SUPPORTING STATEMENT 0579-XXXX
HIGHLY PATHOGENIC AVIAN INFLUENZA, ALL SUBTYPES, AND EXOTIC NEWCASTLE DISEASES; ADDITIONAL RESTRICTIONS

December 9, 2010

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.

The U. S. Department of Agriculture (USDA) is responsible for preventing the introduction or dissemination of contagious or communicable diseases of animals, including birds and poultry from a foreign country into the United States, or from one State to another. USDA's Animal and Plant Health Inspection Service (APHIS), through its Veterinary Services (VS) program, carries out this disease prevention mission. VS regulations for preventing the introduction of foreign animal diseases into the United States are contained in title 9, *Code of Federal Regulations*, subchapter D, Exportation and Importation of Animals and Animal Products. Parts 93, 94, 95, and 96 of this subchapter govern the importation of certain live animals, birds, and poultry (including hatching eggs); and meat, other animal products and byproducts, hay, and straw into the United States to prevent the introduction of various animal diseases.

Through an interim rule, APHIS is clarifying its restrictions on the importation of bird and poultry products from regions where HPAI subtype H5N1 is considered to exist and is adding prohibitions or restrictions on the importation of bird and poultry products from regions where other subtypes of HPAI are considered to exist. These restrictions supplement existing restrictions on the importation of live birds and poultry, and bird and poultry products and byproducts from regions where exotic Newcastle disease (END) or HPAI subtype H5NI are considered to exist. Because this rule adds restrictions for HPAI subtypes other than subtype H5NI, new approval is needed for information collection activities that APHIS already conducts for END and HPAI subtype H5NI. Many of the activities overlap since the countries involved have both END and HPAI. Consequently, the information collection activities incorporate END, HPAI subtype H5NI, and other subtypes of HPAI.

HPAI and END are extremely infectious and often fatal viral diseases of birds and poultry. HPAI and END do not currently exist in birds or poultry in the United States, but can strike quickly. Infection and mortality can reach 100 percent of a given population of birds or poultry. Once established, either disease can spread rapidly from flock to flock in commercial poultry.

APHIS' efforts to continue to effectively prevent the introduction of foreign animal diseases of poultry, such as HPAI and END, into the United States require the use of the following information collection activities: 1) Application to Import Controlled Materials or Transport Organisms and Vectors (VS 16-3); 2) Agreement for Handling Restricted Imports of Animal Byproducts and Controlled Materials (VS 16-26); 3) Report of Entry, Shipment of Restricted Imported Animal Products and Animal By Products, and other Material (VS Form 16-78); 4) application of seals to shipping containers;
5) recordkeeping by processing establishments; and 6) cooperative service agreements.

APHIS is asking the Office of Management and Budget (OMB) to approve its use of these information collection activities for 6 months.

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.

Application for Permit to Import Controlled Material; Import or Transport Organisms or Vectors (specifically bird carcasses or parts of carcasses) (VS Form 16-3)
Carcasses or parts or products of carcasses of poultry, game birds, and other birds from regions where END or HPAI are considered to exist, and that do not otherwise qualify for importation, may be imported only if the U.S. importer, using the VS 16-3, applies to APHIS and is granted a permit authorizing such importation. Permission will be given only when APHIS determines that the importation will not risk introduction or dissemination of END or HPAI into the United States. Application for a permit may be made in accordance with the regulations contained in 9 CFR 94.6.

This permit application contains the importer's name, address, telephone number, fax number, and e-mail address; a description of the products to be imported; the quantity and frequency of importation; the proposed use of the material; a description of the applicant's facilities for handling the material; the qualifications of the technical personnel who will be working with the materials; and a description of any processing the material may have undergone before importation into the United States. This information enables APHIS to carefully scrutinize the products and determine what, if any, disease threat they may pose to the U.S. poultry population. If APHIS decides to issue an import permit, information on the VS 16-3 also enables APHIS to determine what safeguards are appropriate for this particular importation. APHIS can then provide port and border personnel with appropriate clearance instructions for the impending shipment.

Agreement for Handling Restricted Imports of Animal Byproducts and Controlled Materials (VS Form 16-26)
Restricted animal products, byproducts, and controlled materials including carcasses (or parts or products of carcasses) of poultry, game birds, and other birds may be imported for consignment to any museum, educational institution, or other establishment that has given APHIS evidence that it has the equipment, facilities, and capabilities to store, handle, process, or disinfect such articles so as to prevent the introduction or dissemination of END and HPAI. This evidence is provided on another VS Form, 16-25, which asks a series of detailed questions about the byproducts or materials handled, the establishment's sewage and storage facilities, and the establishment's disinfection procedures. Approximately 10 establishments are approved to receive restricted products and controlled materials from poultry, game birds, or other birds, but none are currently receiving materials. No new applications are pending.

Report of Entry, Shipment of Restricted Imported Animal Products and Animal By-Products, and other Material (VS Form 16-78)
This form accompanies all restricted animal products moving from the port of entry to APHIS-approved establishments or APHIS-approved storage facilities. Part A of this form is completed by U.S. Government inspectors at the port of entry. Part B of this form is completed by approved establishments; that is, museums, educational institutions, or other establishments that are approved to receive bird or poultry carcasses for educational purposes (see above). The establishments forward a copy of this form to the VS Area Office. The completed form helps APHIS ensure that the imported restricted materials are stored and processed in accordance with the requirements of 9 CFR 94.6.

Application of Seals to Shipping Containers
Carcasses, and parts or products of carcasses, including meat, of poultry, game birds, or other birds, that originated in a region considered to be free of END and any subtype of HPAI, and that are processed in a region where END or HPAI other than subtype H5N1 is considered to exist, must be in closed containers sealed with serially numbered seals applied by an official of the national government when they are shipped from either region. Upon inspection at the port of entry, U.S. Government inspectors ensure that the seals are in place and unbroken. There is no paperwork associated with this task.

Recordkeeping by Processing Establishments
When products originating from a region considered to be free of END and any subtype of HPAI are processed in a region where END or HPAI other than subtype H5N1 is considered to exist, the processing establishments must keep required records on file, including certificates, at the facility for at least 2 years after exporting processed products to the United States. These records need to be available when USDA inspects the establishments to help ensure that the establishments meet all USDA requirements.

Cooperative Service Agreements
Operators of processing establishments must enter into a cooperative service agreement with APHIS to pay all expenses incurred by APHIS in inspecting the establishment. The agreement is valid for 5 years.

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.

The application for a Permit to Import Controlled Material or Transport Organisms or Vectors (VS 16-3) is available to the public electronically at http://www.aphis.usda.gov/forms/vs16-3.pdf or at http://www.aphis.usda.gov/animal_health/permits/downloads/vs16_3.pdf. Respondents can submit the VS 16-3 electronically through the e-Permits system, which requires E-authentication. Respondents can apply for E-authentication at http://www.eauth.egov.usda.gov/ and access E-permits at https://epermits.aphis.usda.gov/epermits.

The Agreement for Handling Restricted Imports of Animal Byproducts and Controlled Materials (VS 16-26) requires an original signature and therefore is not a candidate for electronic submission.

The Report of Entry, Shipment of Restricted Imported Animal Products and Animal By-Products, and other Material (VS 16-78) must accompany all shipments of restricted animal products and therefore is not a candidate for electronic submission.

Application of seals to shipping containers entails no paperwork.

The cooperative service agreement requires an original signature and therefore is not a candidate for electronic submission.

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 detecting and controlling contagious animal diseases in 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 will collect in connection with this program is the minimum needed to protect U.S. birds and poultry from the introduction of END and HPAI. Approximately 12 percent of the respondents in this information collection are small entities.

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 establish an effective line of defense against introduction of END and HPAI. The introduction and spread of these diseases within the United States could have serious economic consequences for the domestic poultry industry.

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.

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.

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

Rosa M. Arjona
Arjona Easter Eggs and Piñatas
2141 Cortez Avenue
McAllen, TX 78503
956-971-9530

Sylvia May Chu
Pioneer Charm International Limited
428 Stephen Road
San Mateo, CA 94403
415-699-0408

Steve Uretsky
Allied Feather and Down Corporation
2661 E 46th Street
Vernon, CA 90058
323-585-1833

APHIS' interim rule (APHIS-2006-0074) will describe its information gathering requirements, and also provide a 60-day comment period. During this time, interested members of the public will have the opportunity to give APHIS their input concerning the usefulness, legitimacy, and merit of the information collection activities APHIS is proposing.

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 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 U.S importers, owners or operators of establishments that handle restricted or controlled materials, and foreign animal health authorities.

•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 the above respondents to be $9,579.24. APHIS arrived at this figure by multiplying the hours of estimated response time (358) by the estimated average hourly wage of the respondents ($27.06). The hourly rates of private industry workers ($23.97) and health related professional specialists ($30.14) are from the U.S. Department of Labor; Bureau of Labor Statistics May 2008 Report - Occupational Employment and Wages in the United States. See http://www.bls.gov/news.release/ocwage.t03.htm. APHIS determined that the hourly wage for foreign animal authorities would be comparable to the wage for U.S. health related professionals.

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.

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 $45,869. (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.

This is a new collection.

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 16-3 is used in five information 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.

VS 16-26 is used in two information 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.

VS 16-78 is composed of multiple parts using carbonless coated paper (NCR – No Carbon Required) to provide for duplicate copies. It is not practical to store these forms for long time periods because the carbonless paper breaks down in storage. It takes months to get these specialized forms reprinted so having an expiration date while waiting for OMB approval would incur higher government printing costs if these forms were to be discarded because of an outdated OMB expiration date. Therefore, 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 under the Act.

B. Collections of Information Employing Statistical Methods

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