,641)		62,002

This renewal request is for 416 responses and 1,462 hours of burden reflecting a decrease of 28 responses and 4,653 hours of burden from the previous amendment.

Estimate figures for the amendment to the previous reinstatement request were not input into ROCIS. The resulting decrease of 1,761 responses and 55,887 hours of burden are reported in this request as estimate adjustments. Further, 6 activities have changes to their response estimates, attributed to improved data collection as the previous request overestimated respondents and responses mainly for recordkeeping, and account for decreases of 106 estimated responses and 4,754 estimated hours of burden.

The remaining 4 activities have discretionary adjustments to their estimated times per response (mainly small rounding increases), as well as response estimate adjustments, and account for increases of 78 responses and 101 hours of estimated burden. The activities are Notification for Intent to Request Approval, Application for APHIS Approval, Notification of Proposed Changes to Assay Protocols, and Request for Removal or Approved Status.

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.