December 2020

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

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, dated May 13, 2002, the Farm Security and Rural Investment Act of 2002. Disease prevention is the most effective method to maintain 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 its disease prevention mission, the Animal and 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 present or prevalent here. The regulations in Title 9 of the *Code of Federal Regulations* (9 CFR), Part 94, prohibit or restrict the importation of specified animals and animal products to prevent the introduction of diseases such as classical swine fever (CSF), rinderpest, foot-and-mouth disease (FMD), swine vesicular disease (SVD), and African swine fever (ASF). Sections 94.2, 94.4, 94.8, 94.9, 94.10, and 94.12 through 94.14 deal with the importation of pork and pork products from regions where these diseases exist. In particular, Section 94.13 concerns restrictions on importation of pork or pork products from specified regions. Section 98.38 defines APHIS' import requirements for swine semen.

APHIS has determined these commodities, imported from specific regions of the European Union (EU), in accordance with other APHIS import requirements, pose a low risk of introducing CSF into the United States. The specific EU regions authorized by APHIS to export breeding swine, swine semen, pork, and pork products are listed on the APHIS website at https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/animal-and-animal-product-import-information/animal-health-status-of-regions.

To further 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 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 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 regulate the importation of live swine, pork and pork products, and swine semen into the United States to guard against the introduction of animal diseases not currently present or prevalent in this country.

Certificate for Pork and Pork Products (9 CFR 94.31(a)); (Foreign Government)
Fresh pork and pork products imported from the APHIS-defined EU CSF region must be accompanied by a certificate stating that all applicable regulatory provisions have been met. This certificate must be issued by an official of the competent veterinary authority of the APHIS-defined EU CSF region Member State authorized to issue the foreign meat inspection certificate.

VS 17-129, Application for Import or In Transit Permit (Certificate for Live Swine) (9 CFR 94.31, 9 CFR 93.504, and 9 CFR 93.505); (Foreign Government, Business)
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. This certificate must state, among other things, that:

- The swine are breeding swine.
- They have not lived in any CSF-affected region or zone or transited a CSF-affected region or zone.
- They have been inspected and found free of clinical evidence of contagious or communicable disease.
- They have not been exposed to contagious or communicable disease during the preceding 60 days they spent in isolation.
- They originate in an EU Member State recognized as low risk for CSF and free of FMD, ASF, and SVD.
- All hay, straw, forage, feed, and bedding aboard the transporting aircraft or vessel originated in an EU Member State designated as free of FMD, ASF, and SVD.
- The equipment or materials used in transporting the swine, if previously used for transporting swine, have been cleaned and disinfected.

In addition to meeting all other applicable APHIS provisions, swine and swine semen imported from regions listed as low risk for CSF must be accompanied by an APHIS-issued U.S. Permit to Import. Anyone APHIS requires to have an import or in-transit permit must submit a VS 17-129 to APHIS. The applicant must describe the type, number, and identification of the animals to be

exported. The applicant must also list the origin, intended date and location of arrival, routes of travel, and destination of the animals. APHIS will use the permit applications to carefully evaluate each import request.

Application for Import or Transit Permit (Certificate for Swine Semen); (9 CFR 98.34, 9 CFR 98.35, and 9 CFR 98.38); (Foreign Government, Business)

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. This certificate must state, among other things, that:

- The semen originated from a semen collection center approved for export by the veterinary service of the national government of the country of origin.
- The donor boar:
  - Originated in an EU Member State recognized as low risk for CSF and free of FMD, ASF, and SVD.
  - Did not live in any CSF-affected region or zone or transit a CSF-affected region or zone.
  - Was inspected and found free of clinical evidence of contagious or communicable disease prior to collection of semen.
  - Was not exposed to contagious or communicable disease during the preceding 60 days spent in isolation.
  - Was held in isolation for 30 days prior to entering the semen collection center.
- Equipment or transports used to move the donor boar from the farm of origin to the semen collection center were cleaned and disinfected.

In addition to meeting all other applicable APHIS provisions, swine and swine semen imported from regions listed as low risk for CSF must be accompanied by an APHIS-issued U.S. Permit to Import. Anyone APHIS requires to have an import or in-transit permit must submit a VS 17-129 to APHIS. The applicant must describe the type, number, and identification of the animals to be exported. The applicant must also list the origin, intended date and location of arrival, routes of travel, and destination of the animals or germplasm. APHIS will use the permit applications to carefully evaluate each import request.

VS-17-29, Declaration of Importation; (9 CFR 93.506); (Business)

This form is completed by businesses and presented to officers of the U.S. Customs and Border Protection. 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 where 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 certification statements employed in this program for pork and pork products are not APHIS Veterinary Services forms, but are documents manufactured, completed, and signed by veterinary authorities in the exporting country. The certification statements employed in this program for live swine and swine semen are also not APHIS Veterinary Services forms, but are documents manufactured, completed, and signed by veterinary authorities in the exporting country.

All shipments of live swine and swine semen in this program require an APHIS Import Permit. Permit applicants must complete the VS 17-129 form and submit it to APHIS. The VS 17-129 can be completed online through the ePermits system at https://epermits.aphis.usda.gov/ePermits. However, the resultant permit, if issued, must physically accompany the shipment to the United States. Therefore, electronic submission of the Import Permit is not an available option.

The VS 17-29 form is currently collected as a paper document and requires an importer's signature. As a part of Customs and Border Protection's International Trade Data System/Automated Commercial Environment, this form can be submitted as a scanned electronic copy for commercial shipments.

APHIS and the private sector continue 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. USDA has been implementing e-signatures and continues to work on e-certificates and forms. However, VS regulations that govern international trade currently require "original certificates," which implies an original signature from the issuing official and that the certificate must physically accompany the shipment to the United States.

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 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 in connection with this program is the minimum needed to ensure that CSF and other swine diseases are not introduced into the United States via the

importation of certain pork and pork products. APHIS has determined that 50 percent of the business respondents are small entities.

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 and other swine diseases being introduced into the United States. Even if the incursion was 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 APHIS is responsible.

If the incursion was not detected soon enough, the disease would have an opportunity to establish itself in 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.

- **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 3 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.**

No special circumstances exist that would require this collection to be conducted in a manner inconsistent with the general information collection guidelines 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 contacted these respondents by email and phone to discuss the information APHIS collects to administer its animal product, live animal, and germplasm import regulations. We discussed with them how we and they obtain the necessary data and how frequently; how much data is available; the convenience and clarity of reporting formats and other collection instruments; and the clarity of, and necessity for, any recordkeeping requirements. The respondents stated via email or phone that they had no concerns with any of these items and had no further recommendations.

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On Thursday, October 1, 2020, APHIS published in the Federal Register (Vol 85 No 191 PG 61920), a 60-day notice seeking public comments on its plans to request a 3-year approval of this collection of information. APHIS received no comments from the public.

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 asks 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 for hour burden estimates. 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 respondents for this collection to be $ 54,805.01. This was computed by multiplying the hours of estimated response time (1,600 hours) by the estimated average hourly wage of the above respondents ($23.97) and then multiplying the result ($38,352.00) by 1.429 to capture benefit costs.

According to DOL BLS news release USDL-20-0451 released March 19, 2020, employee benefits account for 30 percent of employee costs, and wages account for the remaining 70 percent. Mathematically, total costs can be calculated as a function of wages using a multiplier of 1.429.

APHIS determined the estimated hourly wage of respondents through discussions with its international contacts, and by averaging the known salary of both junior and senior Government officials.

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.

There is zero annual cost burden 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 $135,592. (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.

	Requested	Program Change Due to New Statute	Program Change Due to Agency Discretion	Change Due to Adjustment in Agency Estimate	Change Due to Potential Violation of the PRA	Previously Approved
Annual Number of Responses	1,611	0		-7,221	0	8,832
Annual Time Burden (Hours)	1,600	0		-7,185	0	8,785

In this renewal, there is an adjustment increase of + 173 respondents; however, there is a decrease of – 7,221 responses, resulting in a decrease of – 7,185 total burden hours. The

respondent adjustment occurred since the last submission to accurately account the number of respondents; however, the decrease in responses in burden hours stems from the decline in live swine, semen, and pork and pork product imports from EU countries owing to the widespread African swine fever outbreak in Europe, Asia, and Africa.

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.

VS 17-129 and the VS 17-29 are both used in multiple collections; 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 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

There are no statistical methods associated with the information collection activities used in this program.