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## DEPARTMENT OF AGRICULTURE

### Animal and Plant Health Inspection Service

[Docket No. APHIS-2013-0023]

#### Notice of Request for Approval of an Information Collection; Approval of Laboratories for Conducting Aquatic Animal Tests for Export Health Certificates

**AGENCY:** Animal and Plant Health Inspection Service, USDA.

**ACTION:** New information collection; comment request.

**SUMMARY:** In accordance with the Paperwork Reduction Act of 1995, this notice announces the Animal and Plant Health Inspection Service's intention to request approval of a new information collection for the approval of laboratories for conducting aquatic animal tests for export health certificates.

**DATES:** We will consider all comments that we receive on or before March 3, 2014.

**ADDRESSES:** You may submit comments by either of the following methods:

- *Federal eRulemaking Portal:* Go to <http://www.regulations.gov/#!documentDetail;D=APHIS-2013-0023-0001>.

- *Postal Mail/Commercial Delivery:* Send your comment to Docket No. APHIS-2013-0023, Regulatory Analysis and Development, PPD, APHIS, Station 3A-03.8, 4700 River Road Unit 118, Riverdale, MD 20737-1238.

Supporting documents and any comments we receive on this docket may be viewed at <http://www.regulations.gov/#!docketDetail;D=APHIS-2013-0023> or in our reading room, which is located in Room 1141 of the USDA South Building, 14th Street and Independence Avenue SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30

p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 799-7039 before coming.

**FOR FURTHER INFORMATION CONTACT:** For information on the approval of laboratories for conducting aquatic animal tests for export health certificates, contact Dr. Christa Speckmann, Import-Export Specialist-Aquaculture, NAHPP-NCIE, VS, APHIS, 4700 River Road Unit 39, Riverdale, MD, 20737; (301) 851-3365. For copies of more detailed information on the information collection, contact Mrs. Celeste Sickles, APHIS' Information Collection Coordinator, at (301) 851-2908.

#### SUPPLEMENTARY INFORMATION:

*Title:* Approval of Laboratories for Conducting Aquatic Animal Tests for Export Health Certificates.

*OMB Control Number:* 0579-XXXX.

*Type of Request:* Approval of a new information collection.

*Abstract:* The Animal Health Protection Act (AHPA) is the primary Federal law governing the protection of animal health. The AHPA 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 export of agricultural commodities, including animals and animal products, is a major business in the United States and contributes to a favorable balance of trade. To facilitate the export of U.S. animals and animal products, the Animal and Plant Health Inspection Service (APHIS) of the U.S. Department of Agriculture maintains information regarding the import health requirements of other countries for animals and animal products, including aquaculture animals, exported from the United States.

Some countries that import aquaculture animals from the United States require these animals to be tested for certain diseases and the test results recorded on the export certificates. In addition, the test results must originate from a laboratory approved by the competent authority of the exporting country, which is APHIS in this case. State, university, and private laboratories can voluntarily seek APHIS

approval of individual diagnostic methods. Though APHIS does not have regulations for the approval or certification of laboratories that conduct tests for the export of aquaculture animals, APHIS provides this approval as a service to U.S. exporters who export aquaculture animals to countries that require this certification.

As part of the approval process, APHIS evaluates diagnostic methods for 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. APHIS maintains a list of approved laboratories<sup>1</sup> and inspects each approved laboratory every 2 years.

The approval of laboratories to conduct tests for the export of aquaculture animals requires the use of certain information collection activities, including notification of intent to request approval, application for APHIS approval, protocol statement, submission and recordkeeping of sample copies of diagnostic reports, quality assurance/control plans and their recordkeeping, notification of proposed changes to assay protocols, recordkeeping of supporting assay documentation, and request for removal of approved status.

We are asking the Office of Management and Budget (OMB) to approve our use of these information collection activities for 3 years.

The purpose of this notice is to solicit comments from the public (as well as affected agencies) concerning our information collection. These comments will help us:

- (1) Evaluate whether the collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility;

- (2) Evaluate the accuracy of our estimate of the burden of the collection of information, including the validity of the methodology and assumptions used;

- (3) Enhance the quality, utility, and clarity of the information to be collected; and

- (4) Minimize the burden of the collection of information on those who are to respond, through use, as

<sup>1</sup> To view the list of APHIS-approved laboratories, go to [http://www.aphis.usda.gov/animal\\_health/lab\\_info\\_services/downloads/ApprovedLabs\\_Aquaculture.pdf](http://www.aphis.usda.gov/animal_health/lab_info_services/downloads/ApprovedLabs_Aquaculture.pdf).

appropriate, of automated, electronic, mechanical, and other collection technologies; e.g., permitting electronic submission of responses.

*Estimate of burden:* The public reporting burden for this collection of information is estimated to average 37.04 hours per response.

*Respondents:* State, university, and private laboratories.

*Estimated annual number of respondents:* 12.

*Estimated annual number of responses per respondent:* 41.25.

*Estimated annual number of responses:* 495.

*Estimated total annual burden on respondents:* 18,336 hours. (Due to averaging, the total annual burden hours may not equal the product of the annual number of responses multiplied by the reporting burden per response.)

All responses to this notice will be summarized and included in the request for OMB approval. All comments will also become a matter of public record.

Done in Washington, DC, this 20th day of December 2013.

**Kevin Shea,**

*Administrator, Animal and Plant Health Inspection Service.*

[FR Doc. 2013-31245 Filed 12-30-13; 8:45 am]

**BILLING CODE 3410-34-P**

## DEPARTMENT OF AGRICULTURE

### Animal and Plant Health Inspection Service

[Docket No. APHIS-2013-0093]

#### Availability of an Environmental Assessment for Issuance of a Permit for Distribution and Sale of an Infectious Hematopoietic Necrosis Virus Vaccine, DNA

**AGENCY:** Animal and Plant Health Inspection Service, USDA.

**ACTION:** Notice of availability.

**SUMMARY:** We are advising the public that the Animal and Plant Health Inspection Service has prepared an environmental assessment concerning authorization to import under permit, for distribution and sale, an Infectious Hematopoietic Necrosis Virus Vaccine, DNA. The environmental assessment, which is based on a risk analysis prepared to assess the risks associated with the use of this vaccine, examines the potential effects that this veterinary vaccine could have on the quality of the human environment. Based on the risk analysis and other relevant data, we have reached a preliminary determination that use of this veterinary vaccine will not have a significant

impact on the quality of the human environment and that an environmental impact statement need not be prepared. We intend to authorize shipment of this vaccine under permit for distribution and sale in the United States following the close of the comment period for this notice unless new substantial issues bearing on the effects of this action are brought to our attention and provided the product meets all requirements for approval.

**DATES:** We will consider all comments that we receive on or before January 30, 2014.

**ADDRESSES:** You may submit comments by either of the following methods:

- *Federal eRulemaking Portal:* Go to <http://www.regulations.gov/#!documentDetail;D=APHIS-2013-0093-0001>.

- *Postal Mail/Commercial Delivery:* Send your comment to Docket No. APHIS-2013-0093, Regulatory Analysis and Development, PPD, APHIS, Station 3A-03.8, 4700 River Road Unit 118, Riverdale, MD 20737-1238.

Supporting documents and any comments we receive on this docket may be viewed at <http://www.regulations.gov/#!docketDetail;D=APHIS-2013-0093> or in our reading room, which is located in Room 1141 of the USDA South Building, 14th Street and Independence Avenue SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 799-7039 before coming.

**FOR FURTHER INFORMATION CONTACT:** Dr. Donna Malloy, Operational Support Section, Center for Veterinary Biologics, Policy, Evaluation, and Licensing, VS, APHIS, 4700 River Road Unit 148, Riverdale, MD 20737-1231; phone (301) 851-3426, fax (301) 734-4314.

For information regarding the environmental assessment or the risk analysis, or to request a copy of the environmental assessment (as well as the risk analysis with confidential business information removed), contact Dr. Patricia L. Foley, Risk Manager, Center for Veterinary Biologics, Policy, Evaluation, and Licensing, VS, APHIS, 1920 Dayton Avenue, P.O. Box 844, Ames, IA 50010; phone (515) 337-6100, fax (515) 337-6120.

**SUPPLEMENTARY INFORMATION:** Under the Virus-Serum-Toxin Act (21 U.S.C. 151 *et seq.*), a veterinary biological product must be shown to be pure, safe, potent, and efficacious before a veterinary biological product license may be issued. Prior to importing an unlicensed product, an applicant must obtain

approval from the Animal and Plant Health Inspection Service (APHIS) to ship the product under permit for distribution and sale.

To determine whether to authorize shipment and approval for the use of the imported product referenced in this notice, APHIS has considered the potential effects of this product on the safety of animals, public health, and the environment. Using a risk analysis and other relevant data, APHIS has prepared an environmental assessment (EA) concerning the use of the following imported veterinary biological product:

*Requester:* Novartis Animal Health US, Inc.

*Product:* Infectious Hematopoietic Necrosis Virus Vaccine, DNA.

The above-mentioned product is a replication-incompetent DNA vaccine consisting of a plasmid vector with an inserted immunogenic gene. The vaccine is intended for the immunization of salmonids as an aid in the prevention of disease due to infectious hematopoietic necrosis virus.

The EA has been prepared in accordance with: (1) The National Environmental Policy Act of 1969 (NEPA), as amended (42 U.S.C. 4321 *et seq.*), (2) regulations of the Council on Environmental Quality for implementing the procedural provisions of NEPA (40 CFR parts 1500-1508), (3) USDA regulations implementing NEPA (7 CFR part 1b), and (4) APHIS' NEPA Implementing Procedures (7 CFR part 372).

Unless substantial issues with adverse environmental impacts are raised in response to this notice, APHIS intends to issue a finding of no significant impact based on the EA and authorize shipment of the above product for distribution and sale following the close of the comment period for this notice, provided the product meets all other requirements for approval.

**Authority:** 21 U.S.C. 151-159.

Done in Washington, DC, this 20th day of December 2013.

**Kevin Shea,**

*Administrator, Animal and Plant Health Inspection Service.*

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