

SUPPORTING STATEMENT - OMB NO. 0579-XXXX
Tuberculosis (TB); Require Approved Herd Plans Prior to Payment of Indemnity

December 10, 2007

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 accordance with Title 21, U.S.C. 111-113, 114, 115, 117, 120, 123, and 134a, the Secretary of Agriculture has the authority to promulgate regulations and take measures to prevent the introduction into the United States and the interstate dissemination within the United States of communicable diseases of livestock and poultry, and to pay claims growing out of the destruction of animals.

The U.S. Department of Agriculture (USDA) is responsible for preventing the introduction or dissemination of contagious or communicable diseases of animals, including birds and poultry, from a foreign country into the United States, or from one State to another. USDA's Animal and Plant Health Inspection Service (APHIS), through its Veterinary Services program, carries out this disease prevention mission. APHIS' regulations regarding general provisions for tuberculosis (TB) are contained in title 9, of the *Code of Federal Regulations* (CFR), part 77, and part 50 governs the regulations pertaining to animals destroyed because of TB and general indemnity to prevent the introduction of various animal diseases.

Since 1998, a total of 70 livestock herds have become affected with TB in the United States, and at least 5 of these herds were on premises where herds previously had been affected with TB and had either been depopulated and the herd owners paid Federal and State indemnity or undergone the approved quarantine, test, and removal program. Research indicates that there are ways to mitigate the spread of infection from wildlife to livestock, and herd plans have been developed for numerous herds specifying the mitigations that owners must implement to prevent re-infection.

The existing regulations require herd owners who have TB-infected livestock to have an approved herd plan. However, except in limited cases, the regulations do not require that an approved herd plan be in place prior to an owner receiving indemnity for livestock destroyed because of TB, nor do the regulations penalize owners whose subsequent failure to follow an approved herd plan results in re-infection of the herd or the infection of a replacement herd.

In order to place more responsibility on owners to adhere to prescribed mitigation measures and protect their herds from re-infection, APHIS is proposing to amend its

regulations to provide that an approved herd plan must be in place prior to the payment of indemnity, and to provide that 10 percent of the gross indemnity payment be held in escrow by APHIS until the conditions of an approved herd plan have been implemented. APHIS is also proposing to amend the regulations to deny any future payments of Federal indemnity for herds where an owner has failed to follow specific recommendations of an approved herd plan, or has violated the conditions of an approved herd plan.

APHIS' proposed amendments will increase the incentive for herd owners to comply with herd plans and therefore would reduce the likelihood of re-infection, which in turn would reduce the amount of Federal funds paid in indemnification. For producers generally, the proposed changes would help achieve the national goal of tuberculosis eradication.

TB is a contagious disease of both animals and humans. It is caused by three specific types of bacteria that are part of the *Mycobacterium* group: *Mycobacterium bovis*, *M. avium*, and *M. tuberculosis*. Bovine TB, caused by *M. bovis*, can be transmitted from livestock to humans and other animals. No other TB organism has as great a host range as bovine TB, which can infect all warm blooded vertebrates. *M. avium* can affect all species of birds, as well as hogs and cattle. *M. tuberculosis* primarily affects humans but can also be transmitted to hogs, cattle, and dogs.

APHIS' proposed amendments require the use of information collection activities in the form of an Approved Herd Plan.

APHIS is asking OMB to approve the use of these information collection activities for an additional 3 years.

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.

Approved Herd Plan

An approved herd plan is a written disease management plan that is designed by the herd owner(s) and/or their representative(s) and a State or Federal veterinarian. The herd plan must include appropriate herd test frequencies, tests to be employed, and any additional disease management or herd management practices deemed necessary to eradicate TB from the herd and prevent further spread of infection in an efficient and effective manner. Approved herd plans generally require a change in herd management, construction of barriers, pest control, and, in some cases, additional surveillance for TB on the owner's property. Thus, in most cases, compliance with an approved herd plan will be evident during a site visit and would not require the owner to provide any additional information or 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.

Herd plans are a written document designed by the herd owner and/or their representative(s) and a State or Federal veterinarian. Once completed, the plan can be sent to APHIS electronically via e-mail for review. Approximately, 20% of the herd plans will be submitted to APHIS electronically.

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 bovine TB 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 an effective indemnification program, which in turn is designed to eradicate bovine TB from the United States via the swift and thorough elimination of affected herds. All of the herd owners 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.

The presence of bovine TB in U.S. herds causes significant economic and market losses to U.S. producers. Collecting this information less frequently or failing to collect it would make it impossible for APHIS to effectively sustain its program to accelerate the eradication of bovine TB from 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.

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 2007, APHIS contacted the following individuals concerning the information collection activities associated with this program:

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APHIS' proposed rule (Docket No. APHIS-2006-0193), *Tuberculosis; Require Approved Herd Plans Prior to Payment of Indemnity*, will describe its information gathering requirements, and also provide 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 APHIS is proposing.

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 bovine herd owners, State animal health authorities, and VS field personnel who routinely engage in bovine TB indemnification activities.

•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 annual cost to these respondents to be **\$7,062.50**. APHIS arrived at this figure by multiplying the hours of estimated burden time (**500**) by the estimated average hourly wage of the above respondents (**\$14.125**) ($\$10.06 = \text{Inspectors}$

and \$18.19 = Agricultural Manager) from the U.S. Department of Labor, Bureau of Labor Statistics June 2003 Report - National Compensation Survey: Occupational Wages in the United States, July 2002. See <http://www.bls.gov/ncs/ocs/sp/ncbl0539.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 \$5,762.8844. (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 collection of information. The existing regulations require herd owners who have TB-infected livestock to have an approved herd plan. However, except in limited cases, the regulations do not require that an approved herd plan be in place prior to an owner receiving indemnity for livestock destroyed because of TB, nor do the regulations penalize owners whose subsequent failure to follow an approved herd plan results in re-infection of the herd or the infection of a replacement herd.

The indemnity program will increase the incentive for herd owners to comply with herd plans and therefore would reduce the likelihood of re-infection, which in turn would reduce the amount of Federal funds paid in indemnification. For producers generally, the proposed changes would help achieve the national goal of TB eradication.

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.