SUPPORTING STATEMENT - OMB NO. 0579-0212
BLOOD & TISSUE COLLECTION
AT SLAUGHTERING ESTABLISHMENTS

August 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.

Title 21, U.S.C. 117, Animal Industry Act of 1884, authorizes the Secretary to prevent, control and eliminate domestic diseases such as brucellosis and chronic wasting disease, as well as to take actions to prevent and to manage exotic diseases such as foot-and-mouth disease, rinderpest, and other foreign animal diseases.

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. The Veterinary Services Program of USDA's Animal and Plant Health Inspection Service (APHIS) is the unit responsible for carrying out this disease prevention mission.

APHIS regulations for governing the interstate movement of animals for the purpose of preventing the dissemination of animal diseases within the United States are contained in Title 9 of the Code of Federal Regulations, Subchapter C --Interstate Transportation of Animals (Including Poultry) and Animal Products.

Disease surveillance plays an important role in the APHIS mission of protecting the health of the U.S. livestock and poultry populations, and testing animals for disease is an important surveillance tool. APHIS can use epidemiological data from tests to assess the prevalence of disease and to identify sources of disease. When testing is coupled with animal identification, APHIS can trace a positive animal's movements and identify other animals with which it may have come into contact.

The surveillance program at slaughter and rendering facilities necessitates the use of a specimen submission form (and, on occasion, it's accompanying supplemental sheet if additional space is needed). APHIS is asking OMB to approve, for 3 years, its use of this information collection activity in connection with APHIS' efforts to perform testing at slaughter and rendering facilities, and thus prevent the spread of animal diseases within 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.

VS Form 10-4 and 10-4A, Specimen Submission Form and Supplemental Sheet

This form, which is used to identify specimens (blood or tissue) submitted for laboratory analysis, will be completed primarily by APHIS or Food Safety Inspection Service (FSIS) personnel working on-site at slaughter or rendering facilities. In certain instances when APHIS or FSIS personnel are occasionally unavailable to do this work, the VS Form 10-4 will be completed by APHIS contractors (slaughter plant personnel). This form identifies the individual animal from which the specimen was taken as well as the animal's herd or flock; the type of specimen submitted, and the purpose for submitting the specimen. Without the information contained on this form, our personnel at the National Veterinary Services Laboratories or other Federal laboratories would have no way of identifying or processing the specimens being sent to them for analysis.

Note: Persons who move livestock or poultry interstate for slaughter must only move the animals to an APHIS-approved slaughter establishment. Since an APHIS permit is already required for any interstate movement of animals, APHIS does not regard the completion of an interstate movement permit as an additional paperwork burden.

Facility Inspection Report (VS 10-5)

CFR 71.21 states that the Administrator will list a slaughtering or rendering establishment after determining that it meets facility and access requirements. Form VS 10-5, Facility Inspection Form, is used for this purpose. The form will be provided, completed, and signed by a VS official where the establishment is located. The VS Area Office will retain the original inspection report.

Sampling Collection Plan

Surveillance programs in APHIS are intended to characterize program diseases, track known disease problems, identify new and emerging disease problems for which Federal and State programs do not exist, and document disease freedom status for exotic diseases that do not exist in the United States. In order to meet the wide variety of animal disease surveillance goals in APHIS, it is necessary to collect blood or tissue samples at slaughter at different times, and under different circumstances. When a disease is suspected in a given area, sampling will be used to determine its presence or absence, and to estimate the incidence or prevalence if it is present. The amount of sampling may increase in selected areas when a disease outbreak is suspected, then later reduced in that area when sufficient tests have been done to prove the suspicion was unfounded or, if found, after the disease is eradicated.

Sampling will also be needed to provide data for new or updated risk analyses in support of disease control programs, and, as required, opening international markets for animal products. Constantly changing diseases, outbreaks, trade, and livestock industry conditions make it necessary for APHIS surveillance experts to continually revise the mix and degree of sampling activities, based on application of their expert knowledge to current conditions.

The amount of testing at a plant, if required, depends on whether APHIS is trying to prove freedom from a disease or delimit a known or suspected disease. For example, for diseases such as pseudorabies or foot-and-mouth disease that are highly infectious and have the potential for fast spread, only a relatively few samples are needed to detect the presence of disease.

On the other hand, chronic diseases such as brucellosis and bovine spongiform encephalopathy -- both of which spread slowly and are a threat to public health -- require many samples to be collected in order to detect the disease or to prove its absence.

Below are sampling statistics from 2007:

Animal	Number Slaughtered	Disease	Samples collected	Samples needed
Cattle	35,500,000	Brucellosis	12,000,000	12,000,000
Cattle	35,500,000	Tuberculosis	1,200	4,000
Hogs	101,100,000	Pseudorabies	750,000	1,200,000
Hogs	101,100,000	Brucellosis	750,000	1,200,000
Sheep	4,000,000	Scrapie	12,000	75,000

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 VS Form 10-4 and 10-4A must physically accompany the blood or tissue specimens to the laboratory. APHIS considered other ways of collecting the information electronically, but because of the requirement of identifying the specimens for the laboratory, electronic transmission is not an option.

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 detecting and preventing the spread of animal diseases within 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 minimum needed to implement its test-at-slaughter surveillance program. APHIS or FSIS presence at slaughter or rendering plants will be low key and should in no way impact day-to-day operations at these facilities.

This information collection does not impact small businesses or 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 effectively operate a test-at-slaughter surveillance program. This would negatively impact APHIS' ability to detect disease in the U.S. animal population, to prevent disease spread within the United States, and to ultimately eliminate certain animal diseases 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 will be 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 engaged in productive consultations with the following individuals concerning the information collection activities associated with this program:
Dr. Beth Lautner
National Pork Producers Council
122 C Street NW, Suite 875
Washington, DC 20204
515-223-2773

Gary Weber

National Cattlemen's Beef Association
1301 Pennsylvania Avenue NW, Suite 300
Washington, DC 20004
202-347-0228

Mr. Paul Rodgers
American Sheep Industry Association
Route 2, Box 94
Ronceverte, West Virginia 24970
304-647-9981

On Monday, March 19, 2007, pages 12754-12755, APHIS published in the Federal Register, a 60-day notice seeking public comments on its plans to request a 3-year renewal of this collection of information. One comment was received and it did not concern burden in this information collection.

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 slaughter facility personnel who would be collecting and submitting blood and tissue samples to Federal laboratories.

•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 respondents to be $148,114.71. APHIS arrived at this figure by multiplying the hours of estimated response time (4,209 hours) by the estimated average hourly wage of the above respondents ($35.19).

$35.19 hourly rate is derived 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 $169,683.00.
(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.

There is a program change of +13 hours due to adding the VS Form 10-5 to this collection and an adjustment of +80 and an adjustment of +80 hours due to the addition of new respondents. Therefore, the burden estimate and associated calculations have increased.

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 "Certification for Paperwork Reduction Act."

APHIS can certify compliance with all provisions in the Act.

B. Collections of Information Employing Statistical Methods

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