SUPPORTING STATEMENT 0579-XXXX
Brucellosis Class Free States and
Certified Brucellosis-Free Herds;
Revisions to Testing and Certification
Requirements

This Interim Rule and request for comments was published on December 27, 2010; however, at the time of publication, APHIS wanted to submit the information collection package as an emergency, like the rule, but was unable to because it did not fit into the new definition of an emergency. The information collection was then inadvertently lost in the process; however, APHIS has not collected any information from the States (public). APHIS is now requesting approval of the information collection activities.

December 2011

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 U.S. Department of Agriculture's Animal and Plant Health Inspection Service (APHIS), Veterinary Services' (VS) ability to allow U.S. animal producers to compete in the world market of animal and animal product trade.

APHIS regulations for preventing the dissemination of animal diseases within the United States are contained in title 9 of the *Code of Federal Regulations* (9 CFR), Subchapter B, Cooperative Control and Eradication of Livestock or Poultry Diseases. Veterinary Services (VS), a division within APHIS, is responsible for administering these regulations.

In connection with this mission, VS participates in the Cooperative State-Federal Bovine Brucellosis Eradication Program, a national program to eliminate bovine brucellosis from the United States. This program is conducted under State and Federal authorities regulating interstate movement of affected animals.

Brucellosis is an infectious disease, caused by bacteria of the genus *Brucella* that affect both animals and humans. The disease mainly affects cattle, bison, and swine; however, goats, sheep, horses, and humans are susceptible as well. In its principal animal hosts, it causes loss of young through spontaneous abortion or birth of weak offspring, reduced milk production, and infertility. There is no economically feasible treatment for brucellosis in livestock. Brucellosis is also a public health concern because humans can contract it. Effectively and expeditiously controlling and eliminating sources of brucellosis is necessary to eliminate further spread of disease and protect human health. The APHIS bovine brucellosis program regulations in 9 CFR part 78 provide a system for classifying States or portions of States according to the rate of *Brucella abortus* infection present and the general effectiveness of a brucellosis control and eradication program. The program also provides for the creation of brucellosis management areas within a State and for testing and movement mitigation activities before regulated animals are permitted to move interstate. This system enhances the ability of States to move healthy, brucellosis-free cattle and bison interstate and internationally. This management area and testing system also enhances the effectiveness of the Bovine Brucellosis Eradication Program by decreasing the likelihood that infected animals will be moved interstate or internationally.

The creation of brucellosis management areas allow States that have found *B. abortus* in wildlife (which are nonregulated animals) to mitigate the risk of transmission and spread of disease while maintaining the State's disease-free status in regulated domestic livestock. The State must sign a memorandum of understanding (MOU) with the Administrator that describes its brucellosis management plan. The brucellosis management plan developed by the State must define the geographic brucellosis management area and describe the surveillance and mitigation activities that the State will conduct to identify occurrence of *B. abortus* in domestic livestock and wildlife and potential risks for spread of the disease.

The use of brucellosis management areas necessitates the use of information collection activities including 1) the brucellosis management plan, and 2) the MOU. The information provided by these documents is critical to APHIS' mission to prevent the introduction or spread of bovine brucellosis. APHIS is asking the Office of Management and Budget (OMB) to approve the use of these information-gathering activities for 3 years in connection with APHIS' bovine brucellosis program.

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 2 information collection activities to prevent the introduction or spread of bovine brucellosis.

Brucellosis management plans (no form)(State)

Any State in which the Administrator has determined wildlife are infected with *B. abortus* must develop and implement a brucellosis management plan approved by the Administrator. The Administrator may also require a Class Free State or area to develop and implement a brucellosis management plan under any other circumstances if the Administrator determines it is necessary to prevent the spread of brucellosis. The Administrator may reclassify to a lower status any State or area that has not implemented an approved brucellosis management plan within 6 months of being required to develop one. The brucellosis management plan, which is written by State animal health and (if necessary) wildlife officials, must 1) define and explain the basis for the geographic area in which a disease risk exists from *B. abortus* and to which the brucellosis management plan activities apply; 2) describe epidemiologic assessment and surveillance activities to identify occurrence of *B. abortus* in domestic livestock and wildlife and potential risks for spread of disease; and 3) describe mitigation activities to prevent the spread of *B. abortus* from domestic livestock and/or wildlife, as applicable, within or from the brucellosis management area. The State officials submit the plan for review to the VS Area or Regional Office. The plan is reviewed by VS officials at the Area, Regional, and Headquarters levels before being signed by State animal health (and, if necessary) wildlife officials as well as VS Regional Office officials. VS retains the original plan. States generally keep a copy for their records, but are not required to by APHIS.

Memorandum of Understanding for Brucellosis management plans (no form) (State)

As part of the process for developing and implementing a brucellosis management plan, the State must enter into an MOU with APHIS which describes the brucellosis management plan the State will administer. The MOU is prepared by VS and State animal health and wildlife (as appropriate) officials and signed by all parties. The MOU must be updated annually.

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.

Both the brucellosis management plan and memorandum of understanding are unique to each situation and may be prepared electronically; however, because original signatures are required, they 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 is not available from any other source. APHIS is the only Federal agency responsible for preventing, detecting, controlling, and eradicating bovine brucellosis 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 in connection with this program is the absolute minimum needed to maintain an effective bovine brucellosis eradication and surveillance program in the United States. The respondents who prepare and administer the two documents described in this information collection are State and Federal animal health and wildlife officials; therefore, there are no 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.

Failure to collect this information would cripple APHIS' ability to conduct an effective State-Federal Cooperative Brucellosis Eradication Program. If this information was not collected, the incidence of brucellosis would begin to rise and the United States would soon lose the favored status it enjoys in national and international animal and animal product trade.

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.**

No special circumstances exist that would require this collection to be conducted in a manner inconsistent with the general information collection guidelines 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 2011, APHIS engaged in productive consultations with the following individuals concerning the information collection activities associated with this program:

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APHIS published an Interim Rule and request for comments on December 27, 2010. The 60-day comment was extended from February 25, 2011 to March 11, 2011 and during the entire comment period APHIS received 30 comments. They were from private citizens, State agencies, industry groups, animal welfare organizations, environmental groups, and members of Congress. The commenters raised a number of issues; including: Depopulation and Indemnity, Reclassification, Slaughter Surveillance, Resources and Funding, Testing Age, Surveillance Activities, and Wildlife. All of the comments are being addressed in the Final Rule. The comments can be viewed at

http://www.regulations.gov/#!searchResults;dct=PS;rpp=10;po=0;s=%255BDocket%252BNo.%252BAPHIS%25E2%2580%25932009%25E2%2580%25930083%255D

9. Explain any decision to provide any payment or gift to respondents, other than remuneration 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 State animal health and wildlife 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 State animal health and wildlife agency officials. APHIS estimates the total annualized cost to these respondents to be $65,232. APHIS arrived at this figure by multiplying the hours of estimated response time (1,800 hours) by the estimated average hourly wage of the above respondents ($36.24). Estimated hourly wages for the respondents were determined from the U.S. Department of Labor; Bureau of Labor Statistics May 2010 Report-National Compensation Survey: Occupational Wages in the United States, May 2009. (See http://www.bls.gov/oes/#tables.)
Wildlife Biologists - $29.17
Veterinarians - $43.32

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 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 $40,668. (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.

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.

APHIS is not seeking permission to omit expiration dates because this collection does not include any forms.

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

APHIS can certify compliance with all provisions of the Act.

B. Collections of Information Employing Statistical Methods

Statistical methods are not employed in this information collection activity.