SUPPORTING STATEMENT - OMB NO. 0579-0192 Infectious Salmon Anemia PAYMENT OF INDEMNITY

March 2011

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 exotic Newcastle disease, infectious salmon anemia (ISA), and others. These regulations are in title 9 of the *Code of Federal Regulations* (9 CFR), chapter I, subchapter D.

Animal health regulations promulgated by the U.S. Department of Agriculture (USDA) under this authority include those specifically addressing control programs and indemnity payments. Under 9 CFR 53 are provisions for paying indemnity for claims made by ISA disease control to program participants arising out of 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. In 2010, salmon production in Maine was approximately 24.5 million pounds with a value of roughly \$75 million.

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

VS Form 1-22 - ISA Program Enrollment Form (Signature Only)

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; (6) submit complete and current fish inventory information to the ISA Program Veterinarian; (7) maintain mortality data and make it available, upon request, to the ISA Program Veterinarian; and (8) cooperate and assist APHIS in completing biosecurity audits. Currently, there is one parent company with several subsidiaries, so more than one form is signed.

VS Form 1-23 - All Species Appraisal and Indemnity Claim Form

Appraisals of salmon must be reported on the VS Form 1-23 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 as to 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 (5 years), APHIS has estimated the costs of one claim form.

Biosecurity Protocols

As a condition of receiving indemnity, program participants must develop and implement biosecurity protocols for use at their salmonid aquaculture operations throughout Maine. 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 is only one parent company, there are 16 fish farms, and each farm develops biosecurity protocols.

Biosecurity Audits

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 16 fish farms participates in biosecurity audits.

ISA Action Plan

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 l6 fish farms creates an ISA action plan.

Fish Inventory

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 therapeutant history for all fish in a particular unit. (This information can be compiled using existing industry records systems and log sheets.) This information will provide APHIS with 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)

As a condition of receiving indemnity, program participants must compile, maintain, and make available to APHIS upon 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 in conjunction 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. Since there has not been an outbreak of ISA since February 2006 (5 years), APHIS has estimated the costs of one submission.

Disease Surveillance

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 that ISA can be diagnosed quickly. Since there are 16 marine sites, 192 total annual responses represent the maximum number of responses. Although there has not been an ISA outbreak in 5 years, APHIS still routinely collects samples monthly from each site.

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 and VS Form 1-23 must be 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.

Since 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, which does not make these activities 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.

The information APHIS is collecting in connection with this program is the minimum needed to protect Maine salmon from ISA. APHIS has no small entities involved with this information collection.

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;
- 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.

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.

In 2011, APHIS engaged in productive consultations with the following individuals concerning the information collection activities associated with this program:

Julia Mullins

Heritage Salmon/Connor Bros. Aquaculture; Trumpet Island Aquaculture 874 Main Street

Blacks Harbor, New Brunswick

E5H 1 E6 Canada Office: 506-694-9923 Fax: 506-694-9922

Nils Steine

Atlantic Salmon of Maine; island Aquaculture; Treats Island Fisheries

57 Little River Drive Belfast, ME 04915 Phone: 207-338-9028

Fax: 207-338-6288

Dan MacPhee

Stolt Sea Farms; International Aqua Food, Inc. Maritime Veterinary Services 90 L'Etete Road Unit 1 St. George, New Brunswick E5C3H6 Canada

Office: 506-755-8908

On Thursday, July 21, 2011, pages 43650-43651, APHIS published in the Federal Register, a 60- day notice seeking public comments on APHIS' plans to request a 3-year extension of this collection of information. During that time APHIS received no comments.

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. 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 83-1.

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) laboratory personnel.

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

The annualized cost to the public is \$51,093.94.

APHIS arrived at this figure by multiplying the total burden hours (1421) by the estimated average hourly wage of the above respondents (\$35.95). Estimated hourly wages or the respondents were determined from the U.S. Department of Labor, Bureau of Labor Statistics May 2010 Report - National Compensation Survey: Occupational Employment and Wages, May 2009. See http://www.bls.gov/oesl/#tables.

Farm, ranch, and other agricultural managers (aquaculture industry employees) - \$31.13 Laboratory personnel (biological scientists, all other) - \$33.38 Veterinarians - \$43.32

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 start-up 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 \$3,130.44 (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:

	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	718	0	0	502	0	216
Annual Time Burden (Hr)	1,421	0	0	777	0	644
Annual Cost Burden (\$)	0	0	0	0	0	0

There is an adjustment of +14 respondents and +502 responses resulting in +777 burden hours due to an increased number of respondents completing the Biosecurity Audits, ISA Action Plan, and Disease Surveillance samples.

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.

APHIS has no plans to seek approval for not displaying the OMB expiration date on VS Form 1-22.

VS Form 1-23 is used in 5 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 date on this form.

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.