

SUPPORTING STATEMENT FOR INFORMATION COLLECTION

UNITED STATES DEPARTMENT OF AGRICULTURE (USDA)

ANIMAL AND PLANT HEALTH INSPECTION SERVICE (APHIS)

VETERINARY SERVICES (VS)

CENTERS FOR EPIDEMIOLOGY AND ANIMAL HEALTH (CEAH),

NATIONAL ANIMAL HEALTH MONITORING SYSTEM (NAHMS)

NAHMS Emergency Epidemiologic Investigations

**SUPPORTING STATEMENT FOR INFORMATION COLLECTION BY THE
CENTERS FOR EPIDEMIOLOGY AND ANIMAL HEALTH (CEAH),
NATIONAL ANIMAL HEALTH MONITORING SYSTEM (NAHMS)¹
OMB NUMBER 0579-XXXX**

NAHMS Emergency Epidemiologic Investigations

May 2011

A. Justification

1. Explain why the collection of this information is necessary

This submission is an emergency request for approval to initiate the National Animal Health Monitoring System's (NAHMS) emergency epidemiologic investigations program, an information collection activity performed by the Animal and Plant Health Inspection Service (APHIS). Early recognition of animal disease conditions and the rapid application of prevention and control measures are fundamental to the Veterinary Services (VS) mission of Safeguarding Animal Health. Disease outbreaks and natural disasters create extraordinary demands for animal health services. Because of the immediacy, complexity, and resources required to respond to these events, States and industry look to VS for short-term epidemiologic and laboratory expertise in a broad variety of disease situations and conditions, as well as expertise in dealing with rare or foreign animal diseases. The primary objective of these investigations is to quickly discover the etiology and mode(s) of transmission of diseases so that prevention and control measures can be rapidly instituted. VS employees (veterinarians, laboratorians, epidemiologists, etc.) work collaboratively with the state or local animal health authorities during most emergency situations. APHIS is requesting a new, three-year OMB approval to collect epidemiologic data during these time sensitive situations.

The circumstances that emergency data collection authority will be used include those where:

- The agent is unknown, and VS must provide assistance in collecting and analyzing data on the conditions surrounding and preceding the onset of the problem
- The agent is known but exhibits uncharacteristic morbidity or mortality
- The outbreak involves more than one state and uniform data are needed
- The outbreak is considered to be an emerging, zoonotic, or a foreign animal disease
- A delay in data collection would result in the loss of epidemiologic information essential to assist laboratory investigations and/or disease control efforts

APHIS is requesting approval for a 180-day outbreak investigation period where data can be collected to perform epidemiologic investigations. If more than 180 days are needed to complete an investigation, APHIS will begin procedures to conduct a full clearance request (regular or emergency).

¹ The National Animal Health Monitoring System is responsible for collecting national data on animal health and productivity from voluntary participants.

2. Indicate how, by whom, and for what purpose the information is to be used. Indicate the actual use the Agency has made of the information received from the current collection.

The primary objective of NAHMS' emergency epidemiologic investigations is to provide for the prevention and control of animal disease conditions and protect the U.S. livestock population from the introduction and spread of domestic, emerging, zoonotic, and foreign animal diseases. APHIS meets this objective by maintaining laboratory capabilities for identifying potential disease agents, collecting and analyzing data to track disease occurrence, and recommending appropriate actions for livestock owners, managers, and animal health officials to protect human and animal health. Data on the conditions surrounding and preceding the onset of an outbreak must be collected in a timely fashion so that information can be used to identify the cause of the outbreak, to interrupt disease transmission, and to develop control strategies. Data may also be used to make recommendations to the public health community to support human health in the event of a zoonotic disease.

In general, VS is the Federal agency most likely to receive the request to assist with an investigation regarding livestock health events in unusual clusters of morbidity or mortality, large outbreaks, and incidents affecting more than one State. VS may also be asked to assist the public health community in the event of a zoonotic disease event. APHIS will use the data collected to:

- Identify the scope of the problem.
- Define and describe the affected population and the susceptible population.
- Predict or detect trends in disease occurrence and movement.
- Understand the risk factors for disease.
- Estimate the cost of disease control and develop intervention options.
- Provide parameters for mathematical models of animal disease to evaluate potential control scenarios.
- Make recommendations for disease control.
- Provide lessons learned and guidance on the best methods to avoid future outbreaks based on thorough analysis of data from current outbreak(s).
- Identify areas for further research e.g. mechanisms of disease transfer, vaccine technology, and diagnostic testing needs.

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.

The majority of these information collections will be performed via direct interview, written questionnaires on-farm, or telephone interview. Interviews are designed to be as unobtrusive as possible, and only the minimum amount of information necessary is collected. Respondents will complete paper surveys for these studies.

4. Describe efforts to identify duplication.

Literature searches and discussions with industry, State, local, and academic officials will be conducted to determine the extent of existing information. For investigations carried out during

the deployment of a National Incident Management System (NIMS) team, the liaison officer has responsibility for coordinating Federal activities with State counterparts and other stakeholders. This liaison officer will be consulted to determine if the potential for duplication exists. Emergency situations generally require the collection of data specific to a particular outbreak, because each occurrence is unique in many aspects and thus contributes to the stated objectives. Typically, no other entity/source is collecting and analyzing this type of information on animal disease outbreaks within the United States.

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

Surveys are designed to collect the minimum amount of data required to respond to the emergency or outbreak situation. All emergency epidemic investigations are voluntary; it is at the discretion of the producer to decide whether or not it is desirable to participate. Less than 5% of the respondents will be from small operations.

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

Without this type of activity VS' ability to determine the etiology and mode(s) of disease transmission would be severely diminished. Emergency epidemiologic investigations will allow VS officials to rapidly implement prevention and control measures, keep the public informed to reduce fear or panic, and keep international markets open by informing trading partners. Timely recognition and response to animal health epidemics is critical to reducing disease spread, minimizing the public health risk for zoonotic diseases, alleviating animal suffering, and preserving market access which has the potential to reduce the impact of an outbreak event on the global marketability of animals, animal byproducts, and meat. Investigations may also be performed retrospectively to help formulate strategies for preventing future outbreaks and discover risk factors that may be critical to preventing future outbreaks. These assessments may also provide valuable parameters for VS to simulate disease spread using mathematical models and identify areas for further research (e.g. vaccine or diagnostic test).

7. *Explain any special circumstances that would cause an information 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;**
- **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.**

This information collection is consistent with guidelines established 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.

During 2011, APHIS consulted with the following individuals concerning this study:

Keith Kliene
 American Association of Equine Practitioners (AAEP)
 Director of Industry Relations
 4075 Iron Works Parkway
 Lexington, KY 40511
kkliene@aaep.org
 859-233-0147

Dudley Hoskins
 American Horse Council
 Health and Regulatory Committee Staff
 1616 H Street, NW, 7th Floor
 Washington, DC 20006
dhoskins@horsecouncil.org
 202-296-4031

Dr. Paul Lunn
 Colorado State University
 College of Veterinary Medicine and Biomedical Sciences
 Chair of Department of Clinical Sciences
 Fort Collins, CO 30523
lunn@colostate.edu
 970-297-1274

The Agency's notice of information collection activity was announced in the Federal Register on May 17, 2011, pages 28414-28415.

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

Free diagnostic testing for disease identification may be used during emergency epidemiologic investigations. If a herd/flock is found to have a regulatory disease (Foot and Mouth Disease, High Path Avian Influenza, Q Fever, etc.) APHIS is authorized to euthanize infected and at risk animals and compensate producers with indemnity payments.

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

Collection and dissemination of animal health data and information is mandated by 7 U.S.C. § 391, the Animal Industry Act of 1884,² which established the precursor of APHIS, Veterinary Services, and the Bureau of Animal Industry. Legal requirements for examining and reporting on animal disease control methods were further mandated by 7 U.S.C. § 8308, 8314 of the Animal Health Protection Act, "Detection, Control, and Eradication of Diseases and Pests," May 13, 2002³. While this statute allows NAHMS to collect information through epidemiologic investigations, it does not allow NAHMS to provide respondents with any assurance of confidentiality. Information on an individual operation may be disclosed if regulatory action is necessary. Whenever possible, NAHMS will attempt to ensure that any findings released publicly will be based on summary estimates. All completed survey forms will be stored securely in a limited-access records vault.

11. Provide additional justification for any questions of a sensitive nature.

Questions that might be considered sensitive such as breeding practices, drug use, and the monetary value of animals may be included when considered necessary for the particular outbreak or emergency situation being investigated. Before administering questionnaires or interviews, VS designated data collectors will inform respondents (either verbally or in writing) that participation is voluntary.

12. Provide estimates of the hour burden of the collection of information.

- A.** A total of 2,175 burden hours are needed to complete emergency epidemiologic investigations over the 3-year clearance period for this information collection. A detailed burden estimate has been included on the enclosed APHIS 71 Form.
- B.** Respondent costs: Estimated respondent costs for the information collection proposed are calculated based on a data collection estimate of \$10.91 per hour.³ The total respondent cost for performing emergency epidemiologic assessments is \$23,729.25 (2,175 hours * \$10.91).

² United States Code § 391, and 7 U.S.C. § 8308 are available upon request.

³ NASS Farm Labor, published report for 2006, released November 20, 2009, available upon request.

13. Provide an estimate of the total annual cost burden to respondents or record keepers resulting from the collection of information (do not include any hour burden shown in items 12 and 14).

There are no capital/start-up costs or ongoing operations and maintenance costs associated with this information collection.

14. Provide an estimate of annualized cost to the federal government.

The estimated cost to the Federal Government is \$92,852.12. For more specific information, please see the enclosed APHIS 79 form.

15. Explain the reasons for any program changes or adjustments reported in items 13 or 14 of the OMB form 83-I.

This is a new information collection to investigate future disease outbreaks. No program adjustments or changes are reported.

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

The primary use of epidemiologic data will be to provide information necessary for controlling an animal health outbreak or other animal health emergency in order to prevent the loss of livestock. Data may be used after an event in presentations or academic/journal articles. Data analysis will be performed primarily by NAHMS staff, however State, local, academic, and industry representatives may be involved as needed. Any publication of data derived from epidemiological studies may be subject to review by these parties. Any published data will be available at http://www.aphis.usda.gov/animal_health/nahms/index.shtml.

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 is not seeking an exemption to display the expiration date for OMB approval.

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

APHIS is able to certify compliance with all provisions in the Act.