SUPPORTING STATEMENT - OMB NO. 0579-0218
RECOGNITION OF ANIMAL DISEASE STATUS OF REGIONS IN THE EUROPEAN UNION

June 13, 2006

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.

Title 21, U.S.C. authorizes sections 111, 114, 114a, 114-1, 115, 120, 121, 125, 126, 134a, 134c, 134f, and 134g of 21 U.S.C. These authorities permit the Secretary of the United States Department of Agriculture (USDA) to prevent, control and eliminate domestic diseases such as brucellosis as well as to take actions to prevent and to manage exotic diseases such as classical swine fever (CSF) and other foreign diseases.

More specifically, 21 U.S.C. 111, 151-158 authorizes the Secretary of Agriculture to take such measures as he/she may deem proper to prevent the introduction or dissemination of contagious or communicable diseases of animals or live poultry from a foreign country into the United States or from one State to another. Disease prevention is the most effective method for maintaining a healthy animal population and for enhancing the ability of the United States to compete in the world market of animals and animal product trade.

Disease prevention is the most effective method for maintaining a healthy animal population and enhancing APHIS' ability to compete in exporting animals and animal products. The agency charged with carrying out this disease prevention mission is the Animal and Plant Health Inspection Service (APHIS) of the USDA. The agency regulates the importation of animals and animal products into the United States to guard against the introduction of exotic animal diseases.

The regulation under which APHIS conducts these disease prevention activities are contained in Title 9, Chapter 1, Subchapter D, Parts 91 through 99, of the Code of Federal Regulations. These regulations govern the importation of animals, birds and poultry products, and animal germplasm. Under these regulations, certain regions of the European Union are allowed to import into the United States live breeding swine and pork and pork products as specified in section 94.24 and swine semen as specified in section 98.38. the specific regions are Greece, Austria, Belgium, France, Netherlands, Portugal, and Spain and designated sub-regions in Germany and Italy. APHIS has determined that these items, imported from these specific regions in accordance with its other import requirements, will pose a low risk of introducing CSF into the United States.

Allowing the importation of these items necessitates the use of an information collection activity in the form of a certificate. This document is designed to provide APHIS with

critical information concerning the origin and history of the items destined for importation into the United States.

APHIS is asking OMB to approve, for an additional 3 years, this information collection activity in connection with its efforts to ensure that swine, pork and pork products, and swine semen pose a low risk of introducing exotic swine diseases 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 an official of the national government of the region from which the pork and pork products originate. The certificate must state that the pork or pork products were not commingled with pork or pork products derived from swine that were in any region when the region was classified in 94.10(a) 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 to be intact upon arrival at the point of destination.

Certificate for Swine

Swine from specified regions must be breeding swine and accompanied by a certificate issued by a salaried veterinary officer of the national government of the region of origin. The certificate must state that the swine are breeding swine and did not live in a region was classified in 94.10(a) 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 to be intact upon arrival at the point of destination; the swine were never commingled with swine that were in a region at a time when the region was classified in 94.10(a) as one in which CSF is known to exist; and that no equipment or materials used in transporting the swine were previously used for transporting swine that did not meet the requirements of applicable regulations, unless the equipment or materials were first cleaned and disinfected.

Certificate for Swine Semen

Swine semen from specified regions must be accompanied by a certificate issued by a salaried veterinary officer of the government of the region of origin. The certificate must state that;

- The semen came from a semen collection center approved for export by the veterinary services of the national government of the country of origin.
- The donor boar had not lived in a region when the region was classified in 94.10(a) 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 upon arrival at the point of destination.

- The donor boar was never commingled with swine that were in a region when the region was classified in 94.10(a) as one in which CSF is known to exist.
- The donor boar was held in isolation for at least 30 days before entering the semen collection center.
- No more than 30 days prior to being held in isolation, the donor boar was tested with negative results with a CSF test approved by the World Organization for Anima Health.
- No equipment or materials used in transporting the donor boar from the farm of origin to the semen collection center has been used previously for transporting swine that do not meet the requirements of the applicable regulations, unless such equipment or materials has first been cleaned and disinfected.
- The donor boar was observed at the semen collection center by the center veterinarian, and exhibited no clinical signs of CSF.
- Before the semen was exported to the United States, the donor boar was held at the semen collection center for at least 40 days following collection of the semen, and along with all other swine at the semen collection center, exhibited no clinical signs of CSF.

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, automation of these forms is not an option.

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.

The information that APHIS is requiring on the certificates must be recorded and certified by Federal animal health authorities in Greece, Italy, Germany, and other countries affected by its rulemaking, not by individual exporters, shippers, or other entities involved with the exportation of swine, pork and pork products, and swine semen to the United States.

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 cripple APHIS' ability to ensure that swine, pork and pork products, and swine semen pose a minimal risk of introducing CSF and other exotic animal diseases into the United States. This would make a disease incursion event much more likely, with potentially devastating affects on the US 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.

APHIS engaged in productive consultations during 2006 with the following individuals concerning the information collection activities associated with this program:

Dr. Lorenzo Terzi
European Commission
Health and Consumer Protection Directorate-General
Rue Froissart/Froissartstraat 101
B-1040 Brussels
Belgium
32-2-296-8555

Dr. Carol Buy
Deputy Counselor for Agriculture
Embassy of France
4101 Reservoir Road, NW
Washington, DC 20007
(202) 944-6358

Dr. Harry Snelson
National Pork Producers Council
122 C Street NW, Suite 875
Washington, DC 20001
(202) 347-3600

On Friday, May 26, 2006, 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. A copy of the Federal Register notice is attached.

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 discussions with Federal animal health authorities in the European Union 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.

Respondents are full-time salaried veterinarians employed by the governments of the regions from which the swine, port and pork products, and swine semen originate.

APHIS estimates the total annualized cost to these respondents to be $9,000. APHIS arrived at this figure by multiplying the hours of estimated response time (300 hours) by the estimated average hourly wage of the above respondents ($30.00).

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 $13,931.11. (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 no change in burden for this information collection.

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.

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.