November 2020

SUPPORTING STATEMENT
National Veterinary Services Laboratories;
Bovine Spongiform Encephalopathy Surveillance Program
OMB No. 0579-0409

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 (7 U.S.C. 8301–8317) 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.

Disease prevention is the most effective method for maintaining a healthy animal population and for enhancing our ability to compete globally in animal and animal product trade.

In connection with this mission, the USDA's Animal and Plant Health Inspection Service (APHIS) National Veterinary Services Laboratories (NVSL) safeguard U.S. animal health and contribute to public health by ensuring that timely and accurate laboratory support is provided by their nationwide animal health diagnostic system.

The USDA complies with the standard set by the World Organization for Animal Health (OIE) for bovine spongiform encephalopathy (BSE) surveillance. This compliance is critical for maintaining our BSE risk status with the OIE. In 2013, the OIE granted the United States negligible risk status for BSE, improving our standing with trading partners and reducing our surveillance requirements. APHIS reduced the target for BSE samples from 40,000 to 25,000 samples annually in 2016, and this remains the current target. Our BSE surveillance program requires several information collection activities, including completing VS Form 17-146, the BSE Surveillance Submission Form; VS Form 17-146a, the BSE Surveillance Submission Form Continuation Sheet; and VS Form 17-131, the BSE Surveillance Data Collection Form.

APHIS is asking the Office of Management and Budget (OMB) to approve its use of these information collection activities for 3 years in connection with APHIS' efforts to ensure that the NVSL can continue to effectively safeguard the U.S. animal health population against BSE.

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 information collection activities to safeguard the U.S. livestock population against BSE.

VS Form 17-146, BSE Surveillance Submission Form; (9 CFR 130.49); (State Gov't, Business)
This form is used to submit diagnostic samples for BSE testing. The form captures contact information for the submitter; information regarding where, and by whom, the sample was collected; unique identifiers for each sample being submitted; and tracking/control numbers.

VS Form 17-146a, BSE Surveillance Submission Form Continuation Sheet; (9 CFR 130.49); (State Gov't, Business)
This form is used to capture additional sample identifiers if the size of the submission exceeds the number of sample ID blanks on VS Form 17-146.

VS Form 17-131, BSE Surveillance Data Collection Form; (9 CFR 130.49); (State Gov't, Business)
This form is used only with VS Form 17-146 and 17-146a. A single VS Form 17-146 is completed for each submission to a diagnostic laboratory, but a single submission may contain samples from multiple animals. Epidemiological information about the animal from which each sample was obtained is critical for an effective surveillance program. Submitters are asked to complete a separate VS Form 17-131 for each animal in the submission described on VS Form 17-146. VS Form 17-131 captures the reason the animal was selected for surveillance; the owner's contact information; slaughter site contact information; the animal's breed, age, gender, and identifying numbers; descriptions of medical conditions the animal exhibited; and the animal's country of origin.

The data for all three of the above forms is routinely provided by slaughter establishments, offsite collection facilities for condemned slaughter cattle, rendering 3D/4D facilities, and accredited veterinarians. The information may also be provided by State animal health personnel or veterinary diagnostic laboratories. The forms are submitted to APHIS (i.e., the NVSL) or a contract laboratory (i.e., State or University veterinary diagnostic laboratory that is part of the National Animal Health Laboratory Network (NAHLN)).

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 data captured on these forms may be entered by authorized respondents directly into a Web-based database administered by APHIS for the NAHLN. The physical forms are used by those who do not want to enter the data directly into the database or do not have access to do so. The forms are available online in fillable PDF format so that they may be completed electronically and printed. Paper copies of the forms (or form-equivalent reports from the database) are included in the physical shipment of samples to the diagnostic testing laboratories.

Fillable PDF versions of the forms can be downloaded from the APHIS forms website at http://www.aphis.usda.gov/library/forms/index.shtml, or for those authorized access, completed on the VS Apps database at https://vsapps.aphis.usda.gov/vslabsub/login.do.

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 APHIS collects in connection with this effort is not available from any other source. APHIS is the only Agency responsible for safeguarding U.S. livestock against the incursion of BSE.

5. If the collection of information impacts small businesses or other small entities, describe any methods used to minimize burden.

APHIS estimates approximately 90 percent of the business respondents in this collection are small entities. APHIS has attempted to reduce the burden to small businesses by providing electronic versions of the forms. Businesses may complete these electronic forms with fixed information for their businesses and save the partially filled forms as a template, leaving only the changed information to be completed with each new submission.

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 monitor and prevent the incursion of BSE into the United States. We would also be unable to validate the surveillance necessary to maintain our negligible risk status for BSE with the OIE. This would cause serious health consequences to U.S. livestock and economic consequences for the U.S. livestock industry, which would be unable to export live animals or animal products due to trade restrictions.

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 3 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.

APHIS contacted the following individuals by email and phone to discuss the information collection activities associated with administering the BSE surveillance program. Discussed were how necessary data was collected and how frequently; how much data is available; convenience and clarity of reporting formats and other collection instruments; and the clarity of, and necessity for, any recordkeeping requirements. The respondents stated that they had no concerns with any of these items and had no further recommendations.

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On Monday, June 29, 2020, APHIS published in the Federal Register (85 FR 38840, pp. 38840-38841), a 60-day notice seeking public comments on its plan to request a 3-year renewal of this collection of information. No comments from the public were received.

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 other than remuneration to contractors.

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. Any and all information obtained in this collection shall not be disclosed except in accordance with 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 NVSL employees and contract 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 $104,317. This was computed by multiplying the estimated average hourly wage ($28.46) by the total number of burden hours (2,565) needed to complete the work, and then multiplying the result by 1.429 to capture benefit costs.

  The average hourly rates used to calculate the estimate are for slaughterers and meat packers [SOCC 51-3023], $14.23; production workers, all others [SOCC 51-9199], $16.26; veterinarians [SOCC 29-1131], $50.39; and animal scientists [SOCC 19-1011], $32.96. The rates were found at the U.S. Bureau of Labor Statistics website https://www.bls.gov/oes/current/oes_stru.htm.

  According to DOL BLS news release USDL-20-0451 released March 19, 2020, employee benefits account for 30 percent of employee costs, and wages account for the remaining 70 percent. Mathematically, total costs can be calculated as a function of wages using a multiplier of 1.429.

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.**

See APHIS Form 79. APHIS estimates the annualized cost to the Federal government to be $103,678.

15. Explain the reasons for any program changes or adjustments reported in Items 13 or 14 of the OMB Form 83-I.

	Requested	Program Change Due to New Statute	Program Change Due to Agency Discretion	Change Due to Adjustment in Agency Estimate	Change Due to Potential Violation of the PRA	Previously Approved
Annual Number of Responses	25,640	0	0	(4,608)	0	30,248
Annual Time Burden (Hr)	2,565	0	0	(461)	0	3,026

This request for renewal reflects a reduction of 4,608 responses and 461 response hours from the previous renewal. APHIS attributes the decline to a drop in the number of tests requested, which in turn is due to APHIS aligning its surveillance efforts with the amount of testing required to maintain the United States' OIE BSE negligible risk status.

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 requests an exemption from displaying the expiration date on the forms. Time and cost constraints may impede the Agency's ability to coordinate editing the PDF and information system versions of the forms. Because the forms do not undergo frequent edits, leaving the expiration dates off also contributes to minimizing confusion surrounding the forms' ICR expiration dates and their edition dates.

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

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