**July 2023**

# **SUPPORTING STATEMENT**

**Importation of Live Swine (From Certain Regions), Pork and Pork Products**

**OMB Control No. 0579-0230**

**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 [7 U.S.C. 8301 et. seq.]

Disease prevention, regulated animal movement and livestock tracing are the most effective methods for maintaining a healthy animal population and for enhancing the Animal and Plant Health Inspection Service’s (APHIS’) ability to help the United States compete globally in animal and animal product trade.

As part of this mission, APHIS Veterinary Services (VS) regulates the importation of animals and animal products to prevent the introduction of animal diseases such as classical swine fever (CSF). To that end, APHIS’ animal import regulations in Title 9, *Code of Federal Regulations* (9 CFR), chapter 1, subchapter D, parts 93 and 94, place certain restrictions on the importation of swine, pork, and pork products into the United States. Regulations regarding other animal products and byproducts can be found at parts 95 and 112.

APHIS engages in several 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. Application of Seal

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 Form 16-3)

7) Cooperative Service Agreement (pork and pork products and ham-specific) (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)

10) Certificates for Meat Processed in Tubes

11) Certification for Importation of Hams

12) Agreement for Processing Procedures

13) Identification Procedures (Hot Brand or Ink Seal)

14) Recordkeeping for Processing Origin of Hams

15) Program Statement

Imports are particularly restricted from three regions, however:

* **Chile:** Importing pork and pork products from Chile continues to pose an undue risk of introducing CSF into the United States, for several reasons. First, Chile supplements its pork supplies by importing fresh (chilled or frozen) pork from CSF-affected regions. Second, Chile shares a common land border with CSF-affected regions. Third, Chile imports swine from CSF-affected regions under less restrictive conditions than the United States considers acceptable for importation.
* **Mexico:** While Mexico (like Chile) is on the list of regions in 9 CFR 94.9 (a)(1) and 9 CFR 94.10 (a)(1), considered free of CSF and allowed to export live swine, pork, and pork products into the United States, importation of these commodities from Mexico continues to pose the same risk of disease introduction as importation from Chile.
* **Brazil:** The Brazilian State of Santa Catarina is also on the list of regions in 9 CFR 94.9(a)(1) and 9 CFR 94.10(a)(1) considered free of CSF and allowed to export live swine, pork, and pork products into the United States, but shares the same issues as Chile and Mexico.

APHIS is asking OMB to approve, for an additional 3 years, its use of these information collection activities to ensure swine, pork, and pork products, in particular those from Chile, the Brazilian State of Santa Catarina, and Mexico, can be safely imported 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.**

APHIS uses the following information collection activities to ensure imported swine, pork, and pork products pose a negligible risk of introducing diseases of livestock and native wildlife into the United States.

**Certification for Importation of Pork or Pork Products of a National Government; (9 CFR 94.9, 9 CFR 94.10, 9 CFR 94.11(c), 9 CFR 94.13(b)); (Foreign Government)**

Restrictions are in place on the importation of pork and pork products from regions where foot-and-mouth disease (FMD), African swine fever (ASF), swine vesicular disease (SVD), and CSF exist. There are also special restrictions 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.

**Application of Seal; (9 CFR 94.1(d)(2)); (Foreign Government)**

The respondent type is being corrected in this renewal.

Fresh (chilled or frozen) pork raised and slaughtered in a region free of FMD and rinderpest which during shipment to the United States enters a port or otherwise transits a region where rinderpest or FMD exists, may be imported if placed in the transporting carrier in a hold, compartment, or, if the meat is containerized, in a container sealed in the region of origin by an official of the region with serially numbered APHIS-approved seals. Application of the seal prevents the meat from contact with any other cargo or handling after the hold, compartment, or container is sealed.

**Location and Reason for Breaking Seal, Application of New Seal; (9 CFR 94.1(d)(3)); Business)**

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 or rinderpest. This information must be readily available to Customs and Border Protection (CBP) Agricultural Inspectors for determining whether the product will be allowed entry.

**Request for Approval of Defrost Facility; (9 CFR 94.4(b)(10)(i)); (Business)**

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 U.S. Department of Agriculture 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 (i.e., FMD or 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 or 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; (9 CFR 94.4(b)(10)(iii)); (Business)**

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 of Approval of Defrost Facility; (9 CFR 94.4(b)(10)(ii) and (iii)); (Business)**

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 or 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 Form 16-3); (9 CFR 94.9(c), 9 CFR 94.12(b)(4)); (Business)**

Laboratories, museums, and States may, in specific cases, request to import small amounts of pork or pork products from regions where SVD or CSF is considered to exist for examination, testing, or analysis if the importer submits a written application to APHIS and receives written approval from APHIS. This permit application contains the importer’s name, address, telephone number, fax number, and email address; the name and address of the exporter of the material or product; a description of the products to be imported; the quantity and frequency of importation; the mode of transportation; the proposed use of the material; a description of the applicant’s facilities for handling the material; the qualifications of the technical personnel who will be working with the materials; and a description of any processing the material may have undergone before importation into the United States.

This information enables APHIS to scrutinize the products and determine what, if any, disease threat they may pose to the U.S. swine population. If APHIS decides to issue an import permit, information on the VS Form 16-3 also enables APHIS to determine what safeguards are appropriate for the importation. APHIS can then provide port and border personnel with appropriate clearance instructions for the impending shipment.

**Pork and Pork Products (Other than Ham) Cooperative Service Agreement and Trust Fund Account; (9 CFR 94.4(c)(1)(iii) and (iv), 9 CFR 94.9(e)(4))); (Business)**

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, 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.

**Ham-Specific Cooperative Service Agreement and Trust Fund Account; (9 CFR 94.17(n)); (Business)**

Processing establishments handling hams in accordance with 9 CFR 94.17 must enter into a cooperative service agreement executed by the operator of the establishment or a representative of the establishment and APHIS. Under the cooperative service agreement, the establishment must be current in paying all costs for an APHIS veterinarian to inspect the establishment up to four times per year, including travel, salary, subsistence, administrative overhead, and other incidental expenses (including an excess baggage provision up to 150 pounds). The establishment operator must deposit with APHIS an amount equal to the approximate costs for a veterinarian to inspect the establishment one time, including travel, salary, subsistence, administrative overhead, and other incidental expenses. As funds from that amount are obligated, bills for costs incurred based on official accounting records will be issued to restore the deposit to its original level. Amounts to restore the deposit to its original level are to be paid within 14 days of receipt of such bills.

**Notification of CBP Inspectors (Department of Homeland Security) for Pork from Specified Regions; (VS Form 16-3; VS Form 16-6A); (9 CFR 94.15)); (Business)**

Various commodities containing Mexican pork are not eligible for importation into the United States but may transit the United States in a sealed, leakproof container or other means of conveyance under certain conditions. A business bringing such articles through the United States must obtain a U.S. Veterinary Permit for Importation and Transportation of Controlled Materials and Organisms and Vectors and notify CBP 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 and tracking of 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 (Cooked Meat from Regions with CSF, SVD, FMD, and Rinderpest); (9 CFR 94.4.(c) (2)(iv), 9 CFR 94.9(e)(2)(iii)); (Business; Foreign Government)**

APHIS regulations restrict the import of cured or cooked meat from regions where FMD, CSF, SVD, or rinderpest exist. 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.

**Certificates for Meat Processed in Tubes; (9 CFR 94.4(b)(6)(i)); (Business)**

Cubes of meat, slices of meat, or anatomical cuts of meat (cuts taken from the skeletal muscle tissue) cooked in tubes in accordance with 9 CFR 94.4(b)(5), if intended for further processing, must be accompanied by a certificate issued by the official who selected the tube for testing and processing. The certificate must provide the date the tube was cooked and the cooker and batch number, and the date the tube was selected for sampling.

**Certification for Importation of Hams; (9 CFR 94.17(d),(o)); (Business (New); Foreign Government)**

FSIS requires certain public health certification statements to accompany imported hams. When hams are imported into the United States from regions where swine diseases of concern exist, APHIS also requires certain disease risk mitigations. These disease risk mitigations are usually written on the back of the FSIS certificate and contain language regarding disease mitigation treatments such as curing and/or cooking. APHIS accounts for this portion of the burden. Foreign governments are required to certify to these mitigation treatments on the back of the FSIS certificate or on a document supplied by the foreign national government as an additional form. The certificate must physically accompany the shipment.

**Agreement for Processing Procedures; (9 CFR 94.17(g)); (Business)**

Before receiving products for processing, such as dry-cured pork products (specifically ham, pork shoulder, or pork loin) from regions where FMD, rinderpest, ASF, CSF, and SVD exist, processing establishments wishing to export those products to the United States must provide APHIS with a written agreement in the form of a letter stating that the products have been processed whole and in accordance with APHIS regulations.

**Identification Procedures (Hot Brand or Ink Seal); (9 CFR 94.17(j)); (Business)**

Dry-cured pork products, specifically Italian-type whole hams, from regions where FMD, rinderpest, ASF, CSF, or SVD exist must bear a hot iron brand or ink seal, placed on the ham before salting, with the identifying number of the slaughtering establishment and the date salting began. The brand or ink seal must be placed on the ham at the slaughtering establishment. Slaughter facilities must also ensure the ham bears on the hock a tamper-proof button seal approved by APHIS that states the month and year the ham entered the processing establishment. Dry-cured pork loins must bear a tamper-proof plastic tag, securely attached to the pork loin, with the identifying number of the slaughtering establishment and the date the pork loin was placed in a pickle preparation under the supervision of personnel from the foreign government of the region of origin.

**Collection of Information and Recordkeeping for Processing Origin of Ham (Maintaining Records); (9 CFR 94.17(k)); (Business)**

Whole dry-cured ham, pork shoulder, or pork loin imported into the United States from regions where FMD, rinderpest, ASF, CSF, or SVD exist must come from an establishment where personnel from the foreign government of the region of origin maintain original records. These records must be kept for a minimum of 2 years. The records must identify the dry-cured ham, pork shoulder, or pork loin by the date it entered the processing establishment, by the slaughtering facility it came from, and by the number of the certificate that accompanied the dry-cured ham, pork shoulder, or pork loin from the slaughtering facility to the processing establishment.

**Program Statement; (9 CFR 94.17(m)(1)); (Foreign Government)**

Regions determined to be free of rinderpest and that process hams in accordance with 9 CFR 94.17(i)(1) must submit a statement to the APHIS Administrator that they conduct a program authorizing personnel to supervise ham preparation.

**Certification for Live Swine, Pork, and Pork Products; (9 CFR 94.9, 9 CFR 94.10, and 9 CFR 94.32)); (Foreign Government – Mexico, Chile, and Brazil)**

APHIS ensures regulatory compliance for mitigation of CSF from imports of swine, pork, and pork products into the United States. One requirement is completion of a certificate issued by a salaried veterinary officer of the Governments of Mexico, Chile, and/or Brazil to accompany swine, pork, and pork products from their respective regions. The certificate must identify both the exporting region and the region of origin as designated in 9 CFR 94.9, 9 CFR 94.10, and 9 CFR 94.32 as free of CSF at the time the swine, pork, or pork products were in the region. This certificate gives APHIS essential information regarding the origin and history of the commodities presented for import into the United States.

In the case of live swine, the certificate must state: (1) The swine have not lived in a region designated in sections 94.9 and 94.10 as affected with CSF; (2) the swine have never been commingled with swine that have been in a region that is designated in sections 94.9 and 94.10 as affected with CSF; (3) the swine have not transited through a region designated in sections 94.9 and 94.10 as affected with CSF unless moved directly through the region to their destination in a sealed conveyance with the seal intact upon arrival at the point of destination; and (4) the equipment or materials used in transporting the swine, if previously used for transporting swine, have been cleaned and disinfected in accordance with the requirements of part 93.

Regarding pork and pork products, the certificate must state: (1) The pork or pork products were derived from swine born and raised in a region designated in 9 CFR 94.32 asfree of CSF, and were slaughtered in such a region at a federally-inspected slaughter plant under the direct supervision of a full-time salaried veterinarian of the Governments of Mexico, Chile, or Brazil, and the region is eligible to have its products imported into the United States under the Federal Meat Inspection Act (21 U.S.C. 601 *et seq.);* (2) the pork or pork products have never been commingled with pork or pork products having been in a region designated in 9 CFR 94.9 and 9 CFR 94.l0 as affected with CSF; (3) the pork or pork products have not transited through a region designated in sections 94.9 and 94.10 as affected with CSF unless moved directly through the region to their destination in a sealed means of conveyance with the seal intact upon arrival at the point of destination; and (4) if processed, the pork or pork products were processed in a region designated in sections 94.9 and 94.10 as free of CSF in a federally inspected processing plant that is under the direct supervision of a full-time salaried veterinary official of the Government of Mexico, Chile, or Brazil.

**Compliance Agreement; (9 CFR 94.9(e)(3)); (Business)**

A compliance agreement is required for the operators of the processing establishment located in a non-CSF free region processing pork products from CSF-free regions. The operator must sign a compliance agreement stating all meat processed for importation to the United States will be processed in accordance with APHIS requirements.

**Cooperative Service Agreement; (9 CFR 94.9(e)(4)); (Business)**

A cooperative service agreement is required for the processing establishment located in a non-CSF free region that processes pork products from CSF-free regions. The operator, or a party on its behalf, must enter into a cooperative service agreement with APHIS to pay all expenses incurred by APHIS for the initial evaluation of the processing establishment and periodically thereafter. The requirements of the agreement are the same as the agreements for establishments processing cooked meats and ham.

**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 Request for Hearing generate too few respondents to make electronic accessibility feasible, although they could be emailed.
* The Cooperative Service/Trust Fund Agreements require 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 to reimburse site inspection costs. Further, agreement text can be emailed back and forth. The compliance agreement and the cooperative service agreement also require original signatures and are therefore not eligible for electronic submission.
* 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.
* The certificate of certification for live swine, pork, and pork products must physically accompany the shipment and requires an original signature from the authorizing veterinarian to be valid. The certificate is therefore not a candidate for electronic submission.
* The agreement for processing procedures (ham) cannot be recorded electronically because the operator writes a letter stating his or her desire to become a processing establishment and that he or she agrees to abide by APHIS regulations. Regulations require original signatures.
* Identification procedures for ham must be physically placed directly on the product, and therefore cannot be candidates for electronic submission.
* Certification of importation of hams must physically accompany the shipment and is therefore not a candidate for electronic submission.
* The Program Statement has not yet been considered for electronic submission. However, APHIS fully participates in the government-wide use of the International Trade Data System (ITDS) via the Automated Commercial Environment (ACE), which allows respondents to electronically submit data on incoming shipments to U.S. Customs and Border Protection and its partner government agencies (PGAs), such as APHIS, through a single window concept. Respondents may submit owner/importer statements and shipping documents electronically via the Document Image System (DIS) in ACE in lieu of paper documents. In addition, APHIS has permitted respondents to electronically submit copies of government certificates via the DIS during the COVID-19 outbreak, due to logistical difficulties and safety concerns associated with hard copy deliveries.

The Application for Permit to Import or Transport Controlled Material or Organisms or Vectors, VS Form 16-3 is a fillable PDF housed on the APHIS Electronic Forms Library at: https://www.aphis.usda.gov/library/forms/pdf/vs16\_3.pdf. The form can be electronically submitted to APHIS via e-File and the VS Permitting Assistant, https://efile.aphis.usda.gov/s/vs-permitting-assistant. e-File automates and reduces burden and allows applicants to submit most VS Form 16-3 information electronically. Information such as 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.

**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 works with both CBP and FSIS (which handles much of the establishment inspection work) in carrying out this work to prevent 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.**

APHIS estimates 50 percent of the business respondents are small entities. The information APHIS collects is the absolute minimum needed to protect the United States from the introduction of animal diseases from foreign animal products and to effectively evaluate the CSF risk associated with Mexican, Chilean, and Brazilian swine, pork, and pork product imports in particular, and imports from elsewhere on a broader scale. The foreign veterinarians who complete the required forms are considered foreign entities and thus are not "small entities" for purposes of Executive Order 12866 or the Regulatory Flexibility Act.

**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 SVD. This would cause serious economic consequences to U.S. agricultural exports and several U.S. livestock industries and have 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;**

CBP must receive notification of shipments of pork and pork products shipped subject to APHIS regulations at the time of shipment; this is usually less than 30 days. Moreover, the trust fund managed under the cooperative services agreement must be reimbursed as expenses are drawn from it; this is also usually less than 30 days.

* **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 other 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 engaged in productive consultations by email and phone with the following individuals regarding the information collection activities in this collection, and the information APHIS collects to administer its swine, port, and pork product import requirements. The respondents stated they did not have any concerns with the activities and the information being collected. The respondents were made aware of the frequency of the data collected; 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.

Laurie Hueneke, International Trade Specialist

Merck

126 E. Lincoln Ave.

P.O. Box 2000

Rahway, NJ 07065

908-740-4000

Robert L. Morris, Jr.

International LLC

8417 Amparan, El Portal Industrial Park

Laredo, TX 78045-1829

nnorris@morrisintl.Jlc.com

956-723-6492

Heather Hill, President

National Pork Board

1776 NW 114th Street

Des Moines, IA 50325

Info@pork.org

800-456-7675

On Monday, January 30, 2023, APHIS published in the Federal Register (88 FR 5850), a 60-day notice seeking public comments on its plan to request a 3-year renewal 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 renumeration 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. 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 bow 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 Mexico, Brazil, and Chile who complete the certificates necessary to export swine, pork, and pork products 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 cost to respondents to be $8,093,316. APHIS arrived at this figure by multiplying the total burden hours (179,712) by the estimated average hourly wage of the above respondents ($31.08) and then multiplying the result by 1.449 to capture benefit costs.

A breakdown of occupations, average salary and the source are listed in the table below.

The occupational codes were found at the U.S. Bureau of Labor Statistics website https://www.bls.gov/oes/current/oes\_stru.htm.

| SOCC Code | Average Salary | Occupation Description |
| --- | --- | --- |
| None | $14.82 | Average hourly wage estimate for foreign government officials, animal health officials, and inspectors was provided by Mexican government officials. |
| None | $32.57 | Average hourly wage for Chilean, Mexican, and Brazilian Federal veterinarians was determined through consultations with APHIS animal health specialists based in Chile, Mexico, and Brazil. |
| None | $25.86 | Average hourly wage for full-time salaried veterinarian employed by the most frequent regions of export was determined by averaging the following contacts: Canadian Food Inspection Agency ($57.86); APHIS contact in South Africa ($4.38); and the Mexican government ($12.39). |
| None | $38.07 | Average hourly wage for a ship’s crewmember responsible for recording information in the ship’s log and was provided by the Merchant marines. |
| None | $53.89 | Average hourly wage of managers of foreign facilities that process restricted animal materials was provided by Industry contacts. |
| 11-1021 | $59.07 | Average hourly wage for 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) [general and operations managers]. |
| 25-4013 | $25.40 | Average hourly wage 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) [museum technicians and conservators]. |
| 13-1020 | $36.13 | Average hourly wage for importers [buyers and purchasing agents]. |
| None | $10.29 | Average hourly wage for exporters for agriculture, meat, and foods was provided by the Laborsta International Web site. |
| 43-5011 | $23.91 | Average hourly wage for individuals transiting various commodities not eligible for importation into the United States [cargo and freight agents]. |
| 53-7081 | $21.91 | Average hourly wage for persons engaged in the business of handling or disposing of regulated garbage [refuse and recyclable material collectors]. |
|  | **$31.08** | **Average Hourly Salary** |

According to DOL BLS news release USDL-23-0488 dated March 17, 2023 (see https://www.bls.gov/news.release/pdf/ecec.pdf), benefits account for 31 percent of employee costs, and wages account for the remaining 69 percent. Mathematically, total costs can be calculated as a function of wages, resulting in a multiplier of 1.449.

**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 or purchase of services. There is cost associated with operation and maintenance expenditures, as operators of processing establishments must deposit in the required trust fund an amount equal to the approximate cost of one inspection by an APHIS representative, including travel, salary, subsistence, administrative overhead, and other incidental expenses.

**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.**

See APHIS Form 79. The annualized cost to the Federal government is estimated at $15,981,983.

**15. Explain the reasons for any program changes or adjustments reported in Items 13 or14 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** | 179,679 | 0 | 100 | 120,620 | 0 | 58,959 |
| **Annual Time Burden (Hr.)** | 179,712 | 0 | 100 | 120,616 | 0 | 58,996 |

This request for renewal is for 179,679 estimated annual responses and 179,712 estimated annual burden hours, reflecting an increase of 120,720 responses and 120,716 burden hours from the previous renewal request. The number of respondents increasing from 101 to 781. This renewal includes program changes.

The largest increases (highlighted) are for imports of pork, pork products, and (to a much lesser extent) live swine. These increases are due in some part to a reconciliation of VS’ calculations of respondents and responses per respondent, but in larger part to releases of restrictions on imports of pork and pork products from a number of trading partners. The United States saw increased imports of these products during the renewal period for this collection.

The respondent type for Application of Seal activity is Foreign Government and is being corrected in this renewal.

A breakdown of additional adjustments and discretionary changes are listed in the following tables.

**CHANGES IN RESPONSES**

FG = Foreign Government; B = Business; NP = Not for Profit; Trib = Tribal

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| 9 CFR | ACTIVITY | RESPONDTYPE | CURRENT  BURDEN | PREVIOUS  BURDEN | CHANGE | TYPE OF  CHANGE |
| 94.9, 94.10, 94.11(c ), 94.13(b) | Certification for Importation of Pork or Pork Products of a National Government | FG | 132,870 | 4,284 | 128,586 | Estimate |
| 94.4(b)(10(i) | Request for Approval of Defrost Facility | B | 16 | 37 | (21) | Estimate |
| 94.9(c), 94.12(b)(4) | Application for Permit to Import or Transport Controlled Material or Organisms or Vectors | B | 15 | 18 | (3) | Estimate |
| 94.4(c ) (1)(iii); (iv)94.9(e) (4) | Pork and Pork Products (Other than Ham) Cooperative Service Agreement and Trust Fund Account | B | 1 | 3 | (2) | Estimate |
| 94.17(n) | Ham-Specific Cooperative Service Agreement and Trust Fund Account | B | 7 | 1 | 6 | Estimate |
| 94.15 | Notification of CBP Inspectors for Pork from Specified Regions | B | 15 | 17 | (2) | Estimate |
| 94.4(b)(6)(i) | Certificates for Meat Processed in Tubes | B | 35,646 | 48,852 | (13,206) | Estimate |
| 94.17(d), (o) | Certificate for Importation of Hams | B | 100 | 0 | 100 | Discretionary |
| 94.17(d), (o) | Certification for Importation of Hams | FG | 100 | 92 | (8) | Estimate |
| 94.17(g) | Agreement for Processing Procedures | B | 7 | 92 | (85) | Estimate |
| 94.17(j) | Identification Procedures (Hot Brand or Ink Seal) | B | 163 | 92 | 71 | Estimate |
| 94.9, 94.10, 94.32 | Certification for Live Swine, Pork, and Pork Products | FG | 10,620 | 5,352 | 5,268 | Estimate |
|  | **Totals** |  | **179,679** | **58,959** | **120,720** |  |

**CHANGES IN BURDEN HOURS**

FG = Foreign Government; B = Business; NP = Not for Profit; Trib = Tribal

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| 9 CFR | ACTIVITY | RESPOND. TYPE | CURRENT  BURDEN | PREVIOUS  BURDEN | CHANGE | TYPE OF  CHANGE |
| 94.9, 94.10, 94.11(c ), 94.13(b) | Certification for Importation of Pork or Pork Products of a National Government | FG | 132,870 | 4,284 | 128,586 | Estimate |
| 94.4(b)(10(i) | Request for Approval of Defrost Facility | B | 16 | 37 | (21) | Estimate |
| 94.9(c), 94.12(b)(4) | Application for Permit to Import or Transport Controlled Material or Organisms or Vectors | B | 15 | 18 | (3) | Estimate |
| 94.4(c)(1)  (iii);iv)94.9  (e)(4) | Pork and Pork Products (Other than Ham) Cooperative Service Agreement and Trust Fund Account | B | 2 | 6 | (4) | Estimate |
| 94.17(n) | Ham-Specific Cooperative Service Agreement and Trust Fund Account | B | 7 | 1 | 6 | Estimate |
| 94.15 | Notification of CBP Inspectors for Pork from Specified Regions | B | 30 | 34 | (4) | Estimate |
| 94.4(b)(6)(i) | Certificates for Meat Processed in Tubes | B | 35,646 | 48,852 | (13,206) | Estimate |
| 94.17(d), (o) | Certification for Importation of Hams | B | 100 | 0 | 100 | Discretionary |
| 94.17(d), (o) | Certification for Importation of Hams | FG | 100 | 92 | 8 | Estimate |
| 94.17(g) | Agreement for Processing Procedures | B | 7 | 92 | (85) | Estimate |
| 94.17(j) | Identification Procedures (hot brand or ink seal) | B | 163 | 92 | 71 | Estimate |
| 94.9, 94.10, 94.32 | Certification for Live Swine, Pork, and Pork Products | FG | 10,620 | 5,352 | 5,268 | Estimate |
|  | **Totals** |  | **179,712** | **58,996** | **120,716** |  |

**16. For collections of information whose results are planned to be published, outline plans for tabulation and publication.**

APHIS has no plans to publish the 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.**

APHIS has many forms which are used across multiple ICRs. In most instances, the ICRs have different renewal dates and keeping up with expiration dates can be difficult. The VS Form 16-3 is used in eight collections and therefore it is not practical to include an OMB expiration date because of the various expiration dates. APHIS and OIRA are currently developing procedures for creating and maintaining a consolidated intra-Agency common form ICR. Upon the forms’ inclusion in the common form ICR upon its approval, the form will be updated with the appropriate PRA banners, ICR control numbers, and OMB approval expiration dates.

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

APHIS can certify compliance with all provisions in the Act.

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

Statistical methods are not employed in this information collection activity.