

SUPPORTING STATEMENT - OMB NO. 0579-0XXX

Reporting, Herd Monitoring, and Management of Swine Enteric Coronavirus Diseases

June 2014

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 the 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.

Disease prevention is the most effective method for maintaining a healthy animal population. APHIS has delegated authority for prevention of animal diseases to Veterinary Services (VS). VS has, under the auspices of the Animal Health Protection Act, just issued a Federal Order establishing a reporting and herd monitoring and management requirement for novel swine enteric coronavirus diseases.

Since its identification in the United States in May 2013, porcine epidemic diarrhea virus (PEDV) has spread within the swine industry to at least 30 States, causing approximately 7 million piglet deaths. In recent months, an additional related virus, porcine delta coronavirus (PDCoV), has been identified in 13 States. Infections with these swine enteric coronaviruses can cause significant morbidity and mortality, particularly in young piglets. The disorders affect only swine; they do not affect other animals or people, and are not a food safety concern. However, the U.S. swine population has minimal immunity against these coronaviruses. The entire population remains at risk. Moreover, the virus can spread easily as no commercially licensed vaccines are available. The disease is spread by fecal/oral contact with infected swine or contaminated materials.

Actions to date, led by producers, herd veterinarians, and industry organizations, have focused primarily on biosecurity and disease management but have not been fully effective in limiting the spread of the virus. Therefore, the Federal government, States, herd veterinarians, and industry are collaborating to manage these infections in the United States. This collaboration leads to a number of activities described in more detail below.

APHIS is asking the Office of Management and Budget (OMB) to approve, for 6 months, its use of these information collection activities in connection with its efforts to collect information to characterize and understand the scope of swine enteric coronavirus diseases (SECD) and inform

future control options, and to decrease shedding and spread of PEDV and PDCoV or other novel enteric coronaviruses from affected herds.

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 activities to collect information necessary to characterize the spread of SECD in the United States and to assist in future disease control options:

Herd Management Plan

Producers and managers of affected herds must establish and maintain herd management plans. These plans must be provided to the Assistant District Director. Herd management plans support continuity of business and to assist in maintaining a plentiful supply of pork and pork products for consumers. Herd management plans are to use best recommended practices for biosecurity and disease control for each specific herd. The plan must be developed with a herd veterinarian. APHIS veterinarians can provide assistance.

The herd management plan must address:

- Biosecurity of visitors and vehicles entering or exiting the premises.
- Monitoring employee biosecurity.
- Periodic herd health observation.
- Animal movement (both into and out of the herd).
- Cleaning and disinfection of facilities.
- Diagnostic testing to monitor the status of the herd infection and assess efficacy of control strategies.
- Maintenance of records on pig movement, which are accessible to State or Federal animal health officials on request.

Having a herd management plan in place is a requirement for reporting herds. Accredited veterinarians performing activities on behalf of producers may be compensated through the fee basis system.

Veterinarians helping producers develop biosecurity/herd plans will submit finalized plans to Federal officials. Once a plan is received veterinarians and producers are eligible for reimbursement.

Disease Reporting

Anyone, including herd owners, producers, veterinarians, laboratory personnel, or others with knowledge of the disease, who identifies an occurrence of PEDV, PDCoV, or another novel swine enteric coronavirus, must report the occurrence to the State animal health official and the VS Assistant District Director overseeing the States where premises are located. A new occurrence may be the initial detection or a reoccurrence of previously detected disease. This includes observation of case-compatible disease with laboratory-based evidence of virus detected from samples originating from swine herds in the United States or its territories. Laboratories will submit reports electronically to VS. Reporting by all will include premises identification number (PIN) or an alternative premises location identifier; date of sample collection or observation of clinical signs; type of herd (sow, nursery, finisher); test methods used to make the diagnosis; and diagnostic test results. The case must

be reported as soon as the herd is believed infected through observation of case-compatible signs and laboratory test positive samples or other knowledge of herd infection. This information will be used to understand the scope of SECD in the United States.

If a sample is submitted to a National Animal Health Laboratory Network (NAHLN) laboratory for testing and is found positive, reporting by the herd owner, producers, veterinarians, and others with knowledge of the disease is not required. A list of NAHLN testing laboratories is available located on the APHIS Web site at http://nsu.aphis.usda.gov/animal_health/nahln/labs.shtml.

Animal Movement Recordkeeping

To assist APHIS in learning about the effectiveness of disease mitigations in the management plan, the plans must contain provisions indicating that producers need to maintain up-to-date records of animals moving onto and off each reported premises. These animal movement records, preferably kept in an easily accessed electronic format, must be made available on request to Federal and State officials. These records will assist in the investigation associated with any newly affected SECD herd.

Fee Basis Agreement and Statement of Work (VS 1-9R or Similar)

The fee basis agreement is a contract that formalizes the requested work to be performed by the herd veterinarian. Work reports for services rendered must be submitted before 30 days after the end of the semi-monthly period during which work was performed. VS will pay the herd veterinarian in accordance with the fee basis schedule approved by VS. This agreement must be signed by the herd veterinarian. The accompanying statement of work requires an additional signature to indicate the herd veterinarian agrees to assist producers, and it provides information on reimbursable activities.

Electronic Funds Transfer Agreements

Both producers and veterinarians must complete this form to receive reimbursement for program activities. The EFT form requests the vendor's tax ID; the vendor's EFT information for payments; the recipient's bank name, address, routing number, and account number; and the account type.

Statement of Work

Accredited Veterinarians must sign the accompanying statement of work to indicate that they agree to assist producers. It also provides information on reimbursable activities.

Statement of Services Performed (VS 8-18)

Once a herd plan is submitted, Federal officials with the aid of the producers and veterinarians will complete the Form VS 8-18, "Statement of Services Completed," to reimburse the veterinarian for assisting in herd plan development.

Producer Reimbursement for Biosecurity Activities (Fee Basis Vendor Agreement and Submission of Itemized Invoice)

Producers can be reimbursed in part for certain biosecurity activities (such as cleaning and disinfecting animal transport vehicles) known to prevent further disease spread, if the producers list those activities in their herd management plans. Producers seeking partial reimbursement for such activities will need to complete the vendor agreement and agree to the statement of work.

The fee basis vendor agreement outlines the responsibilities of the producer for the services performed. The producer also must agree to the statement of work, which explains which services are

reimbursable. To obtain partial reimbursement, producers must also submit an itemized invoice outlining the agreed-on biosecurity activities set forth in their herd plans and statements of work. The vendor agreement and statement of work only need to be completed once, but the itemized invoices must be submitted before each payment.

Certifying Statement for the Addition of Herds to a Herd Management Plan

Producers with multiple infected premises, in collaboration with their veterinarians, may use existing herd plans on file for additional reported premises, provided the herds are under the same management and the existing plans meet the biosecurity needs of the additional premises. A certifying statement (signed by both the producer and the veterinarian) is required to add additional herds to a plan.

Statement of Services Performed – Producers (VS 8-18)

Federal officials with the aid of the producers and veterinarians will complete the Form VS 8-18, “Statement of Services Completed,” to reimburse the producer for certain biosecurity activities.

Application for Federal Assistance (includes SF 424-Discretionary (4040-0004))

APHIS anticipates issuing cooperative agreements with States and other entities to help diagnose and manage SECDs as prescribed in the Federal Order. The agreements include, but are not limited to, agreements with States to assist in herd management plan development and management of reported premises. The activities cooperating States and institutions perform to support SECD activities will be outlined in the work plan. Cooperators will also complete Standard Form 424, which is the application for Federal assistance. The SF 424 requires the address of both the recipient organization and the payee; the employer and recipient’s identifying numbers; and the descriptive title of the projects.

Request for Advance or Reimbursement (SF 270)

Cooperators submit this form to request reimbursement for cooperative agreement activities. Information collected on the form includes the name and address of both the recipient organization and the payee; the employer and recipient’s identifying numbers; and the computation (amount and formula) for the amount of reimbursement or advance requested. The form must be certified (signed) by the appropriate official.

State Animal Health Control Orders or Quarantines

States may need to issue control orders or quarantines if producers do not comply with the Federal Order. The information included will vary by State. APHIS estimates few (about 15) will be issued.

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.

To reduce the reporting burden on laboratories for Disease Reporting, electronic automated data submission through the Laboratory Messaging System (LMS) will occur. Laboratory messaging allows laboratories to automatically submit their testing information as well as premises identifying information to Federal data systems.

Data on reported herds, including herd management plans, will be managed through the Emergency Management Response System. This electronic database allows the capture of electronic submissions, laboratory records, and other documentation submitted to State and Federal animal health officials. Herd management plans are documents between a producer and his or her herd veterinarian. The documents could be provided to Federal or State official in an electronic version, if they are accompanied by information validating their authenticity.

SF 424 and 270 are available on grants.gov.

apply07.grants.gov/apply/forms/sample/SF424_2_1-V2.1.pdf

<http://www.whitehouse.gov/sites/default/files/omb/grants/sf270.pdf>

VS 1-9 and VS 8-18 will be available on the APHIS Forms Web site.

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 in connection with this program is not available from any other source. APHIS is the only Agency responsible for preventing the introduction of animal diseases into the United States and their spread.

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

Approximately 85 percent of the respondents in this information collection are small businesses. The information APHIS collects is the minimum needed to determine if swine produced on these sites have had minimal exposure or no exposure to the risk factors for infection with swine enteric coronavirus diseases.

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, it would significantly cripple APHIS' ability to understand the scope and spread of PEDV and PDCoV-like viruses in U.S. swine herds. This will undermine APHIS's ability to decrease shedding and spread of PEDV and PDCoV or other novel enteric coronaviruses from affected herds, with potentially serious effects on the U.S. pork industry. Trading partners are beginning to restrict the importation of live animals and animal-derived products, such as blood products and other byproducts, from the United States. Meat product restrictions may follow.

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;**

Fee Basis Agreement and Statement of Work (VS 1-9 or Similar)

The fee basis agreement is a contract that formalizes the requested work to be performed by the herd veterinarian. Work reports for services rendered must be submitted before 30 days after the end of the semi-monthly period during which work was performed. VS will pay the herd veterinarian in accordance with the fee basis schedule approved by VS. This agreement must be signed by the herd veterinarian. The accompanying statement of work requires an additional signature to indicate the herd veterinarian agrees to assist producers, and it provides information on reimbursable activities.

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

Fee Basis Agreement and Statement of Work (VS 1-9 or Similar)

The fee basis agreement is a contract that formalizes the requested work to be performed by the herd veterinarian. Work reports for services rendered must be submitted before 30 days after the end of the semi-monthly period during which work was performed. VS will pay the herd veterinarian in accordance with the fee basis schedule approved by VS. This agreement must be signed by the herd veterinarian. The accompanying statement of work requires an additional signature to indicate the herd veterinarian agrees to assist producers, and it provides information on reimbursable activities.

- **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 three 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 program.

Dave Schmitt
State Veterinarian
Department of Agriculture
Wallace Building, 2nd Floor
502 E. 9th Street
Des Moines, IA 50319
Phone: 515-281-8601

Patrick Halbur
Chair, Veterinary Diagnostic and Production Animal Medicine
Iowa State University, College of Veterinary Medicine
2203a Lloyd Vet Med Center
Ames, IA 50011
Phone: 515-294-6970
Email: pghalbur@iastate.edu

Tom Ray
Veterinary Division, Livestock Health Programs
North Carolina Department of Agriculture and Consumer Services
2 West Edenton Street
Raleigh, NC 27601
919-733-7601

On Thursday, June 5, 2014, APHIS published a Federal Order for Emergency Action on its APHIS and USDA Web sites. APHIS will follow up with a notice of request for a 3-year renewal of this information collection in the Federal Register within the next 6 months.

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

APHIS will pay producers for some activities outlined in their herd plans pertaining to cleaning and disinfection. This information collection activity otherwise involves no payments or gifts to respondents.

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

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

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

This information collection activity 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 pork producers, accredited veterinarians, State animal health officials, and personnel from approved laboratories.

• 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 \$3,258,259.30. APHIS arrived at this figure by multiplying the total burden hours (113,965) by the estimated average hourly wage of the above respondents (\$28.59).

Pork producers: \$35.20 [Farmers, ranchers, and other agricultural managers]; \$11.91 [45-2093 Farm workers, Farm and Ranch Animals]

Veterinarians \$46.22

Slaughter facilities and approved laboratories: \$21.02 [19-4021 Biological Technicians]

The average hourly rate is derived from the U.S. Department of Labor; Bureau of Labor Statistics May 2013 Report – National Occupational Employment and Wage Estimates United States. See http://www.bls.gov/oes/current/oes_nat.htm#19-0000

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.

The annualized cost to the Federal government is estimated at \$25,783,855. (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.

This is a new collection.

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

Data regarding animals tested, the number of reported premises, herd management plans implemented, and information on cleaning and disinfection activities may be tabulated and provided to stakeholders. Reporting of SECD activities to stakeholders is necessary to track disease trends and measure the success of mitigation activities

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 will display the expiration dates on VS form 1-9 and 8-18.

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

APHIS is able to 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.