

**SUPPORTING STATEMENT OMB NO.0579-0237
CWD HERD CERTIFICATION PROGRAM**

May 2012

Background

After publication of the July 21, 2006 final rule, but before its effective date, APHIS received three petitions requesting reconsideration of several requirements of the rule. On September 8, 2006, APHIS published a notice in the Federal Register (71 FR 52983, Docket No. 00-108-4) that delayed the effective date of the CWD final rule while APHIS considered those petitions. On November 3, 2006, APHIS published another notice in the Federal Register (71 FR 64650-64651, Docket No. 00-108-5) that described the nature of the petitions and made the petitions available for public review and comment, with a comment period closing date of December 4, 2006. APHIS subsequently extended that comment period until January 3, 2007, in a Federal Register notice published on November 21, 2006 (71 FR 67313, Docket No. 00-108-6). We received 77 comments by that date. On March 31, 2009, we published in the Federal Register (74 FR 14495-14506, Docket No. 00-108-7; "the March 2009 proposed rule") a proposal to amend the July 2006 final rule. This final rule sets an effective date for the July 2006 final rule and makes changes to it based on the March 2009 proposal and on the comments we received on that proposal.

During this time, APHIS decided to let the approved information collection (0579-0237) expire at OMB's suggestion so that when APHIS was ready to republish the final rule, APHIS could simply reinstate 0579-0237. Aside from the final rule, APHIS published a reinstatement notice and request for comments (60-day comment period) in the Federal Register (described in question 8 below).

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

Chronic Wasting Disease (CWD) is a transmissible spongiform encephalopathy of elk, deer, and moose typified by chronic weight loss leading to death. The presence of CWD in cervids causes significant economic and market losses to U.S. producers. In an effort to accelerate the control and limit the spread of this disease from the United States, APHIS is publishing an amended CWD final rule to create a cooperative, voluntary Federal-State-private sector CWD Herd Certification Program designed to actively identify farmed or captive herds infected with CWD and provide for the management of these herds in a way that will prevent further spread of CWD.

Owners of elk, deer, and moose herds who choose to participate in this program would need to follow program requirements for animal identification, testing, herd management, and movement of animals into and from herds. APHIS' amended CWD final rule would also establish interstate movement requirements for the movement of cervids to prevent the interstate movement of elk, deer, and moose that pose a risk of spreading CWD.

Implementing this program will entail the use of several information collection activities:

- 1) A Memorandum of Understanding (MOU) between APHIS and participating States initiated by a request from the State
- 2) A formal request to participate in the program
- 3) A formal request to participate by States
- 4) Wild Cervid Identification (for Interstate Movement)
- 5) Farmed Cervid Identification

- 6) Reporting of cervid escapes, disappearances, and deaths
- 7) Recordkeeping: herd records including inventory
- 8) Certificates and/or animal identification documents to move cervids interstate
- 9) An appeal letter to contest a suspension from the program
- 10) A herd or premises plan if CWD is discovered
- 11) Lab submission

APHIS is asking OMB to approve, for 3 years, its use of these information collection activities in connection with APHIS' efforts to identify, prevent, and control CWD 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.

APHIS uses the following information activities to identify, prevent, and control CWD in the United States.

MOU between State and APHIS Animal Health Authorities

State animal health authorities who desire to enter their State into the State-Federal Cooperative CWD Herd Certification Program must sign a MOU between APHIS and the State that delineates the respective roles of each in the program's implementation. States need only sign the MOU once to enroll in the program. Once enrolled, this form of burden is eliminated.

Letter to Request Participation – Business (VS form 11-1 and 11-1A)

Captive cervid herd owners may apply to enter the CWD Herd Certification Program by sending a written request to APHIS, if a State program does not exist. Captive cervid herd owners need only apply to participate once. Once enrolled in the program, this form of burden is eliminated.

Letter to Request Participation – State (VS form 11-2)

Any State that operates a State program to certify the CWD status of deer, elk, or moose may request the Administrator to designate the State program as an Approved State CWD Herd Certification Program. The State must submit their request, as well as a copy of the State's program, for the Administrator to review. The Administrator will approve or disapprove a State program in accordance with subpart 55.23(a) of the Code of Federal Regulations. Once a State is approved, this form of burden is eliminated.

Wild Cervid Identification (for Interstate Movement)

Each captive wild cervid must be identified with at least two forms of identification attached to the animal by the originating State. One form of identification must be official. The animal also must be accompanied by a certificate documenting the source population to be low risk for CWD. APHIS role in cervid identification is to supply electronic identification tags to the producers that request them.

Farmed Cervid Identification

Each animal in a participating herd must be identified with at least two forms of identification. One form of identification must be official. The official identification must provide a unique identification number that is applied by the owner of the herd or the owner's agent and must be linked to that herd in a State or National CWD Database. APHIS role in cervid identification is to supply electronic identification tags to the producers that request them.

Report of Cervid Escapes, Disappearances, and Deaths

Herd owners must immediately report to an APHIS employee or State representative all animals that escape or disappear, and all deaths (including animals killed on premises maintained for hunting and animals sent to slaughter) of deer, elk and moose in the herd aged 12 months or older. APHIS employees or State representatives may approve reporting schedules other than immediate notification when herd conditions warrant it in the opinion of both APHIS and the State.

Recordkeeping: Herd Records

The participating herd owner must maintain herd records that include a complete inventory of animals that states the species, age, and sex of each animal, the date of acquisition and source of each animal that was not born into the herd, the date of disposal and destination of any animal removed from the herd, and all individual identification numbers (from tags, tattoos, electronic implants, etc.) associated with each animal. These written records will be of critical importance during any trace-back investigation that APHIS may need to conduct and must be maintained as long as the herd remains in the program. In addition, a herd owner must complete physical herd inventory must be performed for all herds enrolled in the CWD Herd Certification Program no more than 3 years after the last complete physical herd inventory for the herd. States will need to review and reconcile the submitted inventories each year for each owner. They may also be involved with the physical inventory that the owner needs to complete.

Interstate Movement Certificate

No applicable cervid may move interstate unless it meets the requirements of section 81.3. This includes but is not limited to; cervid originates from a herd enrolled in the CWD Herd Certification Program, has reached Certified Status, and is accompanied by a certificate completed by an accredited veterinarian that documents the origin, identity, and health status of the animal being moved. The certificate must show the official identification numbers of each animal being moved, the number of animals covered by the certificate, the purpose for which the animals are being moved, the points of origin and destination, the consignor, and the consignee. The certificate must also include a statement by the issuing accredited veterinarian that the animals were not exhibiting clinical signs associated with CWD at the time of examination. States receiving a request for import of animals into their State will review the Interstate Health Certificate and any other documents that are received with the import request before deciding to allow the animal(s) to be imported. APHIS receives requests for capture and interstate movement of wild cervids.

Letter to Appeal Suspension

If a herd owner's enrollment in the CWD Herd Certification Program is canceled or their status is lowered, the herd owner may appeal the proposed cancellation or status reduction in writing to the Approved State or APHIS, for those herds that are in States that do not have a Herd Certification program. The appeal letter must include all of the facts and reasons on which the herd owner relies to show that the reasons for the proposed cancellation are incorrect or do not support the cancellation.

Herd or Premises Plan

When CWD is discovered in a captive cervid herd the owner must participate in a herd or premises plan. This written management plan will be developed by APHIS with input from the herd owner and State animal health authorities. The plan sets out the steps to be taken to eliminate CWD from a CWD- positive herd, or to prevent the introduction of CWD into another herd. A herd plan will require specified means of identification for each animal in the herd; regular examination of animals in the herd by a veterinarian for signs of disease; reporting to a State or APHIS representative of any signs of central

nervous system disease in herd animals; maintaining records of the acquisition and disposition of all animals entering or leaving the herd, including the date of acquisition or removal; the name and address of the person from whom the animal was acquired or to whom it was disposed, cause of death, and whether the animal died while in the herd. A herd plan may also contain additional requirements to prevent or control the possible spread of CWD depending on the particular condition of the herd and its premises—including but not limited to: specifying the time for which a premises must not contain cervids after CWD positive, exposed, or suspect animals are removed from the premises; fencing requirements; selective culling of animals; restrictions on sharing and movement of possibly contaminated livestock equipment; cleaning and disinfecting requirements; or other requirements.

Lab Submission

Accredited/Attending Veterinarians and State Animal Health Officials will collect samples of cervid tissue. The tissue will be submitted to labs for testing. All samples must be appropriately labeled. These same individuals report the test results back to the owners and if the results are a suspected positive, the sample will be retested by APHIS in Ames, IA. It is then the States' responsibility of how to handle the potential outbreak.

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 information collection requirements associated with this program will be submitted electronically once these methods are developed. In the meantime, required information will be submitted by mail. Except for the identification of cervids (requiring that cervids be physically identified with ear-tags, tattoos, or microchips) and the interstate movement certificate, which requires original signatures in order to be valid. The program intends on taking advantage of electronic scanners to capture and transmit animal identification as well the on-line Veterinary Services Laboratory Submission system whenever possible.

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 preventing, detecting, and controlling CWD 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 is collecting in connection with this program is the absolute minimum needed to effectively operate a certification program designed to identify and track farmed cervids in the United States. Of the cervid herd owners, APHIS anticipates working with directly or indirectly in the Federal CWD herd certification program (HCP), APHIS would expect that the majority, perhaps 75% or more, would be considered 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 make it impossible for APHIS to launch its CWD Herd Certification Program, thereby hindering APHIS' ability to prevent and control the spread of CWD in the United States.

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;**
- **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;**

APHIS is requiring herd owners to maintain their herd records for as long as the herd remains in the CWD program. This time varies from herd to herd.

- **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 conducted in a manner consistent with the guide lines 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 record keeping, 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 2012, APHIS engaged in productive consultations with the following individuals concerning the information collection activities associated with this program:

Shelly Chavis, DVM
District 3 Field Veterinarian
Chronic Wasting Disease Director
4154 North Keystone Avenue
Indianapolis, IN 46205
cell: 260-450-2139
office: 317-544-2400

Mary Martin
Chronic Wasting Disease Program
Pennsylvania Department of Agriculture
408 Agriculture Building
2301 N Cameron St
Harrisburg, PA 17110
Phone: 717-783-5309
Fax: 717-787-1868

Gary Edwards
Owner: Thunder Bay Whitetails
United Deer Farmers of Michigan Board Member &
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On Tuesday, January 24, 2012, APHIS published a reinstatement of an information collection and 60-day comment period in the Federal Register. During the 60 days, APHIS received 2 comments. Both comments were in support of the program.

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 institute, 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 begin 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 cervid herd owners, industry representatives, and State animal health authorities.

- **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 **\$3,687,005.52**. APHIS arrived at this figure by multiplying the hours of estimated response time (**157,536 hours**) by the estimated average hourly wage of the above respondents (**\$21.02 for business, \$39.20 for State**). APHIS determined the estimated hourly wage from the U.S. Department of Labor, Bureau of Labor Statistics May 2009 Report - Occupational Employment and Wages in the United States. See <http://www.bls.gov/oes/> .

13. Provide estimates of the total annual cost burden to respondents or record keepers resulting from the collection of information (do not include the cost of any hour burden shown in items 12 and 1"). The cost estimates should be split into two components: (a) a total capital and start-up cost component annualized over its expected use full 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 \$83,133 (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.

Overall, the burden hours decreased 242,066 hours from 399,602 hours to 157,536 hours. The responses also decreased 104,860 responses from 150,002 responses to 45,142 responses.

After careful evaluation, the Program determined several updates needed to be reflected in this reinstated collection. The Participation of States, a necessary addition of burden, was previously unaccounted for in the collection. The figures used in the collection are an estimate as the implementation of the CWD program has been delayed and the amended final rule is expected to be published in 2012.

MOU between State and APHIS Animal Health Authorities

The number of MOU's APHIS will be entering into with Approved States was increased from five to 20. Twenty is the number of States that will be approved within the first year of the program.

Letter to Request Participation (Application for Enrollment)

The Participation of States, a necessary addition of burden in this collection, was previously unaccounted for in the collection. It was originally thought that all Requests for Participation would come from the herd owner directly to APHIS (5000) but now with the necessary addition of State involvement, it is anticipated that only 100 herd owners will be directly applying to APHIS. These herds will be from States that do not presently have a Chronic Wasting Disease Herd Certification program. Herd owners need only apply to participate once.

Participation by States

The State Request for Participation was decreased to 20. APHIS anticipates only 20 States applying for Approved State Status the first year. The actual time it will take for each State to write a written request that meets all of the requirements stated in accordance with subpart 55.23(a) of the Code of Federal Regulations was increased from 1 hour to 20 hours. This increased time is to allow States to have adequate time to answer all the questions as accurately as possible. Once a State is approved, they will no longer have to complete this burden item.

Report of Cervid Escapes, Disappearances, and Deaths

Using current Chronic Wasting Disease sample submission to APHIS, number of responses per respondent was decreased from 12 to 6 for both the herd owner and the State receiving the report. The number of States that will be enrolled in the program was decreased to 20 as stated above.

The number of escapes, disappearances and deaths being reported to APHIS was decreased from 30,000 to 600. This large drop is due to the increase in the States involvement in the program. APHIS will only be reviewing notifications from the 100 herds it is managing in the program.

Recordkeeping: Herd Records

States participation in the Herd records has been added as a burden. Approved States will be required to reconcile the written and physical inventory of every herd enrolled in the Herd Certification Program. There will only be one response per herd to the State. It will take the State approximately 5 hours to reconcile the inventories.

The number of herd records APHIS will be responsible for reconciling and storing decreased from 5000 to 100 is again because of the involvement of States in the program now. The hours per response increased from one to ten because of the reconciliation process and the physical inventories APHIS may be called to be involved with.

Interstate Movement Certificate

After conferring with State Agencies, the number of responses per respondent was decreased for ten to three. APHIS also added a new burden for the States on their involvement with Interstate Movement Certificates. There will be up to 50 States involved with the interstate movement of farmed or captive cervids. They will receive

approximately 300 requests and it will take them 1 hour to approve/disapprove each interstate movement request.

Letter to Appeal Suspension

The number of suspension letters was increased from 5 to 40 per year. This was increased after gathering information from State Agencies on the number of herds that receive a suspension each year. States report an average of 2 suspensions per year. This would mean two suspensions from the 20 Approved State herds. Number of responses per herd owner was dropped from ten to one; owners would only need to submit one appeal letter. APHIS has added the State burden to the owners appeal. Each Approved State would receive two letters of appeal and would spend two hours on response to the appeal.

Herd or Premises Plan

The number of herds needing a Herd Plan was increased from one herd to two and the time the herd owner spends on the Plan was increased from one hour to ten. This increase is due to the increased negotiations that are occurring when APHIS develops these Herd Plans. States are also now becoming involved in the development of the Herd Plan. The time burden of the State is 20 hours.

Herd Plan number was increased from one to two. The time for the herd plan was increased from two hours to 50 hours. This large increase is due to a more thorough scientific evaluation, planning, and legal advisement that is now required for each plan.

Lab Submission

This activity was added to the information collection, because it was previously overlooked.

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 we collect 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 in appropriate.

Not applicable. APHIS will display the expiration date.

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

APHIS can certify compliance with all provisions.

B. Collections of Information Employing Statistical Methods

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