

**SUPPORTING STATEMENT - OMB NO. 0579-NEW
PROHIBITED AND RESTRICTED IMPORTATION OF FRESH (FROZEN OR CHILLED)
PORK OR PORK PRODUCTS, INTO THE UNITED STATES**

July 30, 2012

INTRODUCTION - This was originally part of the larger collection [0579-0015]. For the purpose of efficiency, the commodities were divided into separate collections. This collection contains all forms of burden related to the importation of Fresh (Frozen or Chilled) Pork or Pork Products into the United States. The Animal and Plant Health Inspection Service (APHIS) feels that it can more accurately account for information being collected with this new collection.

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 importation of restricted and controlled animal products into the United States.

- 1) Certification for Importation of Pork or Pork Products of a National Government
- 2) Location and Reason for Breaking Seal, Application of New Seal
- 3) Request for Approval of Defrost Facility
- 4) Termination of Agreement
- 5) Request Hearing for Denial or Approval of Defrost Facility

- 6) Application for Import of Small Amounts of Pork or Pork Product for Analysis, Testing, or Examination (VS 16-3)
- 7) Cooperative Service Agreement (i.e., Trust Fund Agreement)
- 8) Notification of Customs and Border Protection Inspectors (Department of Homeland Security) for pork from specific regions
- 9) Recordkeeping Requirements for Certificates (cured or cooked meat from regions with Foot-and-Mouth Disease (FMD) or rinderpest)

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 importation of restricted and controlled animal products into the United States.

Certification for Importation of Pork or Pork Products of a National Government (Foreign Health Certificate)

Restrictions are in place on the importation of pork and pork products from regions where FMD, African Swine Fever (ASF), Swine Vesicular Disease (SVD), and Classical Swine Fever (CSF) exist. There are also Special Restrictions (SR) in place on specified foreign regions where FMD and/or SVD exist due to land border sharing with disease affected regions, supplementation of their national pork supply by importation of fresh pork from disease affected regions, or trade practices with disease affected regions that are less restrictive than are acceptable to the United States. These products must be accompanied by certification that APHIS regulations concerning the importation of such products have been met. The certification must be issued by a government official of the region of origin. When the pork or pork products arrive in the United States, the certificate must be presented to an authorized inspector. The certificate must physically accompany the shipment. These certifications ensure procedures which mitigate diseases of concern have been performed.

Location and Reason for Breaking Seal, Application of New Seal

If any member of a ship's crew breaks the original seal on the hold, compartment, or container having ruminant or swine meat that has passed through a region where rinderpest or FMD exists, the serial number of the original seal as well as its location and the reason for breaking it must be recorded in the ship's log. The person responsible for recording information in the ship's log must also record the serial numbers of the new seals used to seal the hold, compartment, or container on the export health certificate that accompanies the meat. This information is used to determine when and why an original seal was broken to ensure products eligible for entry at ports within the United States were not exposed to, or commingled with, products not eligible for entry, thus preventing cross contamination of materials which may be affected by FMD/Rinderpest. This information must be readily available to Customs and Border Protection (CBP) Agricultural Inspectors for determination of whether or not the product will be allowed entry.

Request for Approval of Defrost Facility

Cooked meat from regions where rinderpest or FMD exist may be imported into the United States under certain conditions. One of these conditions is that the meat be inspected by a Food Safety and Inspection Service (FSIS) inspector at an FSIS I-House or in a defrost facility approved by FSIS and APHIS, to ensure that the meat has been thoroughly cooked (i.e., Pink Juice Test). Only meat which has been thoroughly cooked is mitigated for diseases of concern (FMD/rinderpest). The Pink Juice Test cannot be performed on frozen products. Operators of defrost facilities must request in writing, and receive APHIS approval, to receive cooked meat from regions where FMD/rinderpest exists. This information is then provided to CBP Agricultural Inspectors who will only allow release of the product to a specified defrost facility. Only facilities which have been shown to maintain sufficient biological controls to prevent the spread of disease if the product fails the Pink Juice Test are approved.

Termination of Agreement

APHIS will withdraw approval of a defrost facility when the facility's operator notifies APHIS, in writing, that the facility is no longer performing defrost services. This information is provided to CBP Agricultural Inspectors to ensure products are no longer released to the previously approved facility.

Request Hearing for Denial or Approval of Defrost Facility

APHIS may deny approval of any defrost facility if it determines that the facility does not meet the conditions for approval. If approval is denied, the operator of the defrost facility will be informed of the reasons for denial and may request, in writing, that he/she be given an opportunity to respond at a hearing with respect to any disputed issues.

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

Laboratories, museums, and States may request to import small amounts of pork or pork products from regions where SVD or CSF is considered to exist, and may, in specific cases, be imported for examination, testing, or analysis if the importer submits a written application to APHIS and receives written approval (VS form 16-6A) from APHIS.

Cooperative Service Agreement (i.e., Trust Fund Agreement)

Before APHIS will approve a processing facility for the export of cooked meat from a region where SVD, CSF, FMD, and/or rinderpest exist, the operator of the facility must allow initial and subsequent periodic site inspections by, and enter into a trust fund agreement with, APHIS. The operator of the processing establishment must deposit with APHIS an amount equal to the approximate cost of one inspection by an APHIS representative, including travel, salary, subsistence, administrative overhead, and other incidental expenses. The account must always contain an amount equal to the cost of one inspection. As funds from the account are obligated, a bill for costs incurred, based on official accounting records, will be issued to restore the deposit to the original level. Required deposits are revised as necessary to allow for inflation or changes in estimated costs. The application is completed by the processing facility. The Cooperative Service Agreement is written and maintained by, and inspections performed by, APHIS VS personnel. These inspections are required to ensure products eligible for export to the United States have not been exposed to or commingled with products ineligible for export to the United States and that time/temperature treatments are adequately applied to mitigate diseases of concern.

Notification of CBP Inspectors (Department of Homeland Security) for pork from specified regions

Various commodities containing pork from specified regions of Mexico affected by CSF are not eligible for importation into the United States but may transit the United States in a sealed, leak-proof container or other means of conveyance under certain conditions. A business bringing such articles through the United States must obtain a United States Veterinary Permit for Importation and Transportation of Controlled Materials and Organisms and Vectors and notify Customs and Border Protection inspectors, in writing, at the U.S. place of arrival prior to such transit. This notification must include the permit number, the time and date of arrival in the United States, the time schedule and route to be followed through the United States, and the serial numbers of the sealed containers. This information is provided to CBP Agricultural Inspectors to allow release of, and track the product, ensuring CSF is not released within the United States. Commodities from other regions are limited to a 72-hour transit limit at the maritime dock or airport terminal of arrival with no overland movement.

Recordkeeping Requirements for Certificates

APHIS regulations restrict the import of cured or cooked meat from regions where FMD, CSF, SVD, or rinderpest exists. Meat processing facilities that process cooked meat for export to the United States must adhere to APHIS provisions to receive APHIS approval. Original certification, including temperature recording charts and graphs, must be kept for all cooked meat by governments of the exporting regions assigned to the meat processing establishment. These certificates must be retained for 2 years and must be presented to personnel when requested during audits. This paperwork provides a means of review for APHIS to determine that processes which mitigate the diseases of concern have been properly performed.

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 following forms of burden are not appropriate for electronic submission:

Certification for Importation of Pork and Pork Products must physically accompany the shipment; therefore, it is not a candidate for electronic submission.

The information in the Location, and Reason for Breaking Seal, Application of Seal is recorded in the log of the ship carrying the product by the person responsible for recording information in the ship's log. The log remains on the ship. The information therefore cannot be submitted electronically.

Request for Approval of Defrost Facility, Termination of Agreement, and/or Request for Hearing generates too few respondents to make electronic accessibility feasible.

Cooperative Service Agreement (Trust fund agreement) requires periodic site inspections and the establishment of a banking account for deposit of funds. These actions are not amenable to

electronic submission. However, funds can be electronically transferred into the bank accounts made available for the reimbursement of site inspections.

Application for Permit to Import or Transport Controlled Material or Organisms or Vectors, VS Form 16-3, can be submitted through USDA's e-Permitting system. It can be found on the Internet at <https://epermits.aphis.usda.gov/epermits>. Other information (i.e.; time and date of arrival in the United States, time schedule and route to be followed through the United States, and serial numbers of the sealed containers) is provided directly to Customs and Border Protection Agricultural Inspectors by the permittee.

Recordkeeping Requirements for Certificates (cooked meat from regions affected with CSF, SVD, FMD, and/or Rinderpest. These records are maintained by, and are the property of, the foreign processing facility. They are made available to APHIS for auditing purposes during annual inspections.

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 the introduction of animal diseases from foreign animal products. Small businesses or other small entities make up approximately 50 percent of respondents.

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 at all, the United States would be at increased risk for the introduction of rinderpest, FMD, ASF, CSF, and/or SVD. This would cause serious economic consequences to U.S. agricultural exports, several U.S. livestock industries, and potentially serious health consequences for U.S. livestock

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:

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On Monday, February 27, 2012, pages 11481 - 11482, 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 Shelf-Stable Food Processors Association (SFPA), which supports the APHIS' efforts to separate commodities from previously approved information collections to more accurately gather information. SFPA encourages the agency to clarify the current process for obtaining an import permit.

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-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 \$12.38
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 (\$3.80); and the Mexican government (\$10.77).
3. Merchant marines provided the hourly wage of a ship's crewmember responsible for recording information in the ship's log to be \$48.51.
4. Industry contacts provided the hourly wage of managers of foreign facilities that process restricted animal materials to be \$53.89.
5. FSIS provided the average hourly wage of operators or owner/operators (of defrost facilities, meat processing establishments, processing establishments that process dry-cured pork products from regions where specific diseases exist, and facilities that slice and package dry-cured pork products) to be \$48.67.
6. 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.
7. The Department of Labor's (DOL) Web site indicates the average hourly wage of importers to be \$8.68.
8. The Laborsta International Web site indicates the average hourly wage for exporters for agriculture, meat, and foods to be \$10.29.
9. The DOL Web site indicates the average hourly wage of individuals transiting various commodities not eligible for importation into the United States to be \$8.69.
10. Industry contacts provided the average hourly wage of persons engaged in the business of handling or disposing of regulated garbage to be \$23.44.

• 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 \$ 113,908.20. APHIS arrived at this figure by multiplying the hours of estimated total burden (4398) by the estimated average hourly wage of the above respondents (\$25.90). 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 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 \$175,672.17. (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 was originally part of the larger collection 0579-0015. For the purpose of efficiency, the commodities were divided into three separate collections. This collection contains all forms of burden related to the importation of Fresh (Frozen or Chilled) Pork or Pork Products. This new collection presents a more accurate account of the information being collected resulting in a program change of 4,378 burden 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.

Form VS 16-3 is used in 8 collections (0579-0015, 0579-0094, 0579-0145, 0579-0213, 0579-0234, 0579-245, 0579-0301 and 0579-XXXX); 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 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.