SUPPORTING STATEMENT 0579-xxxx
Approved Test for Bovine Tuberculosis in Cervids

January 2013

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.

In connection with this mission, the USDA's Animal and Plant Health Inspection Service (APHIS) works with the nation's livestock industry and State animal health agencies to eradicate bovine tuberculosis (TB) from domestic livestock in the United States and prevent its recurrence. Federal regulations implementing this program are contained in Title 9, *Code of Federal Regulations* (CFR) part 77. Subpart C (9 CFR 77.20 to 9 CFR 77.41) addresses captive cervids.

TB is a contagious and infectious granulomatous disease caused by the bacterium *Mycobacterium bovis*. Although commonly defined as a chronic debilitating disease, TB can occasionally assume an acute, rapidly progressive course. While any body tissue can be affected, lesions are most frequently observed in the lymph nodes, lungs, intestines, liver, spleen, pleura, and peritoneum. Although cattle are considered to be the true hosts of *M. bovis*, the disease has been reported in several other species of livestock, most notably bison and captive cervids.

APHIS recently received a request to evaluate the CervidTB Stat-Pak® test, a primary test, and Dual Path Platform (DPP)® test, a supplemental test, as official tests for TB in the following species of captive cervids: elk, red deer, white-tailed deer, fallow deer, and reindeer. APHIS has determined that the tests can reliably detect the presence or absence of antibodies to TB in these species of captive cervids. Accordingly, APHIS is amending the captive cervid regulations to recognize these two tests as official tuberculosis tests. These tests require the submission of samples to the National Veterinary Services Laboratories (NVSL).

The performance of these tests requires the use of the "Specimen Submission Form" (VS 10-4) and the application of pre-printed labels to provided shipping containers for shipping samples to

the NVSL. The use of "Tuberculosis Test Record" (VS 6-22) is also required; however, this requirement is covered by an existing information collection (Bovine Tuberculosis, OMB Number 0579-0146) and no additional burden is added by this interim rule and associated information collection regarding this form.

APHIS is asking OMB to approve its use of these information collection activities so that the Stat-Pak® and DPP® tests may be used to help prevent the spread of TB in captive cervids.

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.

All of the requested information will be used to determine the disease status of the captive cervid herd being tested.

Specimen Submission Form (VS 10-4): This form must accompany any shipment of samples to the NVSL for official testing. The form is used by accredited veterinarians (including State animal health officials) to record information about the animals being tested and the tests to be performed. About 95 percent of the veterinarians submitting samples from captive cervids are private accredited veterinarians, 2.5 percent are State-employed veterinarians, and 2.5 percent are federally employed veterinarians. The following information is recorded on the form: The submitter's name; NVSL ID; email address; phone number, fax number, and mailing address; the herd owner's name, city, and State; the premises identification number, county, and State where the herd is located; number of animals in the herd; number of affected animals in the herd; number of dead animals in the herd; examinations requested; name of the sample collector; date of collection; purpose of the submission; referral number; sample preservation type; specimen type; total number of specimens; total number of animals sampled; species sampled; official identification of sampled animals; and the signature of the submitter.

Application of Labels to Packaging for Shipment to NVSL: Accredited veterinarians performing TB testing on captive cervids are provided with pre-printed labels and shipping materials to be used when shipping samples to NVSL. The labels, which bear the NVSL address (1920 Dayton Ave., Ames, IA 50010), must be applied to the package to ensure proper delivery. About 95 percent of the veterinarians submitting samples from captive cervids are private accredited veterinarians, 2.5 percent are State-employed veterinarians, and 2.5 percent are federally-employed veterinarians.

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 Specimen Submission Form (VS 10-4) is available electronically on APHIS' Web site at http://www.aphis.usda.gov/animal_health/lab_info_services/forms_publications.shtml. The document cannot be submitted electronically because it must physically accompany the shipment of samples it describes.

The NVSL provides the pre-printed shipping labels to accredited veterinarians performing TB tests on captive cervids. The labels cannot be submitted electronically because they must physically accompany the shipment to the NVSL.

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 program is not available from any other source. APHIS is the only Federal agency responsible for preventing, detecting, controlling, and eradicating bovine TB or other foreign animal diseases from 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 effectively evaluate the submitted samples for the presence of TB. APHIS estimates about 95 percent of the respondents are small businesses (private accredited veterinarians).

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 TB in captive cervids. An outbreak of bovine TB in a captive cervid population would have serious health consequences for all U.S. cervids and serious economic consequences for the U.S. cervid industry. APHIS would be unable to operate an effective bovine TB surveillance, containment, and eradication program.

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;**

- **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 special circumstances associated with this information collection. 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 2012, APHIS engaged in productive consultations with the following State veterinarians concerning the information collection activities associated with this program:

Dr. Keith Roehr
Colorado Department of Agriculture
700 Kipling St., Suite 4000
Lakewood, CO 80215-8000
Office Telephone: (303) 239-4166
Email: Keith.roehr.@ag.state.co.us

Dr. Dee Ellis
Texas Animal Health Commission
P.O. Box 12966
Austin, TX 78711-2966

Office Telephone: (512) 719-0704
Email: dee.ellis@tahc.state.tx.us

Dr. Richard Wilkes
Virginia Department of Agriculture and Consumer Services
Division of Animal & Food Industry Services
P.O. Box 1163
Richmond, VA 23218
Office Telephone: (804) 692-0601
Email: richard.wilkes@vdacs.virginia.gov

On Wednesday, January 9, 2013, APHIS published an interim rule in the Federal Register (APHIS -2012-0087) which describes its information gathering requirements, and also provides a 60-day comment period. During this time, interested members of the public will have the opportunity to provide APHIS with their input concerning the usefulness, legitimacy, and merit of the information collection activities.

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 accredited veterinarians (including State animal health officials).

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

Respondents are accredited U.S. veterinarians, including State animal health officials. The burden on federally employed veterinarians is not included in the public burden estimate. APHIS estimates the total annualized cost to the above respondents to be $11,099. APHIS arrived at this figure by multiplying the hours of estimated response time (253 hours) by the estimated average hourly wage of the above respondents ($43.87).

The average hourly rate is derived from the U.S. Department of Labor; Bureau of Labor Statistics May 2011 Report – National Occupational Employment and Wage Estimates United States. See http://www.bls.gov/oes/current/oes_nat.htm

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 $64,860. (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 information collection resulting in an additional 253 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 the 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.

The VS Form 10-4 is used in multiple OMB-approved collections; therefore APHIS is seeking approval to not display the OMB expiration date on these forms.

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

APHIS can certify compliance with all the provisions in the Act.

B. Collections of Information Employing Statistical Methods

Statistical methods will not be used in this information collection.