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

March 2010

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 i**s** 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.

Veterinary Services (VS), a program within USDA's Animal and Plant Health Inspection Service (APHIS), administers regulations governing the interstate movement of animals to prevent the dissemination of animal disease within the United States. These regulations are contained in title 9, *Code of Federal Regulations* (9 CFR), subchapter C, Interstate Transportation of Animals (Including Poultry) and Animal Products, part 71. The regulations also address animal testing for disease surveillance. APHIS uses epidemiological data from tests to assess the prevalence of disease and to identify sources of disease.

Disease surveillance activities at slaughtering and rendering facilities are conducted under a listing agreement signed by Federal personnel and slaughter/rendering establishment personnel. An establishment is listed after it undergoes inspection to ensure that it meets facility and access requirements).

APHIS may withdraw or deny the listing of an establishment if it determines that the establishment is no longer in compliance with APHIS regulations. APHIS must notify the establishment in writing of the denial or withdrawal. The establishment may appeal the denial or withdrawal but must do so in writing.

APHIS will also withdraw the listing if the owner or operator of the establishment notifies the Administrator, in writing, that the establishment no longer handles animals moved interstate under APHIS regulations or that the person who signed the listing agreement is no longer responsible for the day-to-day operations of the establishment.

To actually conduct surveillance activities at slaughtering and rendering facilities for certain animal diseases such as bovine spongiform encephalopathy (BSE), APHIS requires submission of a completed VS Form 10-4

(and, on occasion, its accompanying supplemental sheet, VS 10-4A, if additional space is needed) to accompany samples being shipped for testing.
APHIS is asking OMB to approve, for an additional 3 years, its use of these information collection activities in connection with its efforts to perform testing at slaughter and rendering facilities to help prevent the spread of animal disease 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.

Request for Appeal of Denial of Listing
If APHIS denies the listing of an establishment, the owner or operator of that facility may appeal the denial in writing within 10 days after receiving notification. The appeal must include all of the facts and reasons which the owner or operator relies to show that the establishment was wrongfully denied listing. The Administrator will grant or deny the appeal in writing as promptly as circumstances permit, stating the reason for his/her decision. If there is a conflict as to any material fact, a hearing will be held to resolve the conflict. The owner or operator must send the request for appeal directly to APHIS.

Request for Appeal of Withdrawal of Listing
If APHIS withdraws approval from a facility, the owner or operator of that facility may appeal the withdrawal in writing within 10 days after receiving notification. The appeal must include all of the facts and reasons upon which the owner or operator relies to show that the reasons for the proposed withdrawal are incorrect or do not support the withdrawal of the listing. The Administrator will grant or deny the appeal in writing as promptly as circumstances permit, stating the reason for his/her decision. If there is a conflict as to any material fact, a hearing will be held to resolve the conflict. The owner or operator must send the request for appeal directly to APHIS.

Withdrawal of a Facility
The Administrator will automatically withdraw the approval of a facility to handle livestock for blood and tissue collection if the operator of the facility notifies the Administrator, in writing, that the facility no longer handles livestock moved interstate; or that the person who signed the listing agreement is no longer responsible for the day-to-day operations of the facility.

Listing Agreement
APHIS surveillance programs 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. Meeting APHIS' wide animal disease surveillance goals requires the collection of blood or tissue samples at slaughter at different times, and under different circumstances. To accommodate these activities, APHIS requires these slaughter or rendering facilities to enter into a listing agreement with APHIS.

The listing agreement requires the plant to allow APHIS to collect samples. It contains the name, address, and telephone number of the slaughter facility and lists the type of animal carcasses handled at the facility. The listing agreement is especially helpful during disease outbreaks to avoid delay and disease spread. 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 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 is also 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.

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, is completed primarily offsite by APHIS contractors for BSE surveillance. (Use of this form for other diseases such as scrapie and bovine tuberculosis is tracked in separate information collections.) VS Form 10-4 contains information identifying the individual animal from which the specimen was taken as well as the animal's herd or flock and the type of specimen submitted. It also sets forth the purpose for submitting the specimen. The form is then sent with the sample to the laboratory for analysis. Without the information contained on the form, APHIS personnel at the National Veterinary Services Laboratories or other Federal laboratories could not identify or properly process the specimens sent to them for analysis.

Note: Under 9 CFR 71.21(a), persons who move livestock or poultry interstate for slaughter must only move the animals to an APHIS-approved slaughter establishment. Because 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 for blood and tissue collection.

Facility Inspection Report (VS 10-5)

The Administrator will list a slaughtering or rendering establishment after determining that it meets facility and access requirements. Form VS 10-5, the 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, using information provided by establishment personnel. The VS Area Office retains the original inspection report.

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 requests for appeal to the denial or withdrawal of an approved facility require an original signature from the facility owner and are therefore not candidates for electronic submission.

The notice of withdrawal also requires an original signature from the facility owner, and is therefore not a candidate for electronic submission.

The Listing Agreement requires the original signatures of plant personnel, and therefore is not a candidate for electronic submission.

The Facility Inspection Report requires the original signatures of plant personnel, and therefore is not a candidate for electronic submission.

The VS Form 10-4 and 10-4A must physically accompany the blood or tissue specimens to the laboratory to permit identification of the specimen. The forms are thus 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 for the test-at-slaughter surveillance program is exclusive to its mission of regulating the interstate movement of animals to prevent the spread of disease, and is not available from any other source.

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 minimum needed to conduct its test-at-slaughter surveillance program. Each slaughter and rendering facility employs fewer than 500 employees; therefore, 100 percent are considered to be 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.

If the information was collected less frequently or not collected, APHIS would be unable to effectively operate a test-at-slaughter surveillance program. This would hamper APHIS' ability to detect disease in the U.S. animal population, to prevent disease spread within the United States, and to 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.

APHIS will conduct this information collection in a manner consistent with the guidelines established in 5 CFR 1320.5.

- **requiring respondents to report information to the agency more often than quarterly;**

1. The listing agreement requires the plant to allow APHIS to collect samples from facilities whenever a disease outbreak is expected to avoid the spread of the disease.

- **requiring respondents to prepare a written response to a collection of information in fewer than 30 days after receipt of it;**

1. If APHIS denies the listing of an establishment, the owner or operator of that facility may appeal the denial in writing within 10 days after receiving notification.

2. If APHIS withdraws approval from a facility, the owner or operator of that facility may appeal the withdrawal in writing within 10 days after receiving notification.

- **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 other special circumstances associated with this information collection.

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 2009, APHIS engaged in productive consultations with the following individuals concerning the information collection activities associated with this program:

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Dr Paul Sundberg
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On Thursday, June 24, 2010, pages 36060 - 36061, 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 from the public. The comment was received from a Jean Public of Florham Park, NJ about her perception of the steps APHIS takes or lack of action to eradicate disease. It had no relevance to the purpose of the collection.

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 slaughter facility personnel.

•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 $109,227.69. APHIS arrived at this figure by multiplying the total burden hours (2,691 hours) by the estimated average hourly wage of the above respondents ($40.59).

The average hourly rate is derived from the U.S Department of Labor; Bureau of Labor Statistics May 2009 Report – National Compensation Survey: Occupational Employment and Wages, May 2008. See http://www.bls.gov/oes/#tables.

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 $190,167.13. (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.

After carefully reviewing procedures for this program, staff determined that a number of forms: VS 10-4 (Specimen Submission Form) and 10-4A (Continuation Sheet for the Specimen Submission Form), which were accounted for on the last renewal of this collection, are prepared by APHIS scrapie and bovine TB program staff (or, in the case of TB, by Food Safety and Inspection Service staff as well) and are being tracked through information collections for those diseases. Brucellosis is also tracked through a different information collection. This information collection renewal has been corrected to track only those VS Forms 10-4 and 10-4A filled out by contractors collecting BSE specimens. Moreover, few plants are currently being added to the APHIS list of approved slaughter facilities through new listing agreements, so the renewal tracks fewer plants signing listing agreements and undergoing inspections requiring the use of VS Form 10-5. There is an adjustment with the number of respondents decreasing by -112 respondents causing the number of responses to decrease by -2031 resulting in a decrease in the total burden hours by -1531.

The Appeal of Denial of Listing, the Appeal of Withdrawal of Listing, and the Withdrawal of Listing through notice from the facility, were not accounted for on the last renewal of this collection. However, they are rarely used and by adding them there is a program change. APHIS now requires Slaughter or Rendering Facilities to enter into Listing Agreement with APHIS causing a program change. The total program change is +23 respondents, +23 responses and +13 burden hours.

For all these reasons, while new burden was added, the overall burden on the public is reduced since the last renewal of this 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.

VS Forms 10-4 and 10-4A are used in 3 collections; therefore, it is not practical to include an OMB expiration date because of the various expiration dates for each collection. APHIS is seeking approval to not display the OMB expiration date on this form.

APHIS will display the expiration date on VS Form 10-5.

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.