January 2022

SUPPORTING STATEMENT
HANDLING SWINE WITH POTENTIAL VESICULAR DISEASE
OMB CONTROL NO. 0579-XXXX

NOTE: Once approved, this information collection request will be merged into 0579-0299, National Animal Health Reporting System (NAHRS), upon its renewal.

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 USC 8301 et. seq.]

Disease prevention is the most effective method for maintaining a healthy animal population and for enhancing the U.S. Department of Agriculture's Animal and Plant Health Inspection Service (APHIS), Veterinary Services' (VS) ability to allow U.S. animal producers to compete in the world market of animal and animal product trade. The regulations in title 9, *Code of Federal Regulations* (9 CFR) Subchapter B (referred to below as the regulations) govern the cooperative control and eradication of livestock and poultry diseases. The regulations establish procedures through which Federal and State animal health authorities coordinate in their collective efforts to eradicate certain communicable animal diseases. Under the AHPA, the Secretary of Agriculture can respond to diseases through movement control, surveillance, and other activities including disease reporting. Further, accredited veterinarians must immediately report all diagnosed or suspected cases of animal diseases not known to exist in the United States to State or Federal animal health officials and take precautions to prevent the spread of communicable diseases under 9 CFR 161.4(f) and (g). Anyone with suspicion of such a disease is encouraged to report their suspicions to a State or Federal animal health official.

Any swine having vesicular lesions are suspects for foreign animal diseases (FADs), such as foot-and-mouth disease (FMD), until determined otherwise by VS through authorized testing at approved National Animal Health Laboratory Network (NAHLN) laboratories with oversight and confirmatory testing, if required, by the Foreign Animal Disease Diagnostic Laboratory (FADDL). Several viral pathogens may cause vesicular lesions in swine, including FMD virus, swine vesicular disease virus, vesicular stomatitis virus, and Senecavalley A virus. Veterinarians are unable to differentiate the etiology of these gross lesions without diagnostic testing. Vesicular lesions on swine should be reported by State, Federal, and accredited veterinarians to ensure rapid detection of FMD or any other FAD, if introduced. This is done to protect the health, public confidence, and marketability of our nation's livestock health, marketability of meat products, and public confidence.

APHIS is asking the Office of Management and Budget (OMB) to approve its use of the information collection activities described below in connection with its efforts to reduce the risk of introducing foreign animal disease, particularly diseases of swine, 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.

Notifiable Swine Disease Reporting; 9 CFR 57.2(d) and 9 CFR 161.4(f); Business, State
Any animal health professional (such as veterinarians, laboratory personnel, biomedical researchers, public health officials, animal health officials, trained technicians, zoo personnel, and wildlife personnel) with knowledge of occurrence or suspected occurrence of an animal with vesicular lesions must report such identification or suspicion to both APHIS and the State where the animal is located.

The information collected may include either test-level or summary-level data. Test-level data provides results for individual samples as well as information about that sample and includes date of collection, date of testing, State of collection, animal species sampled, type of test performed, test result (i.e., quantitative measure), and test result interpretation (i.e., positive, not detected). Summary-level data provides results for multiple samples tested for the same disease and includes date or date range of collection, date or date range of testing, State of collection, animal species sampled, type of test performed and disease tested for, and total count of each test type (positive, not detected, inconclusive). Test-level data is the preferred level of data collection, preferably collected via electronic messaging directly from laboratory data systems, requiring no data entry. Reports may also be made by phone, email, fax, mail, or online interface.

Data collected for emerging disease investigations and outbreaks may require more information depending on the situation. APHIS will use diagnostic testing results, number of detections, and epidemiological information to detect and evaluate the status of a potential emerging disease threat. Once APHIS confirms there is an emerging animal disease, it will use this information to create specific case definitions and disease reporting criteria. At the time of first reporting, the specific agent causing a potential emerging disease may be unknown, or the agent may be a newly identified but incompletely characterized strain.

AVIC Reports; VSG 7406.4; Business
Reports of FADs often lead to investigations. When vesicular FAD investigations involve imported hogs (from Canada or the low-risk CSF region of the European Union), the VS Area Veterinarian in Charge (AVIC) notifies VS Strategy & Policy, Live Animal Imports of the investigation. For imported feeding and breeding swine from Canada, the AVIC must immediately report lesions noted within the immediate post-import period (14 days). For imported breeding swine (low-risk CSF region of the EU), the AVIC must immediately report lesions noted during the entry quarantine required for these animals. For immediate slaughter swine from Canada in immediate slaughter facilities where vesicular FAD investigations involving imported animals occur, the AVIC provides immediate reports (NAHLN and FADDL testing results when they become available) to VS Strategy & Policy, Live Animal Imports, for discussions with the competent authority of the country of origin.

FAD Data Collection; VSG 7406.4; Business, State

AVICs and State animal health officials assign foreign animal disease diagnosticians (FADDs) to oversee each case of vesicular disease identified in pigs. Assigned staff enter all investigation information into the VS Emergency Management Response System (EMRS). AVICs, State animal health officials, and FADDs evaluate all information known about the case to determine and assign the FADDL and NAHLN submission priority level. These officials prioritize the FAD investigation and diagnostic testing for disease suspicion; however, they may consider the need to move pigs or products when designating priority.

FAD Investigation; VSG 7406.4; Business, State

In situations where epidemiologically-linked sites show evidence of vesicular disease and the origination site has FAD-negative results confirmed by FADDL within 14 days prior to the start date of the FAD investigation, accredited veterinarians may conduct a follow-up investigation only under the following conditions:

- A FAD investigation by a FADD has been completed within the last 14 days at an epidemiologically linked production flow site, and the epidemiologically linked site has FAD-negative results confirmed by FADDL.

- The accredited veterinarian (or veterinarians) agree(s) to collect, package, and send samples to FADDL and the NAHLN (if applicable) per AVIC and SAHO instructions.

- The accredited veterinarians understand that the VS role is to perform diagnostic testing to identify or rule out FADs. Production-based disease testing may require additional tissue volume for further diagnostics at a veterinary diagnostic laboratory following rule out of FADs at an approved NAHLN laboratory and/or FADDL. VS does not test for other diseases.

Accredited veterinarians immediately contact the AVIC or SAHO and report any unexpected change in morbidity, mortality, or clinical findings of vesicular disease within epidemiologically linked production flow sites. If necessary, the AVIC or SAHO initiates a new FAD investigation.

NAHRS Monthly State Report Form (NAHRS 1); 9 CFR 57.2(d)(2); State

The process for States to report diseases listed as monitored in the NLRAD (comprised of endemic (present) diseases in the United States) is housed in the National Animal Health Reporting System (NAHRS). States voluntarily track and report information on monitored and notifiable diseases to VS via the NAHRS (using the Data Integration System, or DIS). The NAHRS collects monthly data from State veterinarians on the presence or absence of diseases reportable to the World Organization for Animal Health (WOAH) within the United States. Reporting requirements for monitored diseases apply only to laboratories and State animal health officials.

Basic reporting fields for monitored diseases include date or date range applicable to knowledge of State, disease, and status (present, absent, unknown); basically, a yes or no answer as to the disease's presence/occurrence. VS may request voluntary submission of additional case and testing information for some monitored diseases, such as number of diagnostic tests conducted, number of confirmed cases, vaccination status, number of susceptible animals, or other epidemiological information. This additional information request will occur when Federal, State, and industry representatives together identify significant diseases where additional information will help monitor disease trends; meet travel and movement requirements; and carry out control, response, and prevention activities.

Information will be collected whenever possible via electronic messaging directly from laboratory data systems, requiring no data entry. Reporting may also be made by phone, email, fax, mail, or online interface.

NAHRS 1 is used by State veterinarians to report data submitted from private practitioners, State and Federal veterinarians, and State laboratories to VS. Most data submitted is based on test results as well as observational data. The form is divided into 11 sections: Multispecies, Bovine, Farmed Cervids, Caprine and Ovine, Equine, Porcine, Poultry, Lagomorph, Other Diseases, Bee, and Aquaculture. The top of the form has a space to indicate the State of origin and the current month and year. Each section lists rows of WOAH notifiable diseases that correspond to each of the species, with a column for the respondent to indicate the presence or absence of each disease as well as a space for comments. There is also an optional section where States may report the presence of unlisted diseases.

Submitters may collect additional data for non-negative results reported for specific diseases or incidents.

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.

AVIC reports may be submitted to APHIS in whatever format the AVIC finds convenient in hard copy by mail or email.

FAD data collection is handled via EMRS.

FAD investigation data is handled via EMRS, the Veterinary Services Laboratory Submissions (VSLS) system, and the Laboratory Messaging Services (LMS).

NAHRS 1 is available online at https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/monitoring-and-surveillance/sa_disease_reporting/ct_info_for_participants). Forms may be completed/submitted electronically via the Internet, emailed to NLRAD.NAHRS@aphis.usda.gov, faxed, or mailed to USDA/APHIS/VS, Attn: NAHRS Coordinator, 2150 Centre Ave, Bldg. B, MS 2E6, Fort Collins, CO 80526. Web-based form completions are performed on a permissions-restricted, secure submission site, open only to approved data providers.

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 for evaluation of swine for vesicular disease is not available from any other source. APHIS is the only Agency responsible for preventing the introduction of exotic animal diseases into the United States. The type, quantity, and frequency of data collected by DIS is unique in 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 that more than 75 percent of the commercial laboratories are small entities. The information collected is the absolute minimum needed to evaluate the risk of introducing and spreading swine vesicular disease in the United States. APHIS anticipates most information collected will come from States and State and commercial laboratories.

6. Describe the consequence to Federal program or policy activities if the collection is not conducted or is conducted less frequently, as well as any technical or legal obstacles to reducing burden.

If the information was collected less frequently or not collected at all, it would significantly cripple APHIS' ability to evaluate the risk of spreading swine vesicular disease in the United States. This would have serious effects on the U.S. livestock industry and international trade.

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;**

  The NAHRS Monthly State Report or equivalent is submitted by State animal health officials (State Veterinarians) on a monthly basis to expedite monitoring for disease presence and control and to report the presence or absence of diseases of interest to the OIE.

- **requiring respondents to prepare a written response to a collection of information in fewer than 30 days after receipt of it;**

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  AVIC Reports - Reports of FADs often lead to investigations. When vesicular FAD investigations involve imported hogs, the VS Area Veterinarian in Charge (AVIC) notifies VS Strategy & Policy, Live Animal Imports of the investigation. For imported feeding and breeding swine from Canada, the AVIC must immediately report lesions noted within the immediate post-import period (14 days).

  FAD Investigation - In situations where epidemiologically-linked sites show evidence of vesicular disease and the origination site has FAD-negative results confirmed by FADDL within 14 days prior to the start date of the FAD investigation, accredited veterinarians may conduct a follow-up investigation. Accredited veterinarians immediately contact the AVIC or SAHO and report any unexpected change in morbidity, mortality, or clinical findings of

vesicular disease within epidemiologically linked production flow sites. If necessary, the AVIC or SAHO initiates a new FAD investigation.

- **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 with the following individuals concerning the information collection activities associated with this initiative. APHIS contacted these respondents by email and phone to discuss the information APHIS collects to administer its disease testing and surveillance practices. 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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APHIS also published in the Federal Register on September 30, 2022 (see 87 FR 59389) a 60-day public comment notice for this new information collection request. The notice received one comment but it did not contain any constructive recommendations for improving the information collection activities.

9. Explain any decision to provide any payment or gift to respondents, other than remuneration of contractors or grantees.

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

10. Describe any assurance of confidentiality provided to respondents and the basis for the assurance in statute, regulation, or agency policy.

No additional assurance of confidentiality is provided with this information collection, and any and all information obtained in this collection shall not be disclosed except in accordance with 5 U.S.C. 552a.

11. Provide additional justification for any questions of a sensitive nature, such as sexual behavior or attitudes, religious beliefs, and other matters that are commonly considered private. This justification should include the reasons why the agency considers the questions necessary, the specific uses to be made of the information, the explanation to be given to persons from whom the information is requested, and any steps to be taken to obtain their consent.

This information collection activity will ask no questions of a personal or sensitive nature.

12. Provide estimates of the hour burden of the collection of information. Indicate the number of respondents, frequency of response, annual hour burden, and an explanation of how the burden was estimated.

- **Indicate the number of respondents, frequency of response, annual hour burden, and an explanation of how the burden was estimated. If this request for approval covers more than one form, provide separate hour burden estimates for each form and aggregate the hour burdens in Item 13 of OMB Form 83-1.**

  See APHIS Form 71. Burden estimates were developed from discussions with swine producers, veterinary medical professionals, laboratory personnel, and animal or public health officials.

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

  APHIS estimates the total annualized cost to these respondents to be $461,412.31. APHIS arrived at this figure by multiplying the total burden hours (6,900) by the estimated average hourly wage of the respondents ($46.15) and then multiplying the result ($318,435) by 1.449 to capture benefit costs.

  The average hourly wage was calculated as the mean for wages obtained from the May 2021 Bureau of Labor Statistics Occupational Employment Statistics survey (see https://www.bls.gov/oes/current/oes_stru.htm) for veterinarians ($52.84, SOCC 29-1131), laboratory personnel ($38.65, SOCC 19-1011), farmers ($37.71, SOCC 11-9013), and public health officials (general and operations managers, $55.41, SOCC 11-1021).

  According to DOL BLS news release USDL-22-0469, (dated 03/18/2022, www.bls.gov/news.release/pdf/archives/ecec 03182022.htm), 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, operation and maintenance expenditures, and purchase of services.

14. Provide estimates of annualized cost to the Federal government. Provide a description of the method used to estimate cost and any other expense that would not have been incurred without this collection of information.

See APHIS Form 79. The annualized cost to the Federal government is estimated at $302,919.

15. Explain the reasons for any program changes or adjustments reported in Items 13 or 14 of the OMB Form 83-1.

This is a new collection.

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

APHIS has no plans to publish information it collects in connection with this program.

17. If seeking approval to not display the expiration date for OMB approval of the information collection, explain the reasons that display would be inappropriate.

The NAHRS 1 is currently associated with both this information collection request and 0579-0299, each with different OMB approval expiration dates. It would not be practical to add an expiration date to the form at this time.

Currently, ROCIS does not provide for intra-agency management of forms used in multiple ICR's. APHIS and OIRA are currently developing a new APHIS common form ICR that would allow the agency to consolidate its multi-ICR forms into one packet.

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

APHIS can certify compliance with all the provisions of the Act.

B. Collections of Information Employing Statistical Methods

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