

SUPPORTING STATEMENT 0579-0338
VOLUNTARY BOVINE JOHNE'S DISEASE CONTROL PROGRAM

June 2010

Introduction

Information collection 0579-0148 will now be combined with 0579-0338 in an effort to increase efficiency and reduce redundancy in collecting information on controlling and eliminating Johne's disease. Collection 0579-0148 is scheduled to expire on 5/31/2012

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 APHIS' ability to compete in the world market of animal and animal product trade.

Johne's disease affects cattle, sheep, goats, and other ruminants. It is an incurable and contagious disease that results in progressive wasting and eventual death. The disease is nearly always introduced into a healthy herd by an infected animal that is not showing symptoms of the disease.

In 1997, the U.S. Animal Health Association's National Johne's Working Group appointed a committee to design an affordable and flexible disease control program based on science. The result was the U.S. Voluntary Johne's Disease Herd Status Program. Instead of certifying herds free of *Mycobacterium avium* subspecies *paratuberculosis* (*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 APHIS in April 2002.

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

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

Supplementing the cooperative agreements are the Uniform Program Standards for the VBJDCP. The standards outline the minimal national program requirements for the control of Johne's disease, providing specifics for States to follow in administering the program such as program elements and procedures and laboratory procedures.

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.

To meet the program elements, participants must: 1) file a State Johne's Disease Control Program Annual Report (VS Form 4-29), 2) file quarterly reports, 3) turn in a Johne's Vaccination Record (VS Forms 4-27 and 4-27A), 4) submit a Cooperative State-Federal Johne's Program Voluntary Bovine Johne's Disease Control Program Test Record (VS Forms 4-30 and 4-30A), 5) file Herd Enrollment forms, (VS Form 4-28), 6) Risk Assessment and Herd Management for Dairy Cattle forms, (VS Form 4-32), and 7) Risk Assessment and Herd Management for Beef Cattle forms (VS Form 4-35).

APHIS regulations also provide that cattle and other domestic animals suspected of having Johne's disease can be moved interstate for purposes other than slaughter, provided certain procedures are strictly followed. For example, sexually intact animals that are positive to the official Johne's disease test may be moved interstate for the collection of germplasm.

Moving Johne's-positive livestock interstate for slaughter or for other purposes without increasing the risk of disease spread requires the use of 1) an owner-shipper statement and 2) official ear tags. This information is currently approved under 0579-0148 and is being included in this package.

APHIS is asking OMB to approve, for 3 additional years, the use of information collection activities associated with its efforts to control Johne's disease in 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.

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

APHIS Veterinary Services (VS) uses the State Johne's Disease Control Program Annual Report (VS Form 4-29), in conjunction with the quarterly reports described below, to track the progress States make in completing program activities and to determine if the State is in compliance with the VBJDCP. APHIS uses this information to make funding decisions for cooperative agreements. Participating States submit one report annually. The information collected includes the name of the reporting State; the date range of the report; name and contact information of the designated Johne's disease coordinator; a link to the State's Web site; the number of education programs the State conducted for producers and veterinarians and the number of producers and veterinarians attending those programs; the number of herds in the education levels, management level and classification levels of the VBJDCP; the estimated beef and dairy populations enrolled in the VBJDCP along with a total estimate of all beef and dairy cattle in the State; estimated State and producer funds contributed to the program; and the names of the approved laboratories the State uses. This form is completed by each of the 50 states and Puerto Rico.

Quarterly Report

APHIS uses 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. This information is entered and validated through a Web-based data collection system and is either entered manually by State personnel or entered by electronic transfer from a State or Federal database. APHIS uses this information to make funding decisions for cooperative agreements. Participating States submit one report quarterly. The information collected includes the name of the reporting State; the date range of the report; the number of tests performed in the State (broken out by species); herd function (i.e., beef or dairy); test type, along with a summary of the test results; a summary of vaccinations given; and the number of herds enrolled, given risk assessments, and for which herd plans were developed. This report is completed by each of the 50 states and Puerto Rico.

Johne's Vaccination Record (VS 4-27 and VS 4-27A)

The Johne's Vaccination Record, VS Form 4-27, and its Continuation Sheet, VS Form 4-27A, identify animals vaccinated for Johne's disease and enable States and APHIS to confirm an animal has been vaccinated. The form must be completed by the accredited veterinarian, or State or Federal veterinary medical officer, 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. The information collected includes the producer's name, address, and other location information (including State and county); herd type; the vaccine given; the vaccine serial number and expiration date; dosage given; identification number of the animal(s); the animal's date of birth, breed, purebred status, or grade; and individual vaccine tattoo location (if a tattoo needs verification).

Animals vaccinated for Johne's disease could react to a tuberculosis test due to cross reactivity. A vaccination record enables 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, are used to record samples submitted and laboratory results from testing done for the VBJDCP, enabling producers to monitor herd prevalence and target herd management. Test results help 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. The accredited veterinarian, or State or Federal veterinary medical officer, fills out all but the test results section which is completed by the laboratory. The information collected includes: the producer's name and address (including State and county); the reason for the testing; herd type and size; the name and address of the accredited veterinarian performing the test(s); the name of the laboratory receiving the results and the date they were submitted; the test(s) requested; the sample number; animal identification information such as vaccine tattoo, age, breed, and sex; and the test results area.

Application for Herd Entry/Renewal into the Voluntary Bovine Johne's Disease Control Program (VS Form 4-28)

Farmers wishing to enroll or renew their herd in the Johne's Program must complete the VS Form 4-28. The information collected includes: the farmer's name and address (including State and county); the owner/manager's name and telephone number; farm/premises ID number; herd type and size; the name

of the accredited veterinarian; the sample number; animal identification information such as vaccine tattoo, age, breed, and sex; and the test results area.

Risk Assessment and Herd Management for Dairy Cattle forms (VS Form 4-32) and Risk Assessment and Herd Management for Beef Cattle forms (VS Form 4-35)

APHIS and State field personnel and Johne's disease certified veterinarians fill out this form on the farm. The risk assessment and management plan sheets for dairy and beef cattle give APHIS and State field personnel and Johne's-certified veterinarians a structure for evaluating the risk of disease transmission on farms. They also provide a consistent format to develop herd management plans for controlling disease transmission. This information further allows State-designated Johne's disease coordinators to review work done by field personnel and Johne's-certified veterinarians. One risk assessment and herd management plan will be prepared for each dairy and beef farm enrolled in the program. The information collected for dairy herds is different from the information collected for beef cattle and requires slight modifications to the forms. Both sets of forms collect information on herd size and composition, past clinical disease rates and testing results, and operational goals. The forms then set forth a set of questions about management and business practices that pose a risk of transmitting *M. paratuberculosis*. The questions discuss calving area management, pre- and post-weaning calf management, heifer management, breeding age heifer management, adult animal management and replacement animal management. This information is summarized to identify management areas that present the greatest risk of disease transmission, and a brief disease herd management plan is developed and recorded.

Owner-Shipper Statement (VS 1-27) (formally in 0579-0148)

The owner-shipper statement can be completed by the owner or shipper of the animals. Use of the form enables these individuals to ship animals sooner than they could if they had to wait for Government personnel to issue a certificate or movement permit. (This, in turn, hastens the removal of sick animals from the farm, reducing the opportunity for disease to spread to healthy animals.)

The owner-shipper statement contains information similar to that contained in a certificate, including: (1) the number of animals to be moved, (2) the species of the animals, (3) the points of origin and destination, and (4) the names and addresses of the consignor and the consignee. The owner-shipper statement, like the certificate, provides written documentation alerting APHIS that affected animals are being moved interstate. This, in turn, enables APHIS to track the movement of these animals to ensure they have reached their appropriate destination.

Official Ear Tags (formally in 0579-0148)

APHIS' current regulations require that cattle positive to an official Johne's disease test that are being moved interstate be identified with an official ear tag that need not bear the inscription "U.S. Reactor." APHIS believes that such ear tags are more than sufficient to properly identify these cattle. Accredited veterinarians typically apply the official ear tag, which is used to trace these animals to their herd of origin even if they become separated from their accompanying documentation.

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 can be completed electronically using the Automated Web-Based Data Submission System (AWBDS) of the VS Animal Health and Surveillance National Reports (<http://gdbnatrpt.aphis.usda.gov/forms90/f90servlet?config=gdbnatrpt>).

The Johne's annual report is a paper report but could be incorporated into the AWBDS within the next 3 years. The forms will be made into fillable PDF forms after approval to enable electronic submission of the data. Forms will be posted on www.aphis.usda.gov/import_export/forms.shtml or www.aphis.usda.gov/library/forms

Test records and vaccination reports require original signatures and thus are not candidates for electronic submission.

The risk assessment documents are available in paper or electronic versions depending on the State receiving the risk assessments. If the State Designated Johne's Disease Coordinator is an APHIS employee, the risk assessment is submitted to that person in paper form. If the State Designated Johne's Disease Coordinator is a State employee, the documents may be submitted in paper form or may be submitted electronically if the State has developed a system for electronic submission. APHIS only receives a copy of the risk assessment for review if the State Designated Johne's Disease Coordinator is an APHIS employee.

The owner-shipper statement requires an original signature, and is therefore not a candidate for electronic submission.

Ear tags and other animal identification move with the animals, being physically attached, and therefore are not candidates 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 in connection with this effort is not available from any other source. APHIS is the only 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 collects is the absolute 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 percent 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.

If the information were collected less frequently or not collected at all, the ability of APHIS to control Johne's disease would be greatly hindered. APHIS needs to be able to identify and protect non-affected

herds as well as other healthy animals to help reduce the national prevalence of the disease to prevent serious economic and health effects for the U.S. livestock industry. This disease is contagious and fatal, and affects many different kinds of ruminants.

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;**

Johne's Vaccination Record (VS 4-27 and VS 4-27A) are prepared monthly.

- **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.**

There are no other special circumstances associated with this information collection.

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 2010, APHIS engaged in productive consultations with the following individuals concerning the information collection activities associated with this program:

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On Friday, November 19, 2010, pages 70896 – 70897, APHIS published in the Federal Register, a 60-day notice seeking public comments on its plan to request a 3-year renewal of this collection of information. During that time APHIS received no comments.

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, Johnes-certified and accredited veterinarians, State personnel who perform VBJDCP work, and livestock shippers.

•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 \$1,071,145.30. APHIS arrived at this figure by multiplying the total burden hours of estimated response time (38,187 hours) by the estimated average hourly wage of the respondents (\$28.05):

State animal health officials: \$29.64
Animal shippers: \$23.64
Animal producers: \$15.90
Veterinarians: \$43

The average hourly rate is derived from the U.S Department of Labor; Bureau of Labor Statistics May 2009 Report – National Compensation Survey: Occupational Employment and Wages, May 2008. See <http://www.bls.gov/oes/#tables>.

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 \$1,688,930. (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.

Information collection 0579-0148 is being merged into Information Collection 0579-0338. The VS Form 1-27 and Official Eartags will now be collected in this collection.

The overall burden has decreased since the last renewal of this information collection. Over the past few years the number of enrolled herds in the VBJDCP has decreased by about half due to the incidence of disease is declining, we are shifting our program activities (not phasing out the program entirely) to education and support of State activities. Funding declines mean we will be shifting more responsibility for monitoring this disease to the States. This reduction of enrolled herds resulted in the development of fewer herd enrollment forms, risk assessments, and herd management plans:

	2007	2010
Herd enrollments	8,550	4,275
Risk assessment – dairy	6,050	2,010
Risk assessment – beef	2,375	790

Further, the number of test reports and continuation sheets prepared dropped from 14,250 in 2007 to 7,125 in 2010. There was a slight increase (by one) in the numbers of annual and quarterly reports. The number of vaccinations given, owner-shipper statements prepared, and ear tags installed did not change from 2007 to 2010.

There is an adjustment decreasing the number of respondents by -38,950 resulting in a decrease in the number of responses -38,120. There is a decrease of -29,263 total burden hours.

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.

Not applicable. APHIS will display the expiration date on all forms except VS Form 1-27. This form is used in 8 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 the VS Form 1-27.

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.