SUPPORTING STATEMENT 0579-0000 VOLUNTARY BOVINE JOHNE'S DISEASE CONTROL PROGRAM

February 6, 2008

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.

In 1997, the United States Animal Health Association's National Johne's Working Group appointed a committee to design an affordable and flexible program based on science. The result was the U.S. Voluntary Johne's Disease Herd Status Program. Instead of certifying herds free of M. paratuberculosis, the herd status program provides minimum requirements to identify herds with a low risk of infection. APHIS used this program as a model for the Uniform Program Standards for the Voluntary Bovine Johne's Disease Control Program (VBJDCP) approved by USDA, APHIS, in April 2002.

The VBJDCP is a cooperative effort between Federal, State, and industry. States administer the program and industry and the Federal Government provide support. APHIS supports the effort through funding cooperative agreements with the States. To track the performance of the State programs and to monitor progress made by producers receiving benefits from the cooperative agreement funds, the collection of data must be standardized.

The cooperative agreement provide that cattle, sheep, goats, and other domestic animals that are positive to an official test for Johne's disease may generally be moved interstate only to a recognized slaughtering establishment or to an approved livestock facility for sale to such an establishment

Supplementing the cooperative agreement is the Uniform Program Standards for the Voluntary Bovine Johne's Disease Control Program (VBJDCP) that outlines the minimal national standards of the program providing specifics on administration of the program, program elements and procedures, and laboratory procedures. The uniform program standards document describes the cooperative VBJDCP to be administered by the State and supported by industry and the Federal Government.

The objective of this program is to provide minimum national standards for the control of Johne's disease. The program consists of three basic elements: (1) education, to inform producers about the cost of Johne's disease and to provide information about management strategies to prevent, control, and eliminate it; (2) management, to work with producers to establish good management strategies on their farms; and (3) herd testing and classification, to help separate test-positive herds from test-negative 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.

State Johne's Disease Control Program Annual Report VS 4-29

Veterinary Services (VS) will use the State Johne's Disease Control Program Annual Report (VS Form 4-29), in conjunction with the quarterly reports, to track the progress States make in completing program activities and to determine if the State is in compliance with the VBJDCP VS uses this information to make funding decisions for cooperative agreements. Participating States will submit one report annually.

Quarterly Report

VS will use the quarterly reports, in conjunction with the annual report, to track the progress States make in completing program activities and to determine if the State is in compliance with the VBJDCP. VS uses this information to make funding decisions for cooperative agreements. Participating States will submit one report quarterly.

Johne's Vaccination Record VS 4-27 and VS 4-27a

Johne's Vaccination Record, VS Form 4-27, and its Continuation Sheet, VS Form 4-27A, identify animals vaccinated for Johne's disease enabling States and VS to confirm an animal has been vaccinated. A form must be completed when a vaccine for Johne's disease is administered to calves in a herd that is enrolled in the program. The continuation sheet is necessary if more than 12 calves in a herd are vaccinated at a time. Animals vaccinated for Johne's disease could react to a tuberculosis test due to cross reactivity. A vaccination record will enable personnel conducting surveillance work for tuberculosis to respond appropriately if a Johne's vaccinated animal reacts to a tuberculosis test.

Cooperative State Federal Johne's Program Voluntary Bovine Johne's Disease Control Program Test Record VS 4-30 and VS 4-30a

VS Form 4-30, and its Continuation Sheet, VS Form 4-30A, will record samples submitted and laboratory results from testing done for the VBJDCP, enabling trace back. Test results are needed to manage disease issues. A continuation sheet is needed when more than 19 animals are tested at a time and would be routinely used when all test eligible cattle in a herd are tested at the same time. APHIS estimates that two forms per year will be generated assuming producers test twice a year.

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.

The Johne's quarterly report will be completed electronically using the Automated Webbased Data Submission System (AWBDS) of the VS Animals Health and Surveillance National Reports (http://gdbnatrpt.aphis.usda.gov/forms90/f90servlet?config=gdbnatrpt).

The Johne's annual report would currently be developed as a paper report but could be incorporated into the AWBDS in the future.

The burden is minimized by the fact that the forms are completed, for the most part, by Federal or State personnel, APHIS accredited veterinarians, or Johne's certified veterinarians (JCV). Fillable PDF forms will allow for electronic submission and filing of the information. Further, quarterly reports are automated through use of an electronic database.

All the other forms are being developed as a paper form but will be made into fillable PDF forms after approval to enable electronic submission of the data. Forms will be posted on gttp://www.aphis.usda.gov/vs/e_forms/ or http://www.aphis.usda.gov/library/forms/.

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 is not available from any other source. APHIS is the only Federal Agency responsible for detecting and controlling contagious animal diseases in the United States.

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

The information APHIS will collect in connection with this program is the minimum needed to assess the disease status of animals and premises, assist and track disease control efforts at the State and premises level, and track vaccination history.

APHIS estimates that 90% of the total respondents are small entities.

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.

Collecting this information less frequently or failing to collect it would greatly hinder the control of Johne's disease and possible lead to increased prevalence. APHIS needs to be able to identify and protect nonaffected herds to help reduce the national prevalence of the disease.

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.

This information collection is conducted in a manner consistent with the 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.

In 2008 APHIS engaged in productive consultations with the following individuals concerning the information collection activities associated with this program:

Elizabeth Patton

WI Department of Agriculture, Trade and Consumer Protection, Division of Animal Health 2811 Agriculture Drive, P.O. Box 8911 Madison, WI 53708-8911 (608) 224-4891, (608) 224-4871 Elizabeth.Patton@datcp.state.wi.us

Ernest Hovingh 115 Henning Bldg. Penn State University University Park, PA 16802 Eph1@psu.edu (814) 863-8526, (814) 863-2160

David R. Griswold, VMD Assistant Director Bureau of Animal Health and Diagnostic Services 2301 N. Cameron Street Harrisburg, PA 17110-9408 (717) 772-2852, fax (717) 787-1868 The Agency's notice of information collection activity was announced in the Federal Register on February 16, 2007, pages 7597-7598. No comments were received.

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. However, the confidentiality of information is protected under 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 program participants, including State animal health officials, herd owners, Johne's certified veterinarians, and State personnel who perform VBJDCP work.

•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 the above respondents to be (\$2,360,750.00). APHIS arrived at this figure by multiplying the total burden hours of

estimated response time (67,450) by the estimated average hourly wage of the respondents (\$35).

\$35.00 hourly rate is derived from the U.S. Department of Labor, Bureau of Labor Statistics June 2003 Report-National Compensation Survey; Occupational Wages in the United State, July 2002. See http://www.bls.gov/ncs/ocs/sp/ncb10239.pdf.

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.

There is zero annual cost burden associated with capital and start-up 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 \$2,803,855.08 (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 program.

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.

If forms were to be discarded because of an outdated OMB expiration date, but otherwise usable, higher printing costs would be incurred by the Federal Government. Therefore, APHIS is seeking approval to not display the OMB expiration date on its forms.

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

APHIS can certify compliance with all provisions under the Act.

B. Collections of Information Employing Statistical Methods

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