

**SUPPORTING STATEMENT
COMMUNICABLE DISEASES IN HORSES
OMB NO. 0579-0127**

January 2018

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.

Disease prevention is the most effective method for maintaining a healthy animal population and for enhancing our ability to compete in the world market of animal and animal product trade.

Veterinary Services (VS), a program within USDA's Animal and Plant Health Inspection Service (APHIS), is responsible for administering regulations intended to ensure that animals affected with equine infectious anemia (EIA) are moved interstate in a way that does not endanger the health of the U.S. equine population. APHIS regulations at title 9, *Code of Federal Regulations* (9 CFR) 75.4 deal specifically with regulating the interstate movement of horses affected with equine infectious anemia (EIA).

Ensuring the safe movement of these equines requires VS to engage in a number of information collection activities such as 1) guiding animal health officials and animal owners in obtaining and completing a Permit for the Movement of Restricted Animals (VS Form 1-27), 2) guiding animal health officials, accredited veterinarians and animal owners in documenting a laboratory test for EIA using VS Form 10-11, the Equine Infectious Anemia Laboratory Test Form, 3) conducting and documenting an investigation of the farm of origin for any equine that returns a positive result for an EIA test using VS Form 10-12, the, Equine Infectious Anemia Supplemental Investigation; and 4) having facilities that conduct EIA-related activities sign an agreement promising adherence to APHIS regulations. Diagnostic and research laboratories must also notify VS in writing when they no longer accept EIA reactors moved interstate. Finally, any stockyard, diagnostic facility, or other facility that loses VS approval may request a hearing regarding the decision, but must do so in writing.

The regulations at 9 CFR 75.4 require laboratories conducting any EIA test be approved by the APHIS Administrator in consultation with the appropriate State animal health officials. In order to approve a request, APHIS needs to collect information regarding the laboratory's capacity to

conduct accurate and reliable testing and meet the regulatory requirements, including director, location, facilities, appropriate resources and the training and proficiency of its employees. Additionally, laboratories must enter an agreement with APHIS and undergo regular inspections to receive and maintain approval. The burden related to the approval of laboratories to conduct EIA testing is being added to this information collection package.

APHIS is asking OMB to approve, for an additional 3 years, its use of these information collection activities in connection with its program to prevent the spread of EIA within the U.S. equine population.

2. Indicate how, by whom, how frequently, and for what purpose the information is to be used. Except for a new collection, indicate the actual use the agency has made of the information received from the current collection.

APHIS uses the following information collection activities to help prevent the spread of EIA within the U.S. equine population:

Permit for the Movement of Restricted Animals (VS Form 1-27) - (Business) - 9 CFR 71.3

At the time animals are loaded and ready for transport, Federal officials use information obtained from the animal owner to complete the VS Form 1-27. The information obtained from the owner and entered on the form includes the owner's name and address, the points of origin and destination of the animals, the number of animals being moved, the purpose of the movement, and various pieces of animal identification data, such as a microchip number or a physical description, so that each animal in the shipment can be identified. This form accompanies the shipment and is submitted to VS after the animals reach their destination.

Equine Infectious Anemia Laboratory Test (VS Form 10-11) - (Business) - 9 CFR 75.4(b)(2)

This form is completed by an accredited veterinarian acting on behalf of the Federal government who has been requested to conduct an EIA test on an equine. The equine's owner – who provides the information the official needs to complete the form – may have several reasons for wanting the equine tested, among them is a desire to move the animal across State lines. The official takes a blood sample from the equine and then sends this sample (along with VS Form 10-11) to a VS-approved laboratory for analysis. The VS Form 10-11 provides a physical description of the equine, the date the sample was taken, the owner's name and address, and the name of the official who took the sample. The laboratory personnel need the information on VS Form 10-11 to link the blood sample to the equine from which the sample was drawn. Laboratory personnel complete the form after obtaining test results and send the form to VS.

Equine Infectious Anemia Supplemental Investigation (VS Form 10-12) - (Business) 9 CFR 75.4(b)(2)

If a blood sample is positive for EIA, then the farm where the equine resides must undergo a full investigation. Federal officials complete this form using information provided by the animal owners during the investigation. The VS Form 10-12 contains such information as the general vaccination history of the equines on the farm, the number of equines with which the positive

equine shares a pasture, and a site sketch of the farm. Receiving this vital information allows VS to effectively coordinate an EIA investigation and make critical decisions concerning which areas to quarantine.

Agreement for Approved Livestock Facility (Signature Only) - (Business) - 9 CFR 71.20

The owner or operator of a participating stockyard, laboratory, or diagnostic or research facility must promise to adhere to VS' guidelines and regulations when carrying out EIA-related activities. These requirements are spelled out in an agreement that the owner or operator must sign and return to VS.

Request for Hearing - (Business) - 9 CFR 75.4(d)(3)

If VS opts to deny or withdraw approval from a stockyard, laboratory, or diagnostic or research facility, the owner or operator of that facility may appeal the denial or withdrawal in writing within 10 days after receiving notification. The appeal must include all of the facts and reasons on which the owner or operator relies to show that the establishment was wrongfully denied listing. The owner or operator of that establishment may also request a hearing on the matter. During the hearing, the owner or operator may present arguments in support of continuing approval. The request for this hearing must be made in writing by the owner or operator and sent directly to VS.

Written Notification of Approval or Withdrawal - (Business) - 9 CFR 75.4

APHIS will automatically withdraw approval for a diagnostic or research facility to receive EIA reactors moved interstate when the facility's operator notifies APHIS, in writing, that the facility no longer receives reactors moved interstate.

The approval process requires the use of the following information collection activities:

Approval of EIA Laboratories and Diagnostic Facilities

The Administrator will approve laboratories and diagnostic facilities to conduct the official EIA test only after the physical facilities have passed an inspection conducted by an APHIS representative and after the Administrator has consulted with the State animal health official in the State in which the laboratory or diagnostic facility is located and has determined that the laboratory applicant:

- Has technical personnel assigned to conduct the official EIA test who have successfully completed training prescribed by the National Veterinary Services Laboratories (NVSL).
- Uses U.S. Department of Agriculture licensed test materials.
- Follows standard NVSL test protocols.
- Meets NVSL annual check test proficiency requirements.
- Refers all samples testing positive, suspect, discrepant, or equivocal (as defined in the diagnostic test kit or NVSL protocols) in any of the licensed EIA diagnostic tests, to NVSL for confirmation.
- The laboratory provides the State animal health official and Assistant Director of the District with timely (within 24 hours) reports of any positive EIA results

- The laboratory provides the Equine Health Team & State animal health official with timely (no more than 30 days lag) reports of monthly totals of negative and positive EIA tests grouped by test type (e.g. AGID and ELISA and sample origin state).
- Maintains a 500 test annual minimum.
- Accepts samples only from a USDA Category II accredited veterinarian and with approval to conduct accredited activities in the state in which the sample was drawn.
- Accepts submissions only with approved, properly and completely filled, EIA test forms.
- Accepts submissions only on animals properly identified with a narrative description of: name, age, breed, sex, color and permanent markings (tattoos, brands, whorls, scars, etc.) in addition to any additional means of identification submitted (microchips, drawings, photographs, breed registration number, etc.).
- Passes an annual laboratory inspection.

New to Information Collection

Proposal to Conduct Laboratory EIA Testing - (Business and State) - 9 CFR 75.4

Applicants for laboratory approval must provide the following information:

- a. Acknowledgment of familiarity with VS Memo 555.16 or Guidance Document (VSG) 15201.1; whichever is current.
- b. A description of the expected client base (sales barn, university, etc.);
- c. A description of the anticipated hours of operation and staffing plan;
- d. Anticipated number of samples to be tested annually;
- e. A description of any plans for mobile or satellite testing;
- f. A description of proposed operational start date and training plans for personnel;
- g. A description of the laboratory space;
- h. Laboratory and laboratory director's contact information; and
- i. Signature of the laboratory director.

The proposal and other available information will be reviewed by the animal health official for the State in which the laboratory is located, who will work with the Assistant Director of the District to reach a consensus on whether to accept or deny the proposal.

Review of Requirements and Interview - (Business and State) - 9 CFR 75.4

A Federal animal health official, in conjunction with a State animal health official, will review with the laboratory director the regulatory and technical requirements for conducting EIA tests. The inspection checklist, standards for accepting samples, reporting results, and reporting summary data will be reviewed. The laboratory director will demonstrate a thorough working knowledge of the requirements detailed in VS Memo 555.16 or VSG 15201.1., whichever is in effect.

Agreement to Conduct EIA Testing - (Business) - 9 CFR 75.4

The laboratory director must sign and date this document and provide the laboratory's address and contact information.

Inspection - (Business) - 9 CFR 75.4

APHIS will conduct an inspection of the laboratory premises, equipment, and functions. The laboratory director (or his or her representative present at the time of inspection) must provide his or her contact information as well as that of the laboratory in general; the names of employees trained and authorized by NVSL to conduct EIA tests and the dates of their authorization; in the case of State, university, or military laboratories: the names of employees for which in-house training has been authorized and the date of their authorization by NVSL.

Memorandum of Recommendation and Justification - (State) - 9 CFR 75.4

This document will be signed by the State animal health official and the AD. The document will be sent to NVSL with the above listed documents via approved electronic or other means.

Monthly Summary Reporting - (Business) - 9 CFR 75.4

Approved laboratories will report summary EIA test results monthly to APHIS via a VS approved Excel spreadsheet, or other VS approved electronic means of data submission.. Laboratories will report the number of positive and negative tests AGID and ELISA tests, and State of origin.

Denial and Withdrawal of Approval of Laboratories - (Business and State) - 9 CFR 75.4

Denial or withdrawal of approval may occur when any EIA laboratory or diagnostic facility fails to meet the criteria for approval discussed above. Further, approval for a laboratory or diagnostic facility to conduct the official EIA test would be automatically withdrawn when the operator notifies the NVSL, in writing, that the laboratory or facility no longer conducts the official test. The AD and the State animal health official will review and approve the request for withdrawal.

In the case of a denial, the operator of the laboratory or facility will be informed of the reasons for denial and may appeal the decision in writing to the Administrator within 10 days after receiving notification of the denial. The appeal must include all of the facts and reasons on which the person relies to show that the laboratory or facility was wrongfully denied approval to conduct the official test. The Administrator will grant or deny the appeal in writing as promptly as circumstances permit, stating the reason for his or her decision.

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.

- **Surveillance Collaborative Services (SCS)**

APHIS or State personnel enter information provided by animal owners into the SCS. Information is from the various official forms and other listed activities, such as owner name, address, contact information, premises identification numbers, premises name, address, type of premises (production unit, market, slaughter plant, etc.), and species.

- **Veterinary Services Process Streamlining (VSPS)**

VSPS provides a consistent and standard method of data capture at all levels and provides data dissemination to the appropriate existing databases. This provides a more comprehensive analysis tool for animal tracking and disease analysis which in turn, would allow VS to respond quickly to any threats to animal health in the United States.

The VS Form 1-27 must physically accompany the shipment of animals from the farm of origin to the slaughtering establishment. This form can be completed using the SCS and VSPS electronic systems.

VS Form 10-11 is available as a paper form and for electronic submission through VSPS.

VS Form 10-12 is available as a paper form and a PDF fillable. It must include a sketch of the affected premises, and is currently not available for purely electronic transmission.

Agreements require original signatures by all signing parties to be valid and are therefore not candidates for electronic submission.

The request for hearing and Written Notification of Approval Withdrawal may be made via a telephone call or email to APHIS. For legal purposes, however, electronic communication must be followed up in writing containing original signatures.

The monthly summary report can be submitted via email using the VS approved Excel spreadsheet or other VS approved electronic means of data submission..

The items related to laboratory approval require original signature and are not a candidate for electronic submission.

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 that APHIS collects for the EIA program is exclusive to its mission of regulating the interstate movement of equines to prevent the spread of disease, and is not available from any other source.

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

The information APHIS collects is the minimum needed to ensure that equines moving interstate do not pose a health threat to the U.S. equine population. APHIS Estimates 90 percent of the respondents are considered small businesses.

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, APHIS would be unable to establish an effective defense against the spread of EIA. This could have serious health consequences for U.S. equines and economic consequences for the U.S. equine industry.

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;**

Request for Hearing - If APHIS denies the listing of an establishment, the owner or operator of that facility may appeal the denial in writing within 10 days after receiving notification.

Written Notification of Approval Withdrawal - If APHIS withdraws approval from a facility, the owner or operator of that facility may appeal the withdrawal in writing within 10 days after receiving notification.

The monthly summary report is due to APHIS from approved labs each month.

- **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 extensive consultations with the following groups: State Animal Health Officials, Academia, the laboratory industry, the American Horse Council, the American Association of Equine Practitioners and others, in the form of an EIA Discussion Group. The following are a few individuals who were directly engaged concerning the information collection activities associated with this program:

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On Monday, September 12, 2016, pages 62701-62702, 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. One comment was received from a concerned citizen about her perception of the general maltreatment of animals. It had no relevance to the purpose of this information collection.

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

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

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

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

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

This information collection activity 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-I.

See APHIS Form 71. Burden estimates were developed from discussions with accredited veterinarians who participate in APHIS' program; laboratory, diagnostic, and research facility personnel; and owners and shippers of equines.

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

Respondents are producers, veterinarians, State Animal Health Officials, and laboratory directors. APHIS estimates the total annualized cost to these respondents to be \$5,077,755.15. APHIS arrived at this figure by multiplying the hours of estimated response time (118,005 hours) by the estimated average hourly wage of the above respondents (\$43.03). Estimated hourly

wages for the respondents were determined from the U.S. Department of Labor, Bureau of Labor Statistics May 2017 Report – See <http://www.bls.gov/oes/#tables>.

Owners and shippers [Farmers, ranchers, and other agricultural managers]: \$34.89

Veterinarians: \$47.48

State veterinarians - \$40.04

Laboratory, diagnostic, and research facility personnel [Animal scientists]: \$49.72

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 \$32,664. (See APHIS Form 79.)

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

	Requested	Program Change Due to New Statute	Program Change Due to Agency Discretion	Change Due to Adjustment in Agency Estimate	Change Due to Potential Violation of the PRA	Previously Approved
Annual Number of Responses for this IC	1,416,075	0	6021	- 271,088	0	1,681,142
Annual IC Time Burden (Hours)	118,005	0	962	-22,504	0	139,547
Annual IC Cost Burden (Dollars)						

There is a program change increase of +477 respondents and +6021 responses resulting in an increase of +962 total burden hours. This increase is due to APHIS now including burden associated with new requirements, associated with the Approval of EIA Laboratories and Diagnostic Facilities, which include:

- Proposal to Conduct Laboratory EIA Testing
- Review of requirements and interview
- Agreement to Conduct EIA Testing
- Inspection
- Memorandum of Recommendation and Justification
- Monthly Summary Reporting
- Denial and Withdrawal of Approval of Laboratories

There is adjustment decrease of -18,776 respondents and -271,088 responses resulting in a decrease of -22,504 total burden Hours. This decrease is due to fewer EIA laboratory tests were conducted in the past year, which accounts for the decreases.

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

APHIS plans to post this information regularly (at least quarterly and annually) on its page: <http://www.aphis.usda.gov/animal-health/equine-health-eia>

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 Form 1-27 is used in multiple information collections; therefore, it is not practical to include an OMB expiration date because of the various expiration dates for each collection. APHIS is seeking approval to not display the OMB expiration date on this form.

VS Forms 10-11 and 10-12 are serially numbered to track the movement of the shipment for regulatory purposes; therefore, APHIS is seeking approval to not display the OMB expiration date on these two forms.

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

APHIS can certify compliance with all provisions of the Act.

B. Collections of Information Employing Statistical Methods

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