

**SUPPORTING STATEMENT - OMB NO. 0579-NEW
PROHIBITED AND RESTRICTED IMPORTATION OF ANIMAL AND POULTRY
PRODUCTS (MILK, EGGS), INTO THE UNITED STATES**

July 30, 2012

INTRODUCTION - This new collection was originally part of the larger collection [0579-0015]. For the purpose of efficiency, the commodities were divided into separate collections. When the milk and eggs were part of the 0015 collection, the different VS staffs thought the burden for this activity was 19,825 hours but now a more accurate count reveals that the burden is in fact 408,230 hours.

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 APHIS' ability to compete globally in animal and animal product trade.

In connection with this mission, APHIS enforces regulations regarding both the importation of controlled materials and the prevention of foreign animal disease incursions into the United States. These regulations can be found at title 9, chapter I, subchapter D, parts 94, 95, and 122 of the *Code of Federal Regulations* (CFR).

APHIS engages in a number of information collection activities to prevent or control the spread of livestock diseases via the prohibited and restricted importation of animal and poultry (Milk, Eggs) products into the United States.

APHIS is asking OMB to approve its use of these information collection activities for an additional 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 activities to prevent or control the spread of livestock diseases via the prohibited and restricted importation of animal and poultry (Milk, Eggs) products into the United States.

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

Restricted animal products, byproducts, and controlled materials, including dry milk or dry milk products and eggs may be imported to an approved business or not-for-profit, establishment if, among other requirements, the establishment is inspected and approved by USDA using the VS Form 16-25. The VS 16-25 serves as an inspection report to help ensure that USDA approved establishments are handling restricted and controlled imports in compliance with APHIS regulations. The VS 16-25 is completed by a U.S. Federal animal health official, who acquires this information from U.S. establishment operators.

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

Dry milk or dry milk products and eggs may be consigned directly to an approved establishment for further processing or breaking and pasteurization if, among other requirements, the operator of the establishment signs the VS 16-26. The VS 16-26 provides APHIS with evidence that the establishment has the equipment, facilities, and capabilities to store, handle, and process the imported dry milk or dry milk product in a manner which will prevent the introduction or dissemination of Foot-and-Mouth Disease (FMD) into the United States. The VS 16-26 provides APHIS with evidence that pasteurization and sanitation procedures for handling eggs, and for disposing of egg shells, cases, and packing materials are adequate to prevent the introduction of Exotic Newcastle Disease (END) into the U.S. The form also shows that APHIS has approved the establishment as evidenced by completion and endorsement of the form by APHIS officials.

Certificate for Importation of Eggs—Other Than Hatching Eggs

Eggs, other than hatching eggs, from regions where END has been determined to exist, may be imported into the United States only in accordance with 9 CFR 94.6. This regulation requires that the eggs be accompanied by a certificate endorsed by the government of the region of origin. The certificate, which is completed by the foreign government, must identify the flock of origin, region of origin, port of embarkation, port of arrival, name and address of the exporter and importer, total number of eggs and cases of eggs shipped with the certificate, and the date the certificate was signed. The certificate must physically accompany the shipment.

Application for Permit to Import or Transport Controlled Material or Organisms or Vectors (VS 16-3)

Eggs, other than hatching eggs, from regions where END has been determined to exist, may be imported into the United States if they are to be used by not for profit entities for scientific, educational, or research purposes, or if they have been cooked or processed, and if APHIS has determined that the eggs can be imported under conditions that will prevent the introduction of

END into the United States. Importers must obtain an APHIS-issued import permit before importation by completing the permit application and submitting it to APHIS in writing or electronically. The eggs must be moved and handled as specified on the permit.

Application for Permit to Import or Transport Controlled Material or Organisms or Vectors (VS 16-3)

Small amounts of milk and milk products from regions where FMD or rinderpest has been determined to exist, and may under certain circumstances, be imported for examination, testing, or analysis. The business or not for profit importer must be granted a permit through the VS 16-3 application after which APHIS will authorize such importation.

Certificate of Origin for Milk and Milk Products from Regions Free of FMD and Rinderpest

Except for milk and milk products imported from Canada, milk or milk products imported from a region listed as free of rinderpest and FMD must be accompanied by a certificate endorsed by a full-time salaried veterinarian employed by the region of export. The certificate, which is completed by the foreign government, must state that the milk was produced and processed in a region recognized as free of rinderpest and FMD or that the milk product was processed in a rinderpest and FMD-free region from milk produced in a rinderpest and FMD-free region. The certificate must name the region where the milk was produced and the region where it was processed. Further, the certificate must state—except for movement that occurs under seal—that the milk or milk product has never been in any region where rinderpest or FMD exist.

Marking Requirements (for eggs from regions with END) – Foreign Government

Eggs, other than hatching eggs from regions where END has been determined to exist, may be imported into the United States only if they are in cases marked by an official of the government of the region of origin with the identity of the flock of origin.

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 Form 16-3 can be submitted through USDA's e-permitting system. The form may be found at the following Web site address: <https://epermits.aphis.usda.gov/epermits>.

Currently, the *VS Form 16-25 and VS Form 16-26* are not available for electronic submission through the Internet. However, these forms have been incorporated into the Veterinary Services Process Streamlining (VSPS) initiative currently under development. The capability to complete the VS Forms 16-25 and 16-26 electronically within VSPS may be made possible through this initiative.

The Certificate for Importation of Eggs, Other Than Hatching Eggs must be an original signed document; therefore, it is not a candidate for electronic submission.

The Certificate of Origin for Milk and Milk Products from Regions Free of FMD and Rinderpest must be an original signed document; therefore, it is not a candidate for electronic submission.

The Marking Requirements for eggs from regions with END requires the eggs to be imported in cases physically marked with the identity of the flock of origin. Therefore, this is not a suitable 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 in connection with this effort is not available from any other source. APHIS is the only Federal Agency responsible for preventing communicable diseases of livestock from entering 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 collects is the absolute minimum needed to protect the United States from animal diseases resulting from imported animal and poultry products and byproducts.

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.

If this information were collected less frequently or not collected, the United States would be at increased risk for the introduction of foreign livestock and poultry disease, especially FMD and END. This would cause serious economic consequences to U.S. livestock and poultry industries and potentially serious health consequences for U.S. livestock and poultry.

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:

Mr. James Sumner, President
 U.S.A. Poultry and Egg Export Council
 2300 W. Park Place Blvd., Suite 100
 Stone Mountain, GA 30087
 Telephone: 770- 413-0006
 Fax: 770-413-0007

Mr. William Roenick, Senior Vice President
National Chicken Council
1015 15th Street NW, Suite 930
Washington, DC 20005
Telephone: 202- 296-2622

Dr. Hilary Thesmar, Director of Scientific and Regulatory Affairs
National Turkey Federation
1225 New York Ave. NW, Suite 400
Washington, DC 20005
Telephone: 202- 898-0100

On Friday, February 3, 2012, pages 5480 - 5481, APHIS published in the Federal Register, a 60-day notice seeking public comments on its plans to request a 3-year approval of this collection of information. During that time, APHIS received one comment from a concerned citizen about her perception of the general maltreatment of animals and the general disregard of the environment by USDA-APHIS. It had no relevance to the purpose of the collection.

9. Explain any decision to provide any payment or gift to respondents, other than remuneration 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 the following entities:

1. Mexican government officials estimate that the average hourly wage for foreign government officials, animal health officials, and inspectors to be \$12.39.
2. The estimated hourly wage of full-time salaried veterinarian employed by the region of export is \$21.63. This figure was arrived at by the average of the following contacts: The Canadian Food Inspection Agency (\$50.31); the APHIS contact in the South Africa (\$3.81); and the Mexican government (\$10.78).
3. Industry contacts provided the hourly wage of managers of foreign facilities that process restricted animal materials to be \$53.89.
4. Michigan State University, Iowa State University, and Johns Hopkins University's (which are common importers with APHIS) Web sites indicate the average hourly wage of \$22.75 for officials at museums, educational institutions, or other establishments importing restricted animal byproducts and controlled materials these are not-for-profit importers i.e. researchers.
5. The Department of Labor's (DOL) Web site indicates the average hourly wage of importers to be \$8.68.
6. The Laborsta International Web site indicates the average hourly wage for exporters for agriculture, meat, and foods to be \$10.29.

• 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 annual cost to these respondents to be \$8,822,952.41. APHIS arrived at this figure by multiplying the hours of estimated response time (408,281) by the estimated average hourly wage of the above respondents (\$21.61). The hourly rates for respondents of foreign countries were derived from the following source: Laborsta Internet Web site and consultations with foreign industry contacts. The hourly rates for U.S. respondents were derived from the is the hourly rate derived from the U.S. Department of Labor, Bureau of Labor Statistics May 2011 Report - Occupational Employment and Wages in the United States. See <http://www.bls.gov/news.release/pdf/ocwage.pdf>.

13. Provide estimates of the total annual cost burden to respondents or record keepers 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 \$21,827,880.47 (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 new collection was originally part of the larger collection [0579-0015]. For the purpose of efficiency, the commodities were divided into separate collections. When the milk and eggs were part of the 0015 collection, the different VS staffs thought the burden for this activity was 19,825 hours but now a more accurate count reveals that the burden is in fact 408,230 hours.

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 Form 16-3 is used in 7 collections (0579-0015, 0579-0094, 0579-0145, 0579-0213, 0579-0234, 0579-245, and 0579-0301); 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 Form 16-26 is used in 3 collection (0579-0015, 0579-0367 and this new collection); 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.

APHIS will display the OMB expiration date on VS Form 16-25.

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.