SUPPORTING STATEMENT SWINE HEALTH PROTECTION OMB NO. 0579-0065

July 2020

Information collection 0579-0323 (Trichinae Certification Program) is being merged into this information collection because both information collections are related to swine health protection. Once this information collection is approved, APHIS will discontinue 0579-0323.

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.ey

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 7, Chapter 109, Sections 8301-8321 of the U.S. Code.

Veterinary Services (VS), a program within the U.S. Department of Agriculture's (USDA), Animal and Plant Health Inspection Services (APHIS), is responsible for administering regulations intended to prevent the dissemination of animal diseases within the United States. These regulations are found in Title 9, *Code of Federal Regulations* (CFR).

The regulations under which APHIS conducts its disease prevention activities are contained in title 9, chapter 1, subchapter A, parts 1 through 167 of the CFR. These regulations govern the importation of animals, birds, and poultry; certain animal and poultry products; and animal germplasm.

Additionally, the Swine Health Protection Act (7 U.S.C. 3801 et seq.; regulations found at 9 CFR Chapters 166 and 167) was enacted because garbage is one of the primary media through which numerous infections or communicable diseases of swine can be transmitted. African swine fever, which is potentially the most dangerous and destructive of all communicable swine diseases, creates a concern due to recent spread outside of the African continent into Asia and Europe. Classical swine fever, another serious disease of swine that was officially declared eradicated from the United States in 1978, is also present in several nearby regions.

The Swine Health Protection Act requires USDA to ensure that all garbage is treated before being fed to swine intended for interstate or foreign commerce or that substantially affect such commerce. The regulations that implement this portion of the legislation are found in 9 CFR part 166.

The Act and the regulations allow only operators of licensed garbage treatment facilities that meet certain specifications to use garbage for swine feeding. Noncompliance with the regulations constitutes grounds for enforcement action and could include suspension or revocation of the license to operate

the garbage treatment facility. The Act and its implementing regulations ensure that all garbage, before being fed to swine, is treated to destroy all potential animal disease agents.

Each State can authorize or prohibit garbage feeding. Currently, 22 States prohibit feeding and 28 states plus Puerto Rico and the U.S. Virgin Islands allow it. Oklahoma plans to prohibit garbage feeding starting November 1, 2019. States that prohibit garbage feeding have a reduced burden for reporting compared to those that allow garbage feeding. The program execution varies from State to State, with some States choosing to hold primary enforcement authority over the Swine Health Protection Act, including licensing and inspection activities. Some States choose to execute the program cooperatively with the Federal government, and still others choose to allow the Federal government to oversee the entire program.

VS also conducts a pseudorabies (PRV) eradication program in cooperation with State governments, swine producers, swine shippers, herd owners, and accredited veterinarians. The program identifies PRV-affected swine, provides herd management techniques, and has eliminated PRV in commercial production herds. However, VS periodically finds infected swine when swine are exposed to feral swine or other swine that have had exposure to feral swine.

APHIS regulations in 9 CFR parts 71 and 85 facilitate the PRV eradication program and general swine health by providing requirements for moving swine interstate within a swine production system. (A production system consists of separate farms that each specialize in a different phase of swine production such as sow herds, nursery herds, and finishing herds. These separate farms, all members of the same production system, may be located in more than one State.)

Implementing these regulations requires the use of a number of information collection activities, including:

- the creation of food waste reports;
- the completion of applications to operate garbage treatment facilities;
- an acknowledgement of the Swine Health Protection Act and implementing regulations;
- garbage treatment facility inspection;
- cancellation of license by State animal health officials;
- request for a hearing;
- cancellation of license by licensee;
- notification by licensee of sick or dead animals;
- notification by licensee of changes to name, address, or management;
- cooperative agreements, for those States that issue garbage feeding licenses under VS supervision but do not have primary enforcement responsibility [4 States];
- swine health protection program inspection summary;
- permit to move restricted animals;
- owner-shipper statement;
- certificate of veterinary inspection;
- accredited veterinarian's statement: Embryo and semen shipments;
- identification for swine moving interstate;
- swine production system health plan;
- interstate movement report and notification;
- cancellation or withdrawal of a swine production system health plan;
- appeal of cancellation of a swine production system health plan;

- shipment to slaughter seal;
- appraisal and indemnity claim form; report of net salvage proceeds;
- herd management plans;
- and recordkeeping.

APHIS is asking OMB to renew, for an additional 3 years, its use of the various information collection activities listed above.

VS also regulates, among other diseases, *Trichinella spiralis*. This is a contagious nematode affecting animals and people. The disease, trichinellosis, is transmitted by consuming the meat of an infected animal containing the *Trichinella* cyst. People can get trichinellosis after eating undercooked meat if the meat contains the organism.

Trichinella spiralis was once a zoonotic concern when consuming pork. However, current swine rearing and modern production practices in the U.S. pork industry have greatly reduced the risk for exposing swine to this organism and minimized the likelihood that people will be exposed and infected by eating commercially raised pork. The public expects that on-farm agricultural production methods ensure that the meat provided for consumption is safe.

Swine producers may obtain added value to their swine when their production practices are audited trichinae free. Research and program pilots have shown that it is more practical and efficient to review and audit production methods rather than test individual pork carcasses to certify that the meat is trichinae-safe. Therefore, auditors trained to recognize and record use of trichinae preventing good production practices on-farm provide information through the official VS program audit form for certification purposes. Use of the certification form ensures that swine raised on a pork production site have had minimal exposure or no exposure to the risk factors for *T. spiralis* infection.

Pork industry organizations have worked with USDA and State animal health agencies to develop uniform program standards necessary to reduce and eliminate risk factors associated with trichinae. These standards provide the national guidelines for implementing the requirements for this program.

APHIS is asking OMB to approve information collection activities that include a request for certification site audit, the program audit form, request for information during a spot audit, animal disposal plan and recordkeeping, animal movement record and recordkeeping, rodent control logbook and recordkeeping, trichinae herd certification, feed mill quality assurance affidavit and recordkeeping, and records for slaughter testing and recordkeeping.

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 ensure that garbage fed to swine does not pose a threat of spreading animal diseases within the United States.

Garbage Feeding:

9 CFR 116.2 - VS Form 13-17, Food Waste Report (Business and State) (no longer in use, will be omitted after this renewal)

This form was used by Federal and State public health officials. These officials contacted food establishments (grocery stores, restaurants, etc.) and inquired about the disposition of the establishment's food waste. The form was forwarded to VS' District Offices or the State animal health office only when the results of the inspection revealed that the destination of the food waste was potentially a garbage feeder. Upon receipt of the information from the public health officials, Federal or State animal health personnel used the information to determine if the waste collector fed garbage to swine, if the garbage was being treated, and if the feeder was licensed or needed to be licensed.

9 CFR 166.10 (a) - VS Form 13-15, Application for Licensing of Garbage Treatment Facility (Business)

This application process provides a system to license and regulate individuals who wish to operate a garbage treatment facility to use garbage for swine feeding. Persons desiring to obtain a permit (license) to operate a facility to treat garbage must apply to VS or the State agency.

9 CFR 166.10 (b) - Acknowledgement of Act and Regulations (Business)

When an applicant is given a licensing application to operate a garbage treatment facility, he or she also receives a copy of the Swine Health Protection Act and the related regulations. At the time of the pre-licensing inspection, the applicant is required to sign a statement that he or she has received a copy of the Act and regulations, understands them, and agrees to comply with them.

9 CFR 166.13 - VS Form 13-16, Garbage Treatment Facility Inspection (Business and State)

This form is used by VS or State inspectors during routine and repeat visits to garbage treatment facilities for the purpose of inspection, and for pre-licensing inspection activity at premises before licensing a garbage treatment facility. This form guides the inspector through the inspection process at the facility and allows the inspector to record satisfactory or unsatisfactory findings at the facility. This form enables review of the sanitation, cooking procedures, cooked product storage, and raw product storage at the facility. This information is obtained via direct observation on the farm and interviews with the owner.

9 CFR 166.11 (a) - Request for Hearing (Business)

A license will be canceled if a licensee fails to treat garbage for a consecutive 4-month period. This regulation reduces the number of periodic inspections of facilities that are not treating garbage after receipt of a license under the Act. A licensee who has been notified of a proposed cancellation of license may request a hearing to retain his or her license. The licensee requests this hearing in writing to VS.

9 CFR 166.12 (a) - Cancellation of License by State Animal Health Official (State)

A license will be canceled if a licensee fails to treat garbage for a consecutive 4-month period. This regulation reduces the number of periodic inspections of facilities that are not treating garbage after receipt of a license under the Act. If a State animal health official cancels a license, the licensee must be informed in writing.

9 CFR 166.12 (b) - Cancellation of License by Licensee (Business)

Any licensee who no longer wishes to treat garbage under the Act may request cancellation of his or her license by writing to the Area Veterinarian in Charge (AVIC) or to the State animal health official in a State that issues licenses under a cooperative agreement. Once received, the AVIC or the State animal health official will cancel the license.

9 CFR 166.13 (b) - Notification by Licensee of Sick or Dead Animals (Business)

A licensee must immediately notify a Federal or State inspector on detecting, in any animal, illness, or death not normally associated with the licensee's operation of the facility. The licensee must also notify VS of any change in the name, address, management, or ownership of the facility within 30 days of the change. This information enables VS to carefully monitor events at the facility. On request, the licensee must also give VS information concerning the sources of garbage at the facility. This information includes the dates of supply and the names and addresses of the suppliers.

9 CFR 166.15 - VS Form 13-2, Swine Health Protection Program Inspection Summary (State)

This document is used by the AVIC and State animal health officials in evaluating the progress of the swine health protection program in each State. The reports include data from the first day of each month to the last day of each month and are sent by the State or Federal epidemiologist to APHIS to be entered and tabulated in a spreadsheet.

9 CFR 166.9- Recordkeeping (Business)

Each licensee must record the destination and date of removal of all garbage removed from the premises. These records must be kept for 1 year. The records are reviewed annually by supervising Federal officials to determine compliance with the Swine Health Protection Act and regulations. In the case of a disease outbreak, this information is essential for disease-tracing actions taken by Federal and State animal health officials.

9 CFR 166.15 - Cooperative Agreement (State)

As noted above, garbage feeding program execution varies from State to State, with some States choosing to hold primary enforcement authority over the Swine Health Protection Act including licensing and inspection activities. Some States choose to execute the program cooperatively with the Federal government, and still others choose to allow the Federal government to oversee the entire program. Those working with the Federal government do so under a cooperative agreement spelling out the specific responsibilities, according to part 166, each side undertakes (i.e., licensing, cleaning and disinfecting, enforcement, etc.)

Pseudorabies:

9 CFR 71.19, 9 CFR 85.1, 9 CFR 85.5, 9 CFR 85.6, 9 CFR 85.11 - VS Form 1-27, Permit to Move Restricted Animals (Business, Accredited Veterinarians, and State)

Herd owners and producers with PRV-infected or exposed animals who wish to have their swine transported to another facility for slaughter, salvage, or disposal must obtain a permit for movement. The application for the permit is filled out by the owner's accredited veterinarian. The swine must also be identified as described in 9 CFR 71.19.

The permit alerts VS that infected or exposed animals are being shipped, and allows VS to carefully monitor this activity. This permit must be sent to the destination State animal health office within 3 days of movement (9 CFR 85.11). For all movements of PRV-infected or exposed swine the permit must include (per 9 CFR 85.1 and 9 CFR 85.5):

- The number of swine to be moved:
- The purpose for which the swine are to be moved;
- The shipment's points of origin and destination; and
- The names and addresses of the consignor and consignee.

To move PRV-infected or exposed animals to a quarantined herd or feedlot, the permit must include the four items above and (per 9 CFR 85.5 (b)):

- Indicate the PRV quarantine status of the farm of origin;
- The date of the official PRV serological test;
- The name of the laboratory providing the test;
- The date of official PRV vaccination; and
- Approval from a State animal health official of the destination State.

To move PRV-vaccinated swine, except swine from a qualified negative gene-altered vaccinate herd, not known to be infected with or exposed to PRV, the permit must include the original four items above and (per 9 CFR 85.6(a)(b)):

- Indicate the PRV status of the herd of origin;
- Date of vaccination; and
- Approval from the State animal health official of the destination State.

To move PRV-vaccinated swine, except from qualified negative gene-altered vaccinate herds, the permit or owner-shipper statement must include the original four items above and certify that the swine are being moved to their destination with no stops (per 9 CFR 85.6 (a)).

9 CFR 85.6, 9 CFR 85.7- Owner-Shipper Statement (Business)

Exposed or infected swine, or those vaccinated with other than a gene-deleted vaccine, can be moved interstate to slaughter, to a quarantined feedlot, or to an approved livestock market if accompanied by an owner-shipper statement. The statement is also used to accompany swine that are non-vaccinated, non-infected, and non-exposed to PRV that are moving to a feedlot, quarantined feedlot, quarantined herd, or approved livestock market (9 CFR 85.7(b)). The owner-shipper statement is not an official form and can be written on any piece of paper as long as it contains the necessary information. Not all owner-shipper statements are collected or inspected. They are usually inspected on a spot-check basis or during an actual outbreak.

The statement is completed by the owner or shipper of swine and lists:

- The number of swine to be moved;
- The shipment's points of origin and destination; and
- The names and addresses of the consignor and consignee.

To move PRV-vaccinated swine, except from qualified negative gene-altered vaccinate herds, the permit or owner-shipper statement must include the three items above and certify that the swine are being moved to their destination with no stops (9 CFR 85.6 (a)).

9 CFR 85.1, 9 CFR 85.6, 9 CFR 85.7, 9 CFR 85.8- Certificate of Veterinary Inspection (Business, Accredited Veterinarians, and State)

Producers and State officials desiring to move swine interstate that are not within a production system, that are not known to be infected with or exposed to PRV, and are not PRV-vaccinated or are vaccinated with a gene-deleted vaccine, must obtain a State-issued certificate to do so.

The certificate (filled out by the herd's accredited veterinarian) contains (per 9 CFR 85.1):

- The number and description of the swine to be moved;
- A statement that the animals are not showing signs of infectious, contagious, or communicable diseases;
- The purpose for which the swine are to be moved;
- The shipment's points of origin and destination, and
- The names and addresses of the consignor and consignee.

For swine vaccinated for PRV with a glycoprotein I (gpI) deleted gene-altered vaccine and not known to be infected with or exposed to PRV, but that are not from a qualified negative gene-altered vaccinated herd, the certificate must also certify (per 9 CFR 85.6 (c)):

- That each animal to be moved was vaccinated for PRV with a gpI-deleted gene-altered vaccine;
- That each animal to be moved was subjected to a gpI enzyme-linked immunosorbent assay (ELISA) or a gpI particle concentration fluorescence immunoassay (PCFIA) approved differential PRV test no more than 30 days prior to the interstate movement and was found negative;
- The date of the gpI ELISA or the gpI PCFIA approved differential PRV test; and
- The name of the laboratory that conducted the gpI ELISA or the gpI PCFIA approved differential PRV test.

Swine not vaccinated for PRV and not known to be infected with or exposed to PRV may be moved interstate if the accompanying certificate includes the original five items above and certifies that the swine (per 9 CFR 85.7(c)):

- Were subjected to an official PRV serological test within 30 days prior to the interstate movement that was found negative, the test date and the name of the laboratory conducting the test; or
- Are part of a currently recognized qualified PRV-negative herd and the date of the last qualifying test; or,
- Are part of a PRV-controlled vaccinated herd and are the offspring subjected to the official PRV serological test to achieve or maintain the status of the herd as a PRV-controlled vaccinated herd, and the date of the last test to maintain said status.

For swine from a qualified negative gene-altered vaccinated herd, the certificate must also certify (per 9 CFR 85.8(b)):

- That the swine are from a qualified negative gene-altered vaccinated herd;
- The date of the herd's last qualifying test;
- The identification for the swine to be moved interstate, in accordance with 9 CFR 71.19; and
- If the swine to be moved are official gene-altered pseudorabies vaccinates, the official gene-altered pseudorabies vaccine used in the herd.

The veterinarian collects this information via conversations with the producer or State official. The accredited veterinarian must mail or deliver the certificate to the State animal health official of the destination State within 3 days of the date the animals are moved interstate (9 CFR 85.11).

9 CFR 85.10, 9 CFR 85.11 - Accredited Veterinarian's Statement: Embryo and Semen Shipments (Business)

Swine semen and swine embryos moved interstate for insemination of swine or implantation into swine are accompanied by a document issued by an accredited veterinarian stating that the donor swine are not known to be infected with or exposed to PRV, were negative to an official PRV serological test within 30 days prior to the collection of the semen or embryos or were members of a qualified PRV negative herd, and had not been exposed to PRV within 30 days prior to the collection of the semen or embryos (per 9 CFR 85.10). The accredited veterinarian bases the statement on his or her knowledge of the herd and test results gained through his or her relationship with the livestock owner.

The veterinarian must send the statement to the State animal health official of the destination State within 3 days of the date the animals are moved interstate (9 CFR 85.11).

9 CFR 71.19(g) - Swine Production System Health Plan (Business and State)

The swine production health plan is an individualized document developed between the participating swine producer, the origin State, and the destination State which requires all farms within a given swine production system to maintain the health of their swine and remain vigilant for any signs of communicable disease. The plan identifies all the farms participating in the swine production system, provides for an accredited veterinarian to perform inspections at these sites, authorizes VS and State animal health officials to inspect animals and review records, documents any specific animal health requirements of a State that is a signatory to the plan, describes the recordkeeping system being used by the swine production system, and acknowledges that failure to abide by the provisions of the plan is a basis to cancel the plan. The plan also allows interstate movement within a production system for other than slaughter or to a livestock market. In this case, it is an agreement among the shipping State, the receiving State, and the producer that outlines the shipment's points of origin and destination as well as any additional information or actions agreed on by the States.

The swine production health plan is not valid until it is signed by all participants, including the producers in the production system and the State animal health officials from each State involved.

9 CFR 71.19(g) - Swine Production System Health Plan - Recordkeeping (Business)

Each premises must maintain, for 3 years after their date of creation, records that will allow a VS representative or State animal health official to trace any animal on the premises back to its previous premises, and must maintain copies of each swine production health plan signed by the producer, all interstate swine movement reports issued by the producer, and all reports the swine production system accredited veterinarians issue documenting the health status of the swine on the premises.

9 CFR 71.19(g) - Interstate Movement Report and Notification (Business)

The Interstate Swine Movement Report is a paper or electronic (email) document initiated by swine producers to notify their accredited veterinarians, VS, and State regulatory officials in the States of origin and destination that a group of animals is being moved across State lines in a swine production system. This report must contain the name of the swine production system; the name, location, and farm identification number of the farm the swine are leaving and the farm to which the swine are going; the date of the movement; the number, age, and type of swine to be moved; the health status of the herd from which the swine are moving; the name of the accredited veterinarian who regularly inspects the swine on the farm; and a statement that the swine have been inspected and found free from signs of communicable disease by the accredited veterinarian.

Producers moving animals within swine health production systems must complete a report each month for all animals moved within the month. This report must be sent to APHIS officials each month. The report can be a simple spreadsheet indicating the number of animals moved, identification numbers, or

any additional information requested in the herd plan. This report is not an official form but must meet the agreed-on criteria of the State veterinarians as specified in the herd health plan.

<u>9 CFR 71.19 - Annual Report of Pseudorabies Control/Eradication Activities and Recordkeeping (Formerly VS Form 7-1) (State)</u>

VS recommends this report be completed annually by each State receiving Federal PRV funding. The report assists States in ensuring surveillance performance criteria are properly tracked and analyzed. It provides both State and Federal program administrators with program data such as the number of PRV-infected herds in each State, the number of herds vaccinated for PRV, and the total number of animals tested. States completing this form are required to keep the form for 3 years.

9 CFR 52.3, 9 CFR 52.4 - VS Form 1-23, Appraisal and Indemnity Claim Form (Business and State)

Herds of swine and individual breeding sows to be destroyed because they are known to be infected with PRV will be appraised by a VS employee and a representative of the State jointly, a representative of the State alone, or, if the State authorities approve, by a VS employee alone.

Appraisals of swine must be reported on a VS 1-23 and signed by the owner of the swine. The form is then signed by a VS veterinary medical officer, who completes and sends it to the AVIC for the applicable State. The AVIC then sends the form to VS headquarters staff; once headquarters staff approves the indemnity amount, the form is returned to the AVIC with appropriate funds to depopulate the animals. The AVIC retains the original form.

For all claims for indemnity, the owner of the swine must certify on the claim form that the swine covered are, or are not, subject to any mortgage as defined in 9 CFR part 52. If the owner states there is a mortgage, the owner and each person holding a mortgage on the swine must sign, consenting to the payment of indemnity to the person specified on the form.

9 CFR 52.5 - Herd Management Plan (Business and State)

On a written herd management plan and before depopulation, removal, or payment of indemnity to any swine herd owner or producer, the producer must agree with either a VS official or a State veterinary medical officer to specified terms to receive indemnity. All producers are considered herd owners for purposes of depopulation and indemnity. The herd plan is an agreement between VS and the herd owner. It outlines biosecurity measures that the producer must comply with to prevent PRV from reentering the herd. This plan also allows VS to depopulate without indemnity if the herd becomes reinfected and VS finds that the herd plan was not followed. The agreements are written specifically for each herd. Producers must sign the document after agreement to specified terms to receive indemnity. The document accompanies the VS 1-23 to VS headquarters and, after indemnity is approved, is kept by the AVIC.

<u>9 CFR 52.5 - VS Form 1-24, Proceeds from Animals/Animal Products/Materials Sold for Slaughter (Business)</u>

Producers with PRV-infected and exposed animals who have had their infected swine transported to a slaughter facility for disposal must report to VS the value received for the depopulation. The owner reports the value minus the trucking expense to VS. VS pays the herd owner the difference between the indemnity price and his or her net salvage proceeds. The herd owner must provide documentation of this amount to APHIS by fax, mail, or in person once the herd has been disposed of to receive compensation.

<u>9 CFR 52.5 - VS Form 1-26, Appraisal Request for Affected Premises Using Contract Growers - (Business)</u>

Producers working with contract growers use this form to apply for a permit to move slaughter swine from the originating slaughter facilities to approved destination facilities. The form is used when the State or Tribal animal health official and the AVIC have determined that animals/animal products on the premises are affected with PRV. Animals on the premises will be depopulated by State, VS, and/or industry personnel; the State-Federal-industry goal is to complete depopulation within 24 hours of detection. Indemnity for destroyed animals and animal products affected by disease is based on their fair market value, as determined by current VS indemnity calculators. In cases where destroyed animals and/or animal products were produced by a contract grower, the appraised value of the animals and animal products will be split between the owner and contract grower based on the terms of the contract currently in place for the growing or care of the affected animals and animal products. If determination of indemnity as described above is deemed to be impractical or inappropriate, VS may use any other method for split payments that the APHIS Administrator deems appropriate. If Federal indemnity is approved for the destroyed animals and animal products, the owner will receive the difference between the total indemnity shown on the VS Form 1-23, Appraisal and Indemnity Claim, and the total indemnity paid to the contract grower.

<u>9 CFR 166.13 (b) - Notification by Licensee of Changes to Name, Address, or Management (Business)</u>

A licensee must immediately notify Federal or State animal health officials of any changes to the name or address of the facility as well as any substantial changes in the control or ownership of the facility.

<u>9 CFR 71.19(e)</u>) - Recordkeeping Required for Buyers/Sellers of Swine Moved Interstate (Business)

Each person who buys or sells, for his or her own account or as the agent of the buyer or seller, transports, receives for transportation, offers for sale or transportation, or otherwise handles swine in interstate commerce, must keep records for 2 years relating to the transfer of ownership, shipment, or handling of the swine, such as yarding receipts, sale tickets, invoices, and waybills on which is recorded:

- All serial numbers and other approved means of identification appearing on the swine necessary to identify them to the person from whom they were purchased or otherwise obtained; and
- The street address, including city and State, or the township, county, and State, and the telephone number, if available, of the person from whom the swine were purchased or otherwise obtained.

<u>9 CFR 71.19(d)</u> - <u>Identification for Swine Moving Interstate (Business, Accredited Vets, and State)</u>

Serial numbers of USDA-approved backtags and official swine tattoos will be assigned to each person who applies to the State animal health official or the AVIC for the State in which that person maintains his/her or its place of business. Serial numbers of official eartags will be assigned to each accredited veterinarian or State or Federal representative who requests official eartags from the State animal health official or the AVIC, whoever is responsible for issuing official eartags in that State. Persons assigned serial numbers of USDA-approved backtags, official swine tattoos, and official eartags must record the following information on a document (per 9 CFR 71.19(d)):

- All serial numbers applied to the swine;
- Any other serial numbers and approved identification appearing on the swine needed to identify the swine to its previous owner and location;

- The street address, including the city and State, or the township, county, and State, of the premises where the approved means of identification were applied; and
- The telephone number, if available, of the person who owns or possesses the swine.

9 CFR 71.19(d) - Identification for Swine Moving Interstate – Recordkeeping (Business) Persons assigned social numbers of USDA approved backtage, official swine tattoes, and official

Persons assigned serial numbers of USDA-approved backtags, official swine tattoos, and official eartags must maintain these records at the person's place of business for 2 years and make these records available for inspection and copying during ordinary business hours on request by any authorized USDA employee and presentation of his or her official credentials.

<u>9 CFR 71.19(h) - Cancellation or Withdrawal of a Swine Production System Health Plan</u> (Business and State)

The following procedures apply to cancellation of, or withdrawal from, a swine production health plan:

- A State animal health official may cancel his or her State's participation in a swine production health plan by giving written notice to all swine producers, VS representatives, accredited veterinarians, and other State animal health officials listed in the plan.
- A swine production system may withdraw one or more of its premises from participation in the plan on giving written notice to the APHIS Administrator, the accredited veterinarians, all swine producers listed in the plan, and State animal health officials listed in the plan.

9 CFR 71.21(a) - VS Guidance Document 7400.2 Appendix 1 (formerly VS Form 1-38), Application for Permit to Move Slaughter Swine from Originating Slaughter Facilities to Approved Destination Facilities (Business and State)

Any business entity wishing to re-transport swine from slaughter facility lairage areas must apply for a permit from the office of the AVIC in the State of origin. The AVIC and the State veterinarian will jointly review and approve (or disapprove) the permit application. Each business entity wishing to transport swine must acquire a separate approved permit application for each originating slaughter establishment. Animals may only be transported to locations listed on the permit and must have identification as well as records that allow traceback from the point of final slaughter to the farm of origin within 48 hours. The permit application will list all eligible facilities for possible swine reshipment within one State. If swine are to be re-transported across State lines a separate application must be filed for each State in which potential reshipment receiving facilities are located.

9 CFR 71.19(h) - Appeal of Cancellation of a Swine Production System Health Plan (Business)

The APHIS Administrator may cancel a swine production health plan by giving written notice to all swine producers, accredited veterinarians, and State animal health officials listed in the plan. Before a swine health production plan is canceled, a VS representative will inform a representative of the swine production system of the reasons for the proposed cancellation. The swine production system may appeal the proposed cancellation in writing to the Administrator within 10 days after being informed of the reasons for the proposed cancellation. The appeal must include all of the facts and reasons upon which the swine production system relies to show that the reasons for the proposed cancellation are incorrect or do not support the cancellation.

9 CFR 52.2 - Shipment to Slaughter Seal (Accredited Vets and State)

Swine to be destroyed because they are from a herd known to be infected with PRV or individual breeding sows known to be infected with PRV must be sent directly to slaughter under permit in a

conveyance closed with an official seal applied and removed by either a VS employee, a State representative, an accredited veterinarian, or an individual authorized for this purpose by a VS employee.

Merged from information collection 0579-0323

Trichina:

VS uses the following information activities to obtain sufficient data to certify swine are raised using practices that will reduce or eliminate *T. spiralis* exposure.

9 CFR 149.2(e)(2) - Temporary Withdrawal (Business)

A producer can request VS in writing to temporarily withdraw from the program.

9 CFR 149.2(e)(3) - Program Withdrawal (Business)

A producer must notify VS in writing of his or her intent to withdraw from the program. APHIS has no approval form for this request.

9 CFR 149.2(f) - Request for Review (Business)

If the producer questions the results of an audit or other determination affecting the producer's program status, the producer may submit a written request for VS review. The request must include the reasons for the review request, any supporting documents, and an explanation why the results or determination should be different. There is no official form for the request.

9 CFR 149.2(a) - Request for Certification Site Audit (Business)

To participate in this program, to receive an enrolled status, and to become certified, pork production sites must call and ask an auditor for an audit of their facilities. The auditor, an accredited veterinarian or State veterinary medical officer who performs other duties on the farm, will already have the contact information (name of producer and phone number) and premises location for the production site and will not need to request that information from the producer.

9 CFR 149.4 - Spot Audit (State)

VS or State auditors can also conduct spot audits of certified sites to confirm the results of regular audits, to verify that good production practices are being maintained between audits, to trace back and investigate positive slaughter verification testing results, and to ensure that audits are conducted consistently across the program. The auditor records the findings on the Trichinae Certification Site Audit Form. The owner or caretaker reviews and signs the form. The auditor sends the form to the VS District Office.

9 CFR 149.3 - VS 7-9 - Trichinae Certification Site Audit Form (Business, State)

VS-accredited, trained, and qualified auditors (accredited veterinarians or State veterinary medical officers) visit pork production sites at the owners' request and collect information needed on the Trichinae Certification Site Audit Form. The purpose of the audit is to reduce, eliminate, or avoid the risk of exposing swine to trichinella. As part of the audit, the auditor observes the swine housing and feeding facilities, reviews specific on-farm records (such as the animal disposal plan, animal movement records, rodent control logbook, and trichinae herd certification feed mill quality assurance affidavit), and gathers responses from the person responsible for care of the swine at the production site regarding good production practices. The auditor records whether the producer uses all of the

required good production practices regarding swine housing, feed, feeding, disposal, animal movement, and general hygiene and sanitation. The owner or caretaker reviews and signs the form. The auditor sends the form and payment, if required (see 9 CFR 149.8), to the APHIS District Office.

9 CFR 149.7 (a)(1) - VS 7-11 - Animal Disposal Plan and Recordkeeping (Business)

The owner or caretaker of the pork production site must complete an animal disposal plan (or similar document). This form should outline the animal disposal practices on the site to include the prompt removal and proper disposal of all dead swine on certified production sites. To be eligible to participate in this program, production sites need to remove all dead swine within 24 hours. This plan is to be updated as animal disposal practices change on the production site or every 2 years. The plan must be signed by the owner or caretaker and retained for 2 years, and be made readily available for the auditor's inspection. The sites do not have to use this form if they have their own records that provide the information the program requires. VS' review of the form is already covered under its time allocated for audit reviews.

9 CFR 149.7 (a)(2) - VS 7-10 - Animal Movement Record and Recordkeeping (Business)

The owner or caretaker of the pork production site must complete the animal movement record (or similar document) listing the arrivals and departures of swine to and from the certified production site. This form documents that swine entering the premises originated from other trichinae-certified production sites. Animal movement records should indicate that all pigs greater than 5 weeks of age acquired for feeding purposes originate from a trichinae-certified site. The site producer or caretaker signs these records and retains them for 2 years. These records must be made readily available for the auditor's inspection. The sites do not have to use this form if they have their own records that provide the information the program requires. VS' review of the form is already covered under its time allocated for audit reviews.

9 CFR 149.7(a)(3)- VS 7-12 - Rodent Control Logbook and Recordkeeping (Business)

The pork production site must also maintain a rodent control logbook or similar rodent control records. The logbook lists the number of traps set and includes information on the type of bait and an index on caught or killed rodents. A complete logbook must also include a site and facility diagram indicating the location of all rodent bait stations and rodent traps. The site producer or caretaker initials the logbook. The record needs to be filled out at least monthly and retained for 2 years. It must be made readily available for the auditor's inspection. The sites do not have to use the logbook if they have their own records that provide the information the program requires. VS' review of the form is already covered under its time allocated for audit reviews.

<u>9 CFR 149.7(a)(4) - VS 7-13 - Trichinae Herd Certification Feed Mill Quality Assurance Affidavit and Recordkeeping (Business)</u>

The feed mill quality assurance affidavit is a written statement that documents the quality and safety of feed delivered to the pork production site. It includes the name of the producer and the identity of the site, the name and address of the feed mill, and the name of the feed mill representative. The affidavit must provide information that the feed mill is following good manufacturing practices including rodent control. The producer obtains this information through discussions with the mill manager or quality assurance officer. The producer can use a document kept at the production site that contains this information. Both the producer and mill representative must sign the affidavit. The affidavit must be retained for 2 years and be made readily available for the auditor's inspection. VS' review of the form is already covered under its time allocated for audit reviews.

9 CFR 149.6(c)(5) - Records for Slaughter Testing and Recordkeeping (Business)

Slaughter plants participating in this program test a certain percentage of samples each month. Slaughter plant personnel record the location where the sample originated and the test results. The records are maintained in either the slaughter plant or in a laboratory approved for trichinae testing by the Agricultural Marketing Service. The approved laboratory may be maintained and operated by the slaughter facility or by another business entity either on the premises of the slaughter facility or at another location. The records must be available for VS inspection and be retained for 2 years. VS' review of the form is already covered under its time allocated for audit reviews.

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.

Currently only the VS Form 13-2 is available for electronic collection of data. It is available on APHIS VS SharePoint site. VS' recent reorganization affected updating and consolidating the remaining forms into VS' electronic data collection process. Now that the reorganization and the revamping of the electronic data collection are complete, VS is making every effort to make the remainder of the forms electronic. APHIS will submit a Non-substantive Change Request on completion of making each form available electronically. Most forms in widespread use have been converted to fillable PDF format to allow completion and electronic filing as email attachments.

The Permit for Movement of Restricted Animals (VS 1-27) is not available in an electronic format. Use of this form requires individuals to seal vehicles. Additionally, original documents with signatures must accompany the animal shipment. Therefore, APHIS has no plans to produce this form in an electronic format.

An electronic Certificate of Veterinary Inspection is available. The electronic version can be completed by accredited veterinarians by accessing www.globalvetlink.com, https://agview.com/login, or through the USDA Veterinary Services Processes Streamlining System located at https://vsps.aphis.usda.gov/vsps. It includes the accredited veterinarian's statement concerning embryos for implantation and semen shipments. Accredited veterinarians can access, complete, and submit all parts of the form electronically. Once completed, the form is automatically tracked in a data management system. An increasing number of swine veterinarians in multiple States now use the electronic form.

The owner-shipper statement cannot be submitted electronically. Owner-shipper statements are not official APHIS forms. These forms are created as needed by the swine herd owner or shipper, and are usually collected or inspected on a spot-check basis or during an actual outbreak.

The swine production health plan, while required by APHIS regulations, is not an official report. Rather, it is an agreement among the shipping State, the receiving State, and the producer regarding movement of swine. It also requires original signatures and thus does not lend itself to an electronic format.

The interstate movement reports can be submitted electronically to State veterinarians in receiving and shipping States, based on individual State requirements. This is not an official report but is created by producers to inform accredited veterinarians, State veterinarians, and AVICs of animal movements. These records are collected by States and periodically reviewed for accuracy. They can be transmitted via email to accredited veterinarians, VS, or appropriate State offices.

The Appraisal and Indemnity Claim Form (VS 1-23) is available in an electronic PDF format. The form is maintained by VS offices and is not available on a public-facing website. Since this form requires original signatures, the electronic version has to be printed, signed, and submitted to all offices manually by mail or in person.

The herd plan is a producer-specific document, not an official APHIS form. This document is written in cooperation with the producer to prevent reentry of disease. Because this document is different for every producer, a standard electronic form is not available. This document accompanies the VS 1-23; as such, it is generally submitted via mail, email, or in person.

The Report of Net Salvage is not an official form and cannot be created electronically as it differs from case to case. For this report, producers provide proof of sales and payment receipts for animals sold for salvage value to government officials by fax, mail, or in person.

Producers request audits through a phone call, so no form is needed for this request.

All five trichinae forms (the VS 7-9, 7-10, 7-11, 7-12, and 7-13) are available electronically at www.aphis.usda.gov/vs/trichinae and also at www.aphis.usda.gov/library/forms. Production sites may use other ways to provide the same information. The site audit form is completed during the audit and sent to VS after the producer reviews it. The remaining forms are maintained on-farm in hard copy to facilitate the auditing process. Since VS does not retain any forms other than the certification audit form, which the producer must sign, electronic submission of the forms is not needed.

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 collected is the absolute minimum needed in connection with U.S. swine health. The information that APHIS collects is not available from any other source. APHIS is the only Federal agency responsible for controlling and eliminating domestic diseases of animals and poultry.

5. If the collection of information impacts small businesses or other small entities, describe any methods used to minimize burden.

Over 80 percent of all respondents in the information collection are considered small entities. This information collection represents VS' efforts to monitor swine health and ensure that husbandry practices and garbage fed to swine do not pose a threat of spreading animal diseases within the United States. Burden is reduced by only asking for the information needed to ensure the Swine Health Protection Act is being followed and by having State or VS personnel available to assist with questions on the needed records. VS further minimizes burden by allowing farms to substitute their own records for official forms if the records provide the information the program requires.

6. Describe the consequences 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.

Failing to collect this information would severely cripple APHIS' ability to prevent the spread of contagious animal diseases within the United States. If this information were not collected, the incidence of animal disease outbreaks would begin to rise, and the United States would lose its favored status for the export of 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;

Certificate of Veterinary Inspection - Producers and State officials desiring to move swine interstate that are not within a production system, that are not known to be infected with or exposed to PRV, and are not PRV-vaccinated or are vaccinated with a gene-deleted vaccine, must obtain a State-issued certificate to do so. The veterinarian collects this information via conversations with the producer or State official. The accredited veterinarian must mail or deliver the certificate to the State animal health official of the destination state within 3 days of the date the animals are moved interstate

Notification by Licensee of Sick or Dead Animals - A licensee must immediately notify a Federal or State inspector on detecting, in any animal, illness or death not normally associated with the licensee's operation of the facility. The licensee must also notify APHIS of any change in the name, address, management, or ownership of the facility within 30 days of the change. This information lets APHIS monitor the facility and helps with disease investigation tracebacks.

Accredited Veterinarian's Statement: Embryo and Semen Shipments - Swine semen and swine embryos moved interstate for insemination of swine or implantation into swine shall be accompanied by a document issued by an accredited veterinarian stating that the donor swine are not known to be infected with or exposed to PRV, were negative to an official PRV serological test within 30 days prior to the collection of the semen or embryos or were members of a qualified PRV negative herd, and had not been exposed to PRV within 30 days prior to the collection of the semen or embryos. The accredited veterinarian bases the statement on his or her knowledge of the herd and test results gained through his or her relationship with the livestock owner. The veterinarian must send the statement to the State animal health official of the destination State within 3 days of the date the animals are moved interstate.

Appraisal Request for Affected Premises Using Contract Growers (VS 1-26) – If it is determined that animals/animal products on this premises are affected with a disease, the animals/animal products on this premises will be depopulated. The goal is to complete depopulation within 24 hours of detection.

Indemnity for destroyed animals/animal products affected by disease will be based on their fair market value, as determined by current APHIS indemnity calculators.

- 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 record keeping, 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 swine health requirements. 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 Tuesday, MAR 3, 2020, pages 12495-12496, Vol. 85, No. 42, 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. APHIS received 2 comments from the public. The first was from a concern citizen about the mistreatment of animals. Her comment has no relevance to the purpose of the collection. The second comment is from Diagnostic Laboratory and they suggested the US pork industry consider implementing a program similar to the NPIP program and offered the following website as a reference: https://usswinehealthimprovementplan.com/.

9. Explain any decision to provide any payment or gift to respondents, other than re-numeration 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 and attitudes, religious beliefs, and others that are 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 bow 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 APHIS headquarters and field personnel, auditors, pork producers, mill managers, slaughter facility personnel, personnel from approved laboratories, State veterinary authorities, herd owners, and owners/operators (licensees) of garbage treatment facilities.

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

Respondents are owners/operators (licensees) of garbage treatment facilities, owners/operators of facilities that have food waste, herd owners, and State animal health authorities. APHIS estimates the total cost to respondents to be \$94,254,320.15 by multiplying the total burden hours (1,715,536) by the estimated average hourly wage of the above respondents (\$37.36) and then multiplying the result (\$64,092,424.96) by 1.4706 to capture benefit costs. According to DOL BLS news release USDL-18-1499, dated September 18, 2018 (see https://www.bls.gov/news.release/pdf/ecec.pdf), benefits account for 32 percent of employee costs, and wages account for the remaining 68 percent. Mathematically, total costs can be calculated as a function of wages using a multiplier of 1.4706."

Owners/Operators of herds: \$38.43 [Farm, Ranch, and Other Agricultural Managers]

Licensees: \$24.42 [First-Line Supervisors of Farm Workers] State Animal Health Authorities: \$50.59 [Veterinarians]

Pork producers: \$13.87 [45-2093 Farm workers, Farm and Ranch Animals]

Auditors: \$55.57 [11-0000 Management Occupations] Mill managers: \$55.57 [11-0000 Management Occupations]

Slaughter facilities and approved laboratories: \$23.10 [19-4021 Biological Technicians]

The average hourly rate is derived from the U.S. Department of Labor; Bureau of Labor Statistics – National Occupational Employment and Wage Estimates at https://www.bls.gov/oes/current/oes_stru.htm.

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 startup 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 most operation and maintenance expenditures, and purchase of services.

If a State or Federal veterinarian performs a site audit under 9 CFR 149.3, then the producer will pay the State or Federal veterinarian at the time the site audit is performed in accordance with the rate and other conditions set by the State or Federal veterinarian's governmental employer. Further, if the State or Federal veterinarian who performs the site audit is employed by VS, then the producer will pay VS for this service at the hourly rate listed in table 1 of 9 CFR 149.8 for each employee required to perform the service. If the VS-employed veterinarian performs the site audit on a Sunday, on a holiday,

or at any time outside the normal tour of duty of that employee, then the producer will pay VS for this service at the hourly rate listed in table 2 of 9 CFR 149.8 for each employee required to perform the service. Payment to VS for the services of a VS-employed veterinarian, by certified check or U.S. money order, must be remitted to the veterinarian at the time the site audit is performed.

The producer must pay VS a program fee at the time of each site audit in the amount of \$51 to cover VS' administrative costs in processing the audit and operating the program. This program fee, payable to APHIS by certified check or U.S. money order, is due at the time of submitting the completed site audit form for APHIS evaluation.

A producer will not be charged for the cost of having a spot audit performed at the pork production site.

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.

Administrative and overhead costs for this certification program are estimated to cost \$1,146,292. (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.

ICR Summary of Burden:

	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	962,899	0	+ 813	-185,703	0	1,147,789
Annual Time Burden (Hr)	1,715,536	0	+142	+27,744	0	1,687,650
Annual Cost Burden (\$)		0	0	0	0	0

There is a program change increase of +812 responses resulting in an increase of +142 burden hours with merger of information collection 0579-0323. The burden for this information collection is greatly reduced; APHIS is maintaining it largely as a placeholder as it intends to discontinue this program.

There is in adjustment decrease of -185,703 responses and an increase of +27,774 in burden hours. Fewer States and businesses are undertaking garbage feeding considering recent disease concerns. While interstate shipments of swine appear to have remained steady, incidences of, and concerns about, PRV infection appear to have decreased.

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 collected 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.

VS 1-23, VS 1-24, and VS 1-27 are used in multiple information collections; therefore, it is not practical to include OMB expiration dates because of the various expiration dates for each collection. APHIS is seeking approval to not display OMB expiration dates on these forms.

APHIS has no plans to seek approval for not displaying the OMB expiration date on the remaining forms in 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.