

SUPPORTING STATEMENT
Infectious Salmon Anemia (ISA); Payment of Indemnity
OMB NO. 0579-0192

TERMS OF CLEARANCE: “Before this ICR is renewed, USDA should consider converting VS 1-23, 1-23A, 1-24, and 1-26 to common forms and establishing a single OMB control number for each one.” APHIS has many forms eligible for conversion to common forms but has lacked the expertise and time to develop a process for doing so efficiently. This has become a priority for the Agency in 2021 and it anticipates making material progress on the project.

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.

Disease prevention is the most effective method for maintaining a healthy animal population and for enhancing the ability of the United States to compete in the world market of animal and animal product trade. As part of this mission, the Animal and Plant Health Inspection Service (APHIS) regulates imports of animals and animal products into the United States to guard against introducing various animal diseases, including infectious salmon anemia (ISA). These regulations are in title 9 of the *Code of Federal Regulations* (9 CFR), chapter I, subchapter D.

Animal health regulations promulgated by APHIS under this authority include those specifically addressing control programs and indemnity payments. The regulations at 9 CFR part 53 contain provisions for paying indemnity for claims made by ISA disease control authorities to program participants arising from the destruction of fish due to ISA under certain conditions.

ISA is the clinical disease resulting from infection with the ISA virus; signs include hemorrhaging, anemia, and lethargy. ISA poses a substantial threat to the economic viability and sustainability of salmon aquaculture in the United States and abroad. In 2000, salmon production in Maine exceeded 36 million pounds with a value of \$82 million. Because of outbreaks of ISA

in Maine, that State's salmon industry had already depopulated approximately 900,000 salmon worth nearly \$11 million by the time of the Secretary's declaration of emergency.

This indemnity program entails the use of several information collection activities, including completing a program enrollment form as well as an appraisal and indemnity claim form; developing biosecurity protocols; conducting biosecurity audits; developing site-specific ISA action plans; compiling fish inventories and mortality reports (and recordkeeping); and disease surveillance.

Program participants, who may include certain aquaculture industry business owners, managers, site employees, and accredited veterinarians, and designated laboratories must also assist APHIS with certain disease surveillance activities.

APHIS is asking the Office of Management and Budget to renew, for an additional 3 years, its use of these information collection activities in connection with its efforts to control ISA and prevent its spread.

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 reimburse aquaculture industry businesses; conduct biosecurity, protocols and audits; develop site-specific ISA action plans; compile fish inventories and mortality reports (and keep records of the inventories and reports); and conduct disease surveillance.

ISA Program Enrollment Form (VS 1-22); (9 CFR 53.10); (Business)

As a condition of receiving indemnity, program participants must sign an ISA Program Enrollment Form in which they agree to participate fully in USDA's and the State of Maine's ISA Program. By signing this document, program participants agree to (1) establish and maintain a veterinary client-patient relationship with an APHIS-accredited veterinarian; (2) cooperate and assist with onsite disease surveillance, testing, and reporting activities; (3) develop and implement biosecurity protocols; (4) develop a site-specific ISA Action Plan for the prevention, control, and management of ISA; (5) participate in Maine's integrated pest management of sea lice on salmonids (the State of Maine requires a management plan, which must be submitted to APHIS with this enrollment form); (6) submit complete and current fish inventory information to the ISA Program Veterinarian; (7) maintain mortality data and make it available, on request, to the ISA Program Veterinarian; and (8) cooperate and assist APHIS in completing biosecurity audits. Currently, one company owns all the sites in Maine.

All Species Appraisal and Indemnity Claim Form and Continuation Sheet (VS 1-23, VS 1-23a), and Recordkeeping; (9 CFR 53.8); (Business)

Appraisals of salmon must be reported on the VS Form 1-23 (and VS Form 1-23a) and signed by both the appraiser (a Federal employee) and the program participant. The VS Form 1-23 is completed by the appraiser with input from the program participant, and contains such

information as the owner's name and address, the number of fish for which the participant is seeking payment, and the appraised value of each fish. The participant's signature on this form indicates agreement with the appraised value. On this form the participant must also certify whether the fish are subject to a mortgage. If the participant states that there is a mortgage, the form must be signed not only by the participant but also by each person holding a mortgage. By signing the form, each mortgage holder is consenting to the payment of indemnity to the participant or lien holder. Since there has not been an outbreak of ISA since February 2006 (15 years), APHIS has estimated the costs of one claim form.

Biosecurity Protocols; (9 CFR 53.10(e)(3)); (Business)

As a condition of receiving indemnity, program participants must develop and implement biosecurity protocols for use at their salmonid aquaculture operations throughout the State. Program participants must submit a copy of these protocols to APHIS. The implementation of effective biosecurity protocols reduces the risk of ISA introduction and spread via moving farmed fish, equipment, and people among marine sites. Though there are currently 13 fish farms, there is only one company, so there is one set of biosecurity protocols for all farms.

Biosecurity Audits; (9 CFR 53.10(e)(8)); (Business)

As a condition of receiving indemnity, program participants must cooperate with and assist APHIS in completing biosecurity audits at their salmonid aquaculture operations throughout Maine. These audits will assess the efficacy of the biosecurity protocols. Each of the 13 fish farms participates in biosecurity audits.

ISA Action Plan; (9 CFR 53.10(e)(4)); (Business)

As a condition of receiving indemnity, program participants must develop an ISA action plan for controlling and managing ISA at each of the operation's marine sites. A copy of this action plan must be submitted to APHIS. The action plan defines the response contingencies for ISA (activities undertaken if disease is detected) should the disease emerge at any given site. Each of the 13 fish farms creates an ISA action plan.

Fish Inventory; (9 CFR 53.10(e)(6)); (Business)

As a condition of receiving indemnity, program participants must compile and submit to APHIS a complete and current fish inventory. Fish inventory information must include the numbers, age, date of saltwater transfer, vaccination status, and previous therapeutic history for all fish in a particular unit. (This information can be compiled using existing industry records systems and log sheets.) This information will give APHIS the data necessary to establish disease control actions and complete epidemiological assessments. Moreover, the information will increase APHIS' ability to effectively monitor fish populations. The parent company submits this information when requested.

Mortality Data and Recordkeeping; (9 CFR 53.10(e)(7)); (Business)

As a condition of receiving indemnity, program participants must compile, maintain, and make available to APHIS on request mortality data for their salmonid aquaculture operations throughout Maine. (This information can be compiled using existing industry records systems and log sheets.) APHIS will use mortality data with the fish inventory to establish disease control actions and complete epidemiological assessments. Moreover, the information will increase

APHIS' ability to effectively monitor fish populations. These records will be retained by the originating office for no less than 3 years and submitted when requested. As there has not been an outbreak of ISA since February 2006 (15 years), APHIS has estimated the costs of one submission.

Disease Surveillance; (9 CFR 53.10(e)(2)); (Business)

As a condition of receiving indemnity, program participants and designated laboratory personnel must cooperate with and assist in onsite monthly disease surveillance, testing, and reporting activities for ISA, which will be conducted by their accredited veterinarian or a Federal official. Surveillance ensures that resources and producers' attention will be directed at routine and regularly scheduled inspections and health assessments of fish so ISA can be diagnosed quickly. As there are 13 marine sites, 156 total annual responses represent the maximum number of responses. Although there has not been an ISA outbreak in 15 years, early detection and removal of infected fish is the goal to minimize potential spread; therefore, samples are still collected monthly from each site and testing results are submitted to APHIS.

Proceeds from Animals Sold for Slaughter Form (VS 1-24); (9 CFR 53.2(b)); (Business)

Program participants may sell animals from premises on which an outbreak has occurred as a way to recover losses. The proceeds of any such sale must be recorded on the VS 1-24. The form records gross income from the sales as well as expenses for transportation, marketing, slaughter, or other disposition. The participant then sends the form to APHIS. The information allows APHIS personnel to arrive at a net salvage value to be used for determining net indemnity amounts. The program participant must describe the animals, products, or materials to be sold; provide the weight or number of units; the price per unit; the gross receipts; and the expenses. As there has not been an outbreak of ISA since February 2006 (15 years), APHIS has estimated the costs of one submission.

Appraisal Request for Affected Premises Using Contract Growers (VS 1-26); (9 CFR 53.2(b)); (Business)

In addition to filling out the forms VS 1-23 and VS 1-23A as described above in cases of depopulation, program participants using contract growers must prepare a VS 1-26, as APHIS splits indemnity payments between owners and contract growers in such cases according to the terms of the contract between them. The form requires the premises ID and address of the premises where the fish are located, the disease of concern (ISA in this case) and the presumptive positive date, and name, address, and phone number for both the contract grower and the program participant. The program participant agrees that at the time of the outbreak, he or she was following a biosecurity plan and to provide a current inventory (see above for both); that the fish must be depopulated in the most humane way possible; to accept the fair market value of the fish; to provide a current copy of the contract as well as proof of any partial payment; and that he or she must obtain and provide a Dun and Bradstreet Data Universal Numbering System (DUNS) number and register in the Federal System for Award Management (SAM) database to receive an indemnity payment. As there has not been an outbreak of ISA since February 2006 (15 years), APHIS has estimated the costs of one submission.

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.

VS Form 1-22, VS Form 1-23, VS Form 1-23a, and VS Form 1-24 are completed onsite and also require original signatures. Therefore, these forms are not practical candidates for electronic transmission.

There are no standard formats for biosecurity protocols, biosecurity audits, and ISA action plans; therefore, these records are not conducive to developing an electronic system.

As fish inventories and mortality data are compiled using existing industry records systems and log sheets, there is no standard format, which means they are not conducive to developing an electronic system.

Disease surveillance consists of onsite monthly disease surveillance, testing, and reporting activities; therefore, these activities are not conducive to developing an electronic system.

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 not available from any other source. APHIS is the only Federal Agency responsible for preventing, detecting, controlling, and eradicating contagious 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 for this program is the minimum needed to protect salmon from ISA.

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 continue implementing its current program to contain and prevent ISA 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.

- **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;**

As a condition of receiving indemnity, program participants and designated laboratory personnel must cooperate with and assist in onsite monthly disease surveillance, testing, and reporting activities for ISA, which will be conducted by their accredited veterinarian or a Federal official.

Participants must submit a new action management plan, an updated State of Maine sea lice management plan, and a new set of biosecurity protocols within 15 days of any changes to any of these documents.

- **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.**

There are no other special circumstances that exist that would require this information 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.

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.

Amy Canam, DVM
Site Veterinarian
Kelly Cove Salmon Ltd.
61 Wallace Cove Road
Blacks Harbour, New Brunswick
E5H 1E6 Canada
Office: (506) 456-6637
Cell: (506) 456-6863

Marcy Nelson
Scientist II, Division of Aquaculture
Maine Department of Marine Resources
194 McKown Point Road, P.O. Box 8
West Boothbay Harbor, ME 04575
Office: (207) 633-9502
Cell: (207) 592-0645

Frank Lank-
Marine Production Manager
Phoenix Salmon/Cooke Aquaculture, United States
133 Small's Point Road
Machiasport, ME 04655
Office: (207) 255-6714
Cell: (207) 214-6725

The program is confined to Maine. Marcy Nelson is the state contact for the Maine Department of Marine Resources, and Amy Canam and Frank Lank are the commercial inspectors of the Maine sites.

On November 20, 2020, APHIS published in the Federal Register (85 FR 74312) a 60-day notice seeking public comments on its plans to request a 3-year renewal of this collection of information. We received one comment opposing fish farming practices in the United States but was not specific with recommendations that affected the activities and estimates described in the information collection request.

9. Explain any decision to provide any payment or gift to respondents, other than re-enumeration 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. Any and all information obtained in this collection shall not be disclosed except in accordance with 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.

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 Form 71. Burden estimates were developed from discussions with program participants (such as certain aquaculture industry business owners, managers, site employees, or accredited veterinarians) and 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 \$32,210. APHIS arrived at this figure by multiplying the estimated hours of burden (549 hours) by the estimated average hourly wage of the above respondents (\$40.49) 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 first-line supervisors of farming, fishing, and forestry workers (SOCC 45-1011, \$26.16), biological scientists (SOCC 19-1029, \$43.22), and veterinarians (SOCC 29-1131, \$52.09). The rates were found at 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 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 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 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 \$5,326 (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-I.

	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	191	0	1	0	0	190
Annual Time Burden (Hr)	549	0	2	0	0	547

This renewal request reports 191 estimated responses and 549 hours of estimated burden, or discretionary increases of 1 response and 2 hours of burden. The change is attributed to adding recordkeeping reporting for the Appraisal and Indemnity Claim activity.

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 1-23, VS 1-23a, VS 1-24, and VS 1-26 are used in multiple information collections; therefore, it is not practical to include an OMB approval expiration date because of the various expiration dates for each collection. APHIS is seeking approval to not display the OMB approval expiration dates.

APHIS has many forms eligible for conversion to common forms but has lacked the expertise and time to develop a process for doing so efficiently. This has become a priority for the Agency in 2021 and it anticipates making material progress on the project.

The VS Form 1-22 will display the OMB approval expiration date.

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

APHIS can certify compliance with all provisions in the Act.

B. Collections of Information Employing Statistical Methods

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