#### SUPPORTING STATEMENT - OMB NO. 0579-0218 IMPORTATION OF LIVE SWINE PORK AND PORK PRODUCTS, AND SWINE SEMEN FROM THE EUROPEAN UNION

May 11, 2009

#### 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 the health of animals under APHIS' regulatory authority. 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, dated May 13, 2002, and the Farm Security and Rural Investment Act of 2002.

Disease prevention is the most effective method to maintain a healthy animal population and to enhance the nation's ability to globally compete in the trade of animals and animal products. The agency responsible for carrying out this disease prevention mission is the U.S. Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS). APHIS regulates the importation of specified animals and animal products into the United States to guard against the introduction of exotic or other animal diseases regulated by APHIS.

APHIS conducts disease prevention activities in accordance with the regulations in Title 9 of the *Code of Federal Regulations* (CFR), Chapter I, Subchapter D, Parts 91 through 99 that govern the importation of animals, animal products and by-products, and animal germplasm. Part 94.24 defines the specific regions of the European Union (EU) that are considered by APHIS to be eligible to export live swine for reproduction purposes ('breeding swine'), and pork and pork products into the United States. Part 98.38 defines APHIS' import requirements for swine semen.

APHIS has determined that these commodities, imported from specific regions of the EU in accordance with other APHIS import requirements, pose a low risk of introducing classical swine fever (CSF) into the United States. The specific EU regions authorized by APHIS to export breeding swine, swine semen, pork, and pork products are listed in the CFR.

APHIS' regulations for the importation of these items necessitate the use of information collection activities in the form of certificates, import permit application, and customs declarations. These documents provide APHIS with critical information regarding the origin, movement history, and health status of the items destined for importation into the United States.

APHIS is asking the OMB to approve, for an additional 3 years, these information collection activities in connection with its efforts to ensure that live breeding swine, swine semen, pork, and pork products pose a low risk of introducing CSF into the United States.

# 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.

#### **Certificate for Pork and Pork Products**

Pork and pork products from specified regions must be accompanied by a certificate issued by a competent veterinary authority of an APHIS-defined EU CSF-Region Member State with authorization to issue foreign meat inspection certificates. The certificate must verify that the pork or pork products were not commingled with pork or pork products derived from swine within any region at a time when the region was classified as one in which CSF is known to exist, or in a restricted zone of an APHIS-defined EU CSF region established because of the detection of CSF in domestic swine or wild boar. The certificate must attest that pork or pork products did not transit such a region unless moved directly through the region in a sealed means of conveyance, with the seal determined by a competent veterinary authority of the receiving member-State to be intact upon arrival at the point of destination. Additionally, the certificate must verify that no equipment or materials used in transporting swine were previously used for transporting swine that did not meet the requirements of applicable APHIS import regulations, unless the equipment or materials were first cleaned and disinfected.

#### **Certificate for Swine**

Live swine that may be exported into the United States from the specified regions are limited to swine for reproductive purposes ('breeding swine'). These animals must be accompanied by a certificate issued by a competent veterinary authority of the national government of the region of origin. The certificate must verify that the swine are breeding swine, did not derive from a region classified as one in which CSF is known to exist, and did not transit such a region unless moved directly through the region in a sealed means of conveyance, with the seal determined by a competent veterinary authority of the receiving member State to be intact upon arrival at the point of destination. Additionally, the certificate must verify that the breeding swine were not commingled with other swine within any region at a time when the region was classified as one in which CSF is known to exist. The certificate must also attest that no equipment or materials used in transporting breeding swine for export to the United States were previously used for transporting other swine that did not meet the requirements of applicable APHIS regulations, unless the equipment or materials were first cleaned and disinfected.

#### **Certificate for Swine Semen**

Swine semen from specified EU regions must be accompanied by a certificate issued by a competent veterinary authority of the national government of the region of origin.

The certificate must attest that the semen came from a semen collection center approved for export by the veterinary authority of the national government of the country of origin; donor boars did not reside in any region when the region was classified as one which CSF is known to exist, and must not have transited such a region unless moved directly through the region in a sealed means of conveyance with the seal determined to be intact by a competent veterinary authority of the receiving member State upon arrival at the point of destination; donor boars were not commingled with swine that were in a region when the region was classified as one in which CSF is known to exist; donor boars were held in isolation for at least 30 days before entering a semen collection center; donor boars tested negative to a CSF test approved by the World Organization for Animal Health no more than 30 days prior to being held in isolation; no equipment or materials used in transporting donor boars from farms of origin to a semen collection center were used for transporting swine that do not meet the requirements of applicable API-US regulations, unless such equipment or materials were cleaned and disinfected prior to transport; donor boars were observed at the semen collection center by the center's veterinarian and exhibited no clinical signs of CSF; and donor boars were held at a semen collection center for at least 40 days following the collection of semen, and prior to exportation of the semen to the United States, and all other swine at the semen collection center exhibited no clinical signs of CSF.

#### Application for Import or In Transit Permit (VS Form 17-129)

VS Form 17-129, Application for Import or In Transit Permit, must be completed by the importer for swine or swine semen intended for entry into the United States. This form provides essential information regarding the type of import, the port of entry into the United States, the date of entry, and the final destination of the commodity. The information on VS Form 17-129 is used by APHIS' National Center for Import and Export (NCIE) to issue an import permit to the importer.

#### **Declaration of Importation (VS Form 17-29)**

The importer must complete and present two copies of VS Form 17-29, Declaration of Importation, to the U.S. Collector of Customs for use by the veterinary inspector. The declaration lists the port of entry, the name and address of the importer, the name and address of the broker, the origin of the swine, the number, breed, species, and purpose of the importation, the name of the person to whom the swine will be delivered, and the location of the place to which such delivery will be made. The information requested on this form facilitates the oversight necessary to ensure that all APHIS import requirements are met to mitigate the introduction of foreign and other animal diseases regulated by APHIS.

# 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 import certificates required by APHIS for these commodities are not VS forms, but are specific EU Member State documents that are completed and signed by veterinary authorities in the exporting countries. The certificates must physically accompany shipments to the United States and must include an original signature from the authorizing veterinarian for validation. Therefore, automation of these forms is not an option.

Much work has been done by VS and the private sector to develop electronic forms and certificates. These efforts have been further driven by the need for traceability in the areas of animal health and trade (e.g., National Animal Identification System and Automated Commercial Environment/International Trade Data System). Further, there is a current USDA-wide plan to implement electronic signatures on electronic certificates or forms and VS continues to investigate ways to address this issue.

Importers must submit VS Form 17-129 to APHIS to obtain an import permit for live swine and swine semen entering or transiting the United States. The importer may request the form in writing to the National Center for Transport/Export (NCIE) or download VS Form 17-129 and instructions for completing the form from the APHIS Web site at

<u>http://www.aphis.usda.gov/import\_export/forms.shtml</u>. If an import permit is granted after review of the application, an electronically-generated original copy of the import permit will be issued to the importer *via* the VS ePermit system. The original import permit must accompany the shipment intended for import into the United States; therefore, this is not a candidate for electronic submission.

The Declaration of Importation (VS Form 17-29) is completed by the importer and submitted with the imported shipment to the Collector of Customs at the port of arrival. The importer may request the form in writing to NCIE or download VS Form 17-29 and instructions for completing the form from the APHIS Web site at <a href="http://www.aphis.usda.gov/import\_export/forms.shtml">http://www.aphis.usda.gov/import\_export/forms.shtml</a>. If an import permit is granted after review of the application, an electronically-generated original copy of the import permit will be issued to the importer *via* the VS ePermit system. The original import permit must accompany the shipment intended for import into the United States; therefore, this 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 APHIS collects in connection with this program is not available from any other source. APHIS is the only 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.

Fifty percent of the respondents are importers that are considered small businesses who are required to complete the requested information on VS Form 17-29 and VS Form 17-129. The remaining 50 percent are foreign Federal government authorities that are required to provide health certificates to the importers.

The information required by APHIIS on VS Form 17-129 and VS Form 17-29 is the minimum amount of data needed to ensure the mitigation of disease. The burden on the importer has been reduced by providing electronic access to the permit application via the ePermit system. Importers can print and submit the permit application to APHIS by fax.

Additionally, the ePermit system provides APHIS the capability to e-mail authorized copies of import permits to importers and designated ports of entry.

# 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 the information was collected less frequently or not collected at all, it would significantly impact APH1S' ability to ensure that breeding swine, swine semen, pork, and pork products pose a minimal risk of introducing CSF and other exotic animal diseases into the United States. Introduction of a foreign animal disease would be more likely to occur with potentially devastating effects on the U.S. swine 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.

In 2009, APHIS engaged in productive consultations with the following individuals concerning the information collection activities associated with this program:

Scott Dotson Traffic Administrator The Semex Alliance 130 Stone Road West Guelph, Ontario NIG 3Z2 Canada (519) 821-5060

David Preisler Minnesota Pork Producers Association 151 Saint Andrews Court, Suite 810 Mankato, MN 5600 1 (507) 345-8814 Jeff Schnell Iowa Pork Producers Association 1636 NW 114 Street Clive, IA 50325 (515) 225-7675

On Tuesday, August 11, 2009, pages 40158-40159, 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. During that time, APHIS received three comments from interested members of the public. None of these comments dealt with information collection issues.

Two comments were received from the same concerned citizen in NJ about her perception of the general maltreatment of animals and how the US should grow and raise its own food. It had no relevance to the purpose of the collection.

The other comment was from a person stating that Cavalier Industries in Stamford, CT do not do drug tests. 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. 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 discussions with foreign animal health authorities in the EU and importers of pork and pork products, live swine, and swine semen to the United States.

## •Provide estimates of annualized cost to respondents for the hour burdens for collections of information, identifying and using appropriate wage rate categories.

Respondents are full-time salaried veterinarians employed by the governments of the regions from which pork and pork products, live swine, and swine semen originate and U.S. importers of these products and animals. APHIS estimates the total annualized cost to be \$281,876.40. APHIS arrived at this figure by multiplying the total burden hours (8242 hours) by the estimated average hourly wage of the above respondents (\$34.20). The average hourly wage is based on conversations with foreign national government authorities, APHIS International Services, and a review of Table 1, National Employment and Wage Data from the Occupational Employment Statistics Survey by Occupation. May 2007.

# 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.

There is zero annual cost burden associated with capital and start-up 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 \$430,129.00 (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-I.

There is an adjustment of +7,939 hours as a result of an increase in the number of pork and pork products imported from the EU. There is a program change of +3 hours with the addition of VS Forms 17-29 and 17-129 to the collection. These required forms were added to this collection to act as an anti-smuggling measure and to simply declare what is being imported into the United States. VS Form 17-29 is submitted by the United States Customs Service and VS Form 17-129 is submitted to USDA-APHIS. These forms should have been included in the last submission but were inadvertently omitted.

## 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.

The VS Forms 17-129 and 17-29 are listed in multiple OMB-approved collections; therefore, APHIS is seeking approval to not display the OMB expiration date on these forms.

## **18.** Explain each exception to the certification statement identified in "Certification for Paperwork Reduction Act."

APHIS can certify compliance with all provisions of the Act.

#### **B.** Collections of Information Employing Statistical Methods

Statistical methods are not employed in this information collection activity.