SUPPORTING STATEMENT 0579-0245
HIGHLY PATHOGENIC AVIAN INFLUENZA, ALL SUBTYPES, AND EXOTIC NEWCASTLE DISEASES; ADDITIONAL RESTRICTIONS

2013

This renewal information collection is merging 0579-0367 into 0579-0245. Upon approval of 0579-0245, 0579-0367 will retire. Please note the title of this information collection also changed to support a broader topic.

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.

Highly pathogenic avian influenza (HPAI) is an extremely infectious and often fatal viral disease affecting all types of birds and poultry. HPAI can strike poultry quickly, without infection warning signs. Once established, the disease can spread rapidly from flock to flock. This form of influenza, when caused by certain viral subtypes such as H5N I, can also adversely affect humans and other animals, such as pigs. HPAI caused by any subtype of HPAI does not currently exist in birds or poultry in the United States.

Like HPAI, exotic Newcastle disease (END) is an extremely infectious and often fatal viral disease of birds and poultry. END does 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 information collection activities.

Information collection 0579-0367 will now be combined with 0579-0245 to increase efficiency and reduce redundancy in collecting information on all subtypes of HPAI and END. The information collected under 0579-0245 was specific to the H5N1 subtype of HPAI. This combined collection reflects those changes. Collection 0579-0367 will retire once this collection is approved.

APHIS is asking the Office of Management and Budget (OMB) to approve its use of these information collection activities for 3 years.

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 collection activities to continue to effectively prevent the introduction of foreign animal diseases of poultry, such as HPAI and END, into the United States

Application for Permit to Import Controlled Material; Import or Transport Organisms or Vectors (specifically bird carcasses or parts of carcasses) (VS Form 16-3) 0367

Carcasses or parts or products of poultry (including feathers, nests, and trophies), 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. The VS Form 16-3 is available on the APHIS Web site.

This permit application contains the importer's name, address, telephone number, fax number, and email address; the name and address of the exporter of the material or product; a description of the products to be imported; the quantity and frequency of importation; the mode of transportation; 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.

Import Permit for Controlled Materials or Transport Organisms and Vectors (VS Form 16-6A) Signature Only

If an importer fills out the VS 16-3 application and VS determines that a shipment qualifies for import, VS will issue the importer an import permit, VS Form 16-6A, which he or she must sign. The importer's signature provides acknowledgment that the importer agrees to abide by all the restrictions and precautions outlined on the import permit. The original hard copy import permit then accompanies the product.

Application for Approval or Report of Inspection Establishment Handling Restricted Animal Byproducts or Controlled Materials (VS Form 16-25)

An establishment must provide evidence that it has the equipment, facilities, and capabilities to store, handle, process, or disinfect restricted animal byproducts or controlled materials so as to prevent the introduction or dissemination of END and HPAI. This evidence is provided on VS Form 16-25. The following information is requested: date of last inspection, agreement expiration date (if applicable), method of transportation by which products are received, countries from which products originate, approximate yearly volume, name and title of contact person for the establishment, byproducts or materials handled at the establishment, method of sewage disposal, capacity and construction material of separate storage facilities (if applicable), whether or not there is adequate separation of restricted and unrestricted materials, the method of transportation by which products are moved to the storage facility, method of transportation by which products are moved to the processing area, detailed description of how restricted materials are processed and/or disinfected, name of the supervisor of processing and disinfection, name of disinfectants used, and the methods used to disinfect containers. The signature of the inspector, the Area Veterinarian in Charge, and the approving official (Staff Veterinarian for Import-Export) are also required.

Agreement for Handling Restricted Imports of Animal Byproducts and Controlled Materials (VS Form 16-26) 0367

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. Establishments that APHIS determines meet the criteria are eligible to enter into an agreement for handling restricted imports of animal byproducts and controlled materials via VS Form 16-26. The form requires signatures from the establishment officer, the Area Veterinarian in Charge, and the Chief Staff Veterinarian for Import-Export.

Report of Entry, Shipment of Restricted Imported Animal Products and Animal Byproducts and Other Material (VS Form 16-78) 0367
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 approved to receive bird or poultry carcasses or products for educational purposes. 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.

Establishments must provide the following information on VS Form 16-78: date products or materials are received; the name of the approved establishment; whether or not the shipment is intact (if not an explanation must be given); date of treatment completion; whether or not the railroad car, truck, etc. has been disinfected; disinfectant used; method of treatment; disposition of refuse; and the name and signature of the establishment owner.

Application of Seals to Shipping Containers 0367
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 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 0367
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 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 0367
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.

Application for Import Permit (VS Form 17-129)
Birds, poultry, and hatching eggs imported to the United States from any region, except for pet birds returning from Canada via a land border port, must be accompanied by an APHIS-issued import permit. The owner of the avian shipment can obtain this permit by completing a permit application, VS Form 17-129, which is available on the APHIS Web site.

The application asks for the name and address of the shipper in the country of origin; the port of embarkation and entry, mode of transportation used; the name, address, and phone number of the importer; the number, breed, species, and description (sex, age, registered name and number, tattoo, tag number, other markings) of the animals imported; the purpose of importation; the route of travel; the proposed shipping date; the proposed arrival date; the name and address of the person to whom delivery will be made; and where the delivery will be made in the United States.

This information allows APHIS to determine the level of risk associated with the shipment and the appropriate risk-mitigating measures to take, if necessary, to ensure the shipment poses a minimal risk of introducing HPAI and END into the United States.

Notarized Declaration or Affirmation
In addition to VS Form 17-129, pet birds, performing birds, and theatrical poultry returning to the United States must be accompanied by a notarized declaration, affirmation, or statement signed by the owner and witnessed by a USDA inspector that states that the birds or poultry were not exposed to other birds or poultry while out of the United States. Completed section B of VS Form 17-8, "Agreement of Pet Bird Owner," can be used for this purpose or importers can supply their own notarized statement. The information captured on both formats of declaration is required by 9 CFR 93.101(c)(3)(E). The information being requested provides APHIS with another means of ensuring that U.S. origin pet birds, performing birds, and theatrical poultry returning to the United States were not exposed to avian populations of unknown health status.

Agreement of Pet Bird Owner (VS Form 17-8)
Owners of U.S.-origin pet birds, non- U.S. origin pet birds, performing birds, or theatrical poultry must sign a pet bird agreement at the first U.S. port of entry at the time of import. This form documents the importation of these categories of birds, noncompliance and rejection of import, the surrender of birds to Federal authority (if the owner chooses to abandon the bird on import) and receipt of a pet bird, performing bird, or performing poultry into home or Federal quarantine. The form is the tool used to inform the importer or owner of the commitment to impose a 30-day home quarantine. The form is also used to allow the APHIS port veterinarian to place the bird into Federal quarantine for 30 days from the time of arrival at the first port of U.S. entry. Owners can obtain this agreement from a Federal inspector at the U.S. port of entry or from the APHIS Web site.

This agreement requires the following information: The owner's name, address, and phone number; the number and kind of birds or poultry the owner is importing into the United States; information on the route of travel; and the date the birds are offered for entry. The form has four sections; depending on which situation applies, the importer or owner will complete different sections. Section A refers to U.S.-origin pet birds, performing birds, and performing poultry and home quarantine situations and requires: Location where the bird will be held in quarantine, name and address of local Federal contact, laboratory specimens taken at the port of entry, and signature of owner. Section B refers to non-U.S. origin pet birds, performing birds, and performing poultry. The owner must certify that the birds have been in his or her possession for at least 90 days before importation and they are apparently healthy. This form accompanies the bird into Federal quarantine. Section C requires a signature only from the importer and states noncompliance and a rejection of import. Section D refers to

abandonment of the bird due to noncompliance and, by owner signature, allows disposal of the bird or poultry.

Notification of Signs of Disease in a Recently Imported Bird Allowed to Enter Home Quarantine

Owners of U.S.-origin pet birds, performing birds, or theatrical poultry imported to a home quarantine must immediately alert Federal officials if the owners note signs of disease during home quarantine. To do this, owners call their local VS Area Offices and inform office staff of the bird's signs of disease. This call should last 5 minutes or less. The Area Office then sends out a veterinarian to assess the bird's condition. This is an informal process involving a small number of respondents. The VS Area Offices do not keep records on whether respondents call them regarding symptoms in recently imported birds; therefore, there is no way to determine how often this occurs.

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 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.
However, some importers may not choose to become e-Authenticated. Those importers must submit the VS 16-3 by fax or mail.

The VS 16-6A is a hard copy permit produced after the VS 16-3 application is accepted by APHIS. This hard copy permit must be signed by the importer (requires an original signature) and accompanies the imported product; therefore, it cannot be produced electronically.

The VS 16-25 is obtained from the VS Area Office. The form requires original signatures and cannot currently be submitted electronically. However, APHIS is working to make the form available for submission via its Veterinary Services Processes Streamlining system. This system is currently used at headquarters and APHIS is working to extend its availability to the field.

The VS 16-26 requires an original signature and therefore is not a candidate for electronic submission at this time. However, APHIS is working to make the form available for submission via its Veterinary Services Processes Streamlining system. This system is

currently used at Headquarters and APHIS is working to extend its availability to the field.

The VS 16-78 is obtained from the Customs and Border Patrol inspector. It must accompany all shipments of restricted animal products and therefore is not a candidate for electronic submission. APHIS is working to create a version of the form that can be filled out electronically and printed for signature.

VS Form 17-129 is available to the public electronically at www.aphis.usda.gov/import_export/forms.shtml and can be submitted by fax or mail. The application can be submitted through the e-Permits system found at: http://www.aphis.usda.gov/permits/login_epermits.shtml

VS Form 17-8 is available to the public electronically at www.aphis.usda.gov/import_export/forms.shtml. However, it is not completed until the time of arrival in conjunction with the port inspection. Data from the VS 17-8 is electronically submitted by Federal inspectors at the U.S. port of entry. To be valid, it requires original signatures from the pet bird owner, the detaining official, the releasing official, and the final releasing official. It is therefore not a candidate for electronic submission.

If an owner notifies a VS Area Office regarding signs of disease in a recently imported bird, he or she does so by phone. This notification can occur via email, but importers are encouraged to notify signs of disease by a phone call directly to the Area Office. There is no form involved.

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 17 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.

- **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.**

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 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:

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The Ornithological Council
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Ellen.paul@verizon.net

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479-549-2813

Zachari Douglas
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On Friday, August 9, 2013, pages 48645-48646, APHIS published in the Federal Register, a 60-day notice seeking public comments on its plans to request a 3-year renewal of this collection of information. No comments from the public were received.

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 $29,920. APHIS arrived at this figure by multiplying the hours of estimated response time (1,055) by the estimated average hourly wage of the respondents ($28.36). The hourly rates of private industry workers and health-related professional specialists are from the U.S. Department of Labor; Bureau of Labor Statistics May 2012 Report - Occupational Employment and Wages in the United States. See http://www.bls.gov/news.release/ocwage.t01.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 $24,903. (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.

	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	1,869	0	761	545	0	563
Annual Time Burden (Hr)	1,055	0	744	146	0	165
Annual Cost Burden ($)	0	0	0	0	0	0

The overall burden increased 890 total burden hours and 1306 responses due to both program changes (744 hours and 761 responses) and adjustments (146 hours and 545 responses).

The Adjustments are due to more countries being considered to be affected with HPAI, the number of approved establishments increasing as more taxidermists apply for approval, and general adjustments in the amount of paperwork received.

The Program Changes are a result of merging 0579-0367 into 0579-0245 and adding the VS 16-25 for better inspection of establishments handling restricted animal byproducts and other controlled materials.

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 16-25, 16-26, and 17-8 are used in two information collections each; 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 these forms.

VS 17-129 is used in 9 information collection; therefore, it is not practical to include an OMB expiration date because of the various expriation dates for this form.

VS 16-78 is composed of multiple parts using carbonless coated paper (NCR – No Carbon Required) to create 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 on the form could increase printing costs if these forms had 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.

APHIS has no other plans for seeking to not display expiration dates on forms.

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.