SUPPORTING STATEMENT - OMB NO. 0579-0265
IMPORTATION OF SWINE AND SWINE PRODUCTS FROM THE EUROPEAN UNION

March 3, 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 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 the United States' ability to compete in the world market of animal and animal product trade.

In connection with this disease prevention mission, the Animal & Plant Health Inspection Service (APHIS) regulates the importation of animals and animal products into the United States to guard against the introduction of animal diseases not currently present or prevalent in this country. The regulations in title 9 of the *Code of Federal* Regulations (CFR) part 94 prohibits or restricts the importation of specified animals and animal products to prevent the introduction into the United States of various animal diseases, including classical swine fever (CSF), rinderpest, foot-and-mouth disease, bovine spongiform encephalopathy, swine vesicular disease, and African swine fever. Section 94.24 deals specifically with the importation of pork and pork products from regions where CSF exists.

To help ensure that CSF is not introduced into the United States, the regulations allow, under specified conditions, the importation of pork, pork products, and swine from the APHIS-defined European Union (EU) CSF region. These requirements necessitate the use of several information collection activities, including certification statements for the importation of pork, pork products, and swine.

APHIS is asking the Office of Management and Budget (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.

Certificate for Pork and Pork Products

In addition to meeting all other applicable APHIS provisions, fresh pork and pork products imported from the APHIS-defined EU CSF region must be accompanied by a certificate issued by an official of the competent veterinary authority of the APHIS-defined EU CSF region Member State who is authorized to issue the foreign meat inspection certificate stating that the applicable provisions have been met.

Certificate for Live Swine

In addition to meeting all other applicable APHIS provisions, live swine imported from regions listed as low-risk regions for CSF must be accompanied by a certificate-issued by an official of the national government of the region of origin--stating, among other things, that the swine are breeding swine, that they have not lived in any CSF-affected region or zone or transited a CSF-affected region or zone, that they have not been vaccinated for CSF, that they are not the progeny of swine that were vaccinated for CSF, and that the equipment or materials used in transporting the swine, if previously used for transporting swine, have been cleaned and disinfected.

Certificate for Swine Semen

In addition to meeting all other applicable APHIS provisions, swine semen imported from regions listed as low-risk regions for CSF must be accompanied by a certificate – issued by an official of the national government of the region of origin—stating, among other things, that the semen originated from a semen collection center approved for export by the veterinary services of the national government of the country of origin, that the donor boar did not live in any CSF-affected zone or region, was not vaccinated for CSF, was held in isolation for 30 days prior to entering the semen collection center, and tested negative for CSF using a test approved by the World Organization for Animal Health; that equipment or materials used in transporting the donor boar from the farm or origin to the semen collection center was cleaned and disinfected, and that the donor boar was held at the semen collection center and closely observed, for any signs of disease, for 40 days following the collection of semen.

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 certification statements employed in this program are not VS forms, but are documents manufactured, completed, and signed by veterinary authorities in the exporting country. These certifications must physically accompany the shipment to the United States, and must contain an original signature from the authorizing veterinarian to be valid; therefore, electronic submission is not an available option.

APHIS and the private sector are working to develop electronic forms and certificates. These efforts have been further driven by the need for traceability, both in the animal health and trade arenas. There is not a current USDA-wide plan or solution for including e-signatures or e-certificates or forms. Furthermore, VS regulations that govern international trade currently require "original certificates," which implies an original signature from the issuing official and must physically accompany the shipment to the United States. APHIS is currently working to develop and pilot a method to begin using e-certificates/forms and e-signatures and to identify a program area which could provide a simple model for testing the implementation of e-certificates/forms and e-signatures.

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 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.

Respondents are foreign Federal government officials and therefore are not considered small businesses or small entities. The information APHIS is collecting in connection with this program is the minimum needed to ensure that CSF is not introduced into the United States via the importation of certain pork and pork products.

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 increase the chances of CSF being introduced into the United States. Even if the incursion is detected relatively early, an enormous amount of money and human resources would be needed to contain the outbreak and prevent the disease from successfully establishing itself in the United States. Such an effort would divert money and other

resources from other vital disease prevention activities for which the Agency is responsible.

If the incursion is not detected soon enough, the disease would have an opportunity to establish itself with the swine population of the United States. An adverse event of this magnitude would require millions of dollars and years of effort to resolve.

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 2008, APHIS engaged in productive consultations with the following individuals concerning the information collection activities associated with this program:

Kim Holzner
JBS Swift and Co.
1770 Promontory Circle
Greeley, Colorado 80634
(970) 506-7791

Sebastiano Brancoli
Consultants International Group
1616 H Street, NW
Suite 400
Washington, DC 20006
sbrancoli@cig-dc.com
t. (202) 783-7000
f. (202) 393-4655

Jeff Schnell
Iowa Pork Producers Association
1636 NW 114 Street
Clive, IA 50325
jschnell@iowapork.org
(515) 225-7675

On Monday, November 24, 2008, pages 70954-70955, 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 remuneration of contractors or grantees.

This information collection activity involves no payments or gifts to respondents.

10. Describeanyassuranceofconfidentialityprovidedtorespondentsandthebasis 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 5U.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 he 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 83-1.**

See APHIS Form 71. Burden estimates were developed from discussions with Foreign Federal animal health authorities in the EU who will be completing the certificates necessary to export swine, pork and pork products, 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.**

APHIS estimates the total annualized cost to these respondents to be $34,680. APHIS arrived at this figure by multiplying the hours of estimated response time (816 hours) by the estimated average hourly wage of the respondents ($42.50). APHIS determined the estimated hourly wage of respondents through discussions with its International contacts.

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 items12 and14). 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 $37,428. (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.

There is an adjusted decrease of -184 hours for the renewal of this previously approved information collection. Previously, the burden hours were 1000. The decrease is the result of a decreased number of respondents.

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 01\18 approval of the information collection, explain the reasons that display would be inappropriate.

There are no forms associated with this information collection.

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.