

**SUPPORTING STATEMENT
TUBERCULOSIS
OMB NO. 0579-0146**

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.

Disease prevention is the most effective method for maintaining a healthy animal population and 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, of the Farm Security and Rural Investment Act of 2002. The U.S. Department of Agriculture's Animal and Plant Health Inspection Service (APHIS), Veterinary Services' (VS) uses the regulations in Title 9, Code of Federal Regulations (9 CFR), Part 77 to manage bovine tuberculosis within the United States.

These regulations provide for the assignment of State TB risk classifications, the creation of TB risk status zones within the same State, and for the conduct of tests before regulated animals are permitted to move interstate. This system enhances the ability of States to move healthy, TB-free cattle, bison, and captive cervids interstate as well as internationally. Further, this zoning/testing system enhances the effectiveness of APHIS' TB Eradication Program by decreasing the likelihood that infected animals will be moved interstate or internationally. Both types of actions prevent the spread of TB and provide mechanisms to help VS trace, locate, and eradicate any outbreaks that occur. These activities enhance the U.S. Department of Agriculture's ability to allow U.S. animal producers to manage bovine tuberculosis and compete in the world market of animal and animal product trade.

APHIS is asking OMB to renew its approval 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.

APHIS uses the following information collection activities to support the TB Eradication Program. APHIS does not share any of this information with any other government agency:

Annual Report for Retention of Status, Entire State or Each Zone Within a State (VS Form 6-38, Accredited Area Surveillance for Tuberculosis), (9 CFR 77.4), (State)

To qualify for renewal of status, State animal health authorities must submit an annual report to APHIS certifying that the State (or zone within the State) is complying with the provisions of the Bovine Tuberculosis Eradication Uniform Methods and Rules, effective January 1, 2005. Federal personnel prepare this report in States lacking sufficient employees to do so. This report must be submitted to APHIS each year between October 1 and November 30. It enables APHIS to carefully monitor State activities with regard to TB surveillance, containment, and eradication.

Each report must include information on the population and status of cattle and bison herds (e.g., numbers of accredited herds and herds under quarantine) within the State or zone, the number of cattle and bison slaughtered, monitoring of slaughter surveillance and test response rates, and the identification of any cattle or bison herds or individual cattle and bison in which TB has been confirmed. Herds designated by State or Federal representatives as being at high risk for harboring TB based on testing history, possible exposure to TB, or other epidemiological linkage, as determined by the Administrator, must also be identified, and the report must indicate whether those herds have undergone required retesting. The report must document that the levels of TB testing, slaughter inspections, and necropsies were sufficient to meet requirements. The report must also include a narrative statement addressing how the State or zone has met these requirements.

Request for Zone Status, Application, (9 CFR 77.4), (State)

State animal health officials may formally request that APHIS designate part of their State as having a different TB status than the rest of the State. In this request, State animal health authorities must clearly delineate the boundaries of the requested zone. They must also provide evidence that the State has an effective veterinary organization and infrastructure, as well as the legal and financial resources, to implement and enforce a TB eradication program.

Memorandum of Understanding (MOU) for Zones, Initial and Yearly Testing Renegotiation, (9 CFR 77.4), (State)

As part of its application for and retention of zones, a State must enter into an MOU with APHIS in which the State agrees to any conditions for zone recognition or future advancement of status. These MOUs are subject to annual review.

Epidemiological Review of Zone Testing, (9 CFR 77.4), (State)

State animal health officials seeking APHIS approval to create a TB status zone must maintain, in each intended zone, clinical and epidemiological surveillance of animal species at risk for TB at a rate that allows detection in the overall livestock population at a 2 percent prevalence rate with 95 percent confidence. To support the formal request for zone status, APHIS requires that the designated TB epidemiologist (who may be either a State employee or a Federal employee) review reports of all testing for each zone within the State within 30 days of the testing.

TB Management Plan - Findings of TB in a Species Not Covered (Typically Wildlife), (9 CFR 77.7, 77.9, 77.11, 77.13, 77.22, 77.24, 77.26, & 77.28), (State)

If TB is diagnosed in a species not covered in 9 CFR part 77, in any State or zone, and if an APHIS risk assessment determines that the outbreak poses a risk to livestock within the State or zone, then the State or zone must implement a TB Management Plan within 6 months of the diagnosis. This plan must include provisions for: (1) An immediate investigation of TB in livestock, wildlife, and animals held for exhibition; (2) the prevention of disease spread to other animals; (3) increased surveillance; (4) eradication in individual herds; and (5) a timeline for achieving this eradication. If the State or zone does not implement this plan within 6 months of diagnosis, APHIS will downgrade the State or zone's TB status.

Accredited Herd Written Herd Plan, (9 CFR 77.1), (State)(Business)

Producers of accredited bovine herds in States or zones with a known wildlife reservoir of bovine TB, or in a State or zone with a TB status of modified accredited or lower, must submit a written herd plan to be approved by the APHIS-designated and State TB epidemiologists. Federal personnel may prepare this plan in States lacking sufficient employees to do so. This plan describes that adequate precautions have been taken and the herd has in place appropriate biosecurity measures documented in the plan that ensure the herd has not been exposed to TB during the accreditation process and will not be exposed to TB following accreditation.

Wildlife Risk Survey, (9 CFR 77.4), (State, Business)

When a wildlife component of disease exists in an area, State and Federal animal health officials may work with herd owners to conduct reviews which identify possible risks of disease infection from wildlife sources.

Report of Tuberculosis Eradication (Monthly Report) (VS Form 6-2), (9 CFR 77.7, 77.9, 77.11), (State)

Each State must prepare a report for the entire State or for each zone within the State within 30 days of the end of each month. The State's designated TB epidemiologist prepares and submits the report which covers the tuberculin testing that took place during the month and the reasons for the testing. Federal personnel may prepare this report in States lacking sufficient employees to do so. The epidemiologist submits data to the Surveillance Collaboration Services (SCS) which APHIS staff accesses as needed.

Report of Suspicious Tuberculosis Lesions or Thoracic Granulomas in Regular Kill Cattle (VS Form 6-35), (9 CFR 77.7, 77.9, 77.11), (State)

This form is submitted by Food Safety and Inspection Service (FSIS) and State meat inspection personnel when they detect suspicious lesions during slaughter examination. Personnel send reports to the National Veterinary Services Laboratory (NVSL); the FSIS laboratory in Athens, GA; or California's Department of Food and Agriculture laboratory for TB histopathology and bacteriology. All identification devices from the suspicious animal must be sent with the specimens to facilitate traceback of laboratory-positive cases to their herd of origin. The form identifies the samples, indicates what testing is needed, and provides any available clinical history.

Specimen Submission Form (VS Form 10-4, Necropsy Specimen Submission), (9 CFR 77.7, 77.9, 77.11, 77.33), (State)(Business)

State and Federal employees use this form to submit specimens for TB examination to NVSL, for any reason other than routine slaughter inspection. Accredited veterinarians also use this form to submit blood samples to NVSL. VS Form 10-4 is completed with information identifying the individual animal from which the specimen was taken, 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, NVSL personnel could not identify or properly process the specimens received for analysis.

Specimen Collection Form Supplement - Livestock/Wildlife (VS Form 10-7, Specimen Collection: Bovine Tuberculosis, Reactors, Suspects, and Trace-Exposed), (9 CFR 77.7, 77.9, 77.11, 77.33), (State)

State and Federal personnel complete this form to accompany samples from domestic livestock or wildlife submitted specifically on behalf of the TB program. It supplements VS Form 10-4.

Restricted Animals Movement Permit (VS Forms 1-27 and VS 1-27A Continuation Sheet), (9 CFR 77.17, 77.40), (State)(Business)

APHIS requires this form, or an equivalent State form, for all movements of TB-restricted animals. APHIS or State officials initiate the form using information obtained from the animal owner at the time animals are loaded for transport. The information includes the owner's name and address, the animals' points of origin and destination, the number of animals being moved, the purpose of the movement, and various pieces of animal identification data to identify each animal in the shipment. This form accompanies the shipment and is completed by Federal or State authorities and submitted to APHIS after the animals reach their destination.

Caudal Fold Test Record (VS Form 6-22, Cooperative State - Federal Tuberculosis Eradication Program Tuberculosis Test Record, and VS 6-22B Continuation Sheet), (9 CFR 77.1), (State) (Business)

Accredited, State, or Federal veterinarians use this form and the other VS 6-22-series forms to record vital data and official identification regarding tuberculin tests conducted on cattle and other animals. The forms are submitted to either the State animal health office or the VS Area Veterinarian in Charge for processing and entry into the SCS database. Individual animals and herds are tested for routine purposes such as sale, show, and milk ordinance and other State regulations. They are also tested for disease investigation where possible TB association has been shown.

Tuberculin Test Record (Special) (VS Form 6-22C), (9 CFR 77.7, 77.9, 77.11), (State)

This form records data for the comparative cervical tuberculin test (CCT) applied by State or Federal veterinarians to animals classified as suspects after a previously applied caudal fold or single cervical test.

Comparative Cervical Tuberculin Test Results (VS 6-22D), (9 CFR 77.1, 77.34), (State)

This form graphs responses recorded on the VS 6-22C report by State or Federal veterinarians to aid in the final classification of an animal as negative, suspect, or reactor.

TB Test Record, Gamma, (9 CFR 77.1), (State)(Business)

Gamma tests are conducted only on cattle classified as suspect after a previously applied caudal fold test. APHIS requires that any laboratory conducting this test report results to the designated State TB epidemiologist so the epidemiologist can classify the animals tested. Federal personnel may classify animals in States lacking sufficient employees to do so.

Affected Herd Data, (9 CFR 77.1), (State)

When a herd is identified as TB-affected, the Federal area epidemiologists, with the designated State epidemiologist and Federal staff epidemiologists, assembles the available epidemiological data regarding the affected herd, proposed testing protocols, and estimated risks and submits them to the National Surveillance Unit (NSU) of the Federal (APHIS VS) Centers for Epidemiology and Animal Health. NSU works with APHIS TB staff to develop recommendations for the APHIS Administrator on whether APHIS will support a test-and-remove plan or a depopulation-and-repopulation plan with Federal indemnity funds.

Affected Herd Testing Results, (9 CFR 77.1), (State)

The Federal area epidemiologists, with the designated State epidemiologist, and Federal staff epidemiologists, assemble the data from each herd test required under a test-and-remove herd plan. The data is submitted to NSU to evaluate further herd management.

Approved Herd Plan (Individual Herd Plan) - Test and Remove Plan, (9 CFR 77.1), (State)(Business)

The owner of a TB-affected herd must develop, with the help of a State and/or Federal veterinarian, a written disease management plan. The plan helps the owner eradicate TB from the herd efficiently and effectively. Owners of infected herds who purchase replacement cattle must have an approved herd plan in place to qualify for APHIS indemnity if the cattle become reactors on subsequent tests. The plan is submitted to APHIS through the VS Area Veterinarian in Charge.

A test-and-remove plan must include appropriate herd test frequencies, tests to be used, and any additional disease or herd management practices deemed necessary to eradicate TB from the herd and to efficiently and effectively prevent further spread of infection.

Herd plans may require a change in herd management, construction of barriers, pest control, and, in some cases, additional surveillance for TB on the owner's property. Compliance with an individual herd plan usually is evident during a site visit and the owner would not have to provide additional information or documentation.

Depopulation and Repopulation Agreement, (9 CFR 77.7, 77.9, 77.11), (State)

The owner of a TB-affected herd must develop, with the assistance of a State or Federal veterinarian, a written disease management plan. A depopulation-and-repopulation plan must be approved by APHIS, State agricultural officials, and State natural resources officials (if applicable). It must be in place before the premises may be restocked. The depopulation and repopulation plan ensures infection is not brought into the new herd. It may contain measures to mitigate the introduction of disease from non-livestock sources and to monitor the herd to ensure that disease has not returned.

Tuberculosis Infected Herd Field Report (VS Form 6-22A), (9 CFR 77.7, 77.9, 77.11), (State)

Using information collected from State or Federal databases, sale yards, or test records, the State epidemiologist completes this form to record all identifying devices, descriptions, and origin information regarding TB reactors to determine sources of infection. Federal personnel may prepare this report in States lacking sufficient employees to do so. The form is sent to the VS Area Veterinarian in Charge, with copies kept at the VS regional office.

Report on Herd Revealing Reactors to Tuberculin Test (VS Form 6-4), (9 CFR 77.7, 77.9, 77.11), (State)

This form, filled out by State or Federal veterinarians, provides a summarized history of the TB testing activities in an affected herd. It lists all TB tests completed on the herd, the number of responders, and the ultimate findings at slaughter. It also indicates the number of reactors by their origin, as well as the number of exposed cattle sold from the affected herd. Such information on sources of reactors and sales of exposed cattle is the focus of APHIS-State epidemiological investigations of affected herds.

Investigation for Evidence of Tuberculosis (Reactor) (VS Form 6-4A), (9 CFR 77.7, 77.9, 77.11), (State)

This form is completed by the State epidemiologist and provides for complete coverage of the investigation made on every animal entering a TB-affected herd. Federal personnel may prepare this form in States lacking sufficient employees to do so. Each purchased affected animal requires its own form. A single form may represent multiple animals if it is highly likely that they came from the same location.

Investigation for Evidence of Tuberculosis (Exposed Animal) (VS Form 6-4B), (9 CFR 77.7, 77.9, 77.11), (State)

This form is completed by the State epidemiologist and provides for complete coverage of the investigation made on every animal that left a TB-affected herd. A separate form must be completed for each animal. A single form may represent multiple animals if it is highly likely their destination was the same location. Federal personnel may prepare this form in States lacking sufficient employees to do so.

Appraisal and Indemnity Claim (VS 1-23), (9 CFR 77.7, 77.9, 77.11), (State)(Business)

Forms are required for indemnity payment for animals depopulated for TB. APHIS and State animal health personnel complete this form and provide the herd owners with the official appraised value of the animals that will be indemnified. Herd owners must sign this form when they obtain an agreed-upon price per animal. The form is faxed to the VS Ruminant Health Center Office for approval and is kept on file in the office of the Area Veterinarian in Charge.

Request for 15-Day Extension, (9 CFR 50.7), (Business)

The Area Veterinarian in Charge (AVIC) may extend the time limit for destruction of animals for TB purposes to 30 days when he or she receives a request from the herd owner for such an extension. The AVIC must receive the request before the original 15-day period expires. Circumstances beyond the control of the owner must warrant the extension. APHIS has no specific form or format for the request.

Proceeds from Animals Sold to Slaughter (VS 1-24), (9 CFR 77.7, 77.9, 77.11), (Business)

The producer uses this form to record gross income from the slaughter sale of individual animals and all expenses related to the transportation, marketing, and slaughtering processes. The producer then sends the form to APHIS, which uses the information to arrive at a net salvage value to be used for determining net indemnity amounts allowable per individual animal.

Certificate for Movement, (9 CFR 77.8, 77.10, 77.12, 77.14, 77.16, 77.17), (State)(Business)

A movement certificate must accompany certain cattle, bison, or captive cervids moved interstate from States or zones with a TB status below accredited free. An accredited veterinarian or a State or Federal official issues the certificate in accordance with 9 CFR 77.10, 9 CFR 77.12, and 9 CFR 77.14. All States use State health certificates for the movement of regulated animals as most State-required health certificates require more information than that indicated in 9 CFR 77; the certificates are used regardless of Federal regulations.

Certificate for Movement - Retention of Movement Certificates, (9 CFR 77.4), (State)

To retain APHIS recognition of a TB status zone, a State must continue to comply with the requirements in 9 CFR 77 as well as APHIS requirements for maintaining the TB risk classification of each zone within the State. This requires monitoring the movement of regulated animals into and out of zones as described above. APHIS requires State animal health authorities to retain for at least 2 years all certificates used for the movement of regulated animals.

Commuter Herd Agreement, (9 CFR 77.7, 77.9, 77.11), (State)(Business)

A commuter herd agreement must be in place between the owner and State and Federal officials before any commuter herd movement and must be reviewed and renewed annually to remain in effect. The commuter agreement allows the herd owner to move animals from pastures on opposite sides of a State or zone boundary without having to comply with interstate movement requirements. The cattle must move in the course of normal ranching operations, without change of ownership, directly to or from another premises owned, leased, or rented by the same individual.

Recordkeeping for Approved Feedlots, (9 CFR 77.7, 77.9, 77.11), (Business)

Approved feedlot owners must keep records for 5 years of all livestock identification, inventory, changes in inventory, and the origin and destination of all livestock moved into and out of approved facilities.

Template for Owner Participation, (9 CFR 77.7, 77.9, 77.11), (Business)

Livestock owners read and sign a document that indicates their voluntary participation in the evaluation of TB tests for approval as official TB eradication program tests.

Apply Label to Shipment, (9 CFR 77.33), (State)(Business)

NVSL provides accredited veterinarians performing TB testing on captive cervids pre-printed labels and shipping materials for shipping samples to NVSL. The labels bear the NVSL address (1920 Dayton Avenue, Ames, IA 50010) and must be applied to the package to ensure proper delivery. About 98 percent of the veterinarians submitting samples from captive cervids are private, accredited veterinarians. The remaining 2 percent are evenly divided between State-employed veterinarians and Federally-employed veterinarians.

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 program has made progress in automating its forms used in this information collection. APHIS is modernizing its Mobile Information Management (MIM) platform which will include VS Forms 1-23, 1-24, 1-27, 1-27A, 6-22, 6-22A, 6-22B, 6-22C, and 6-22D. The target date for full implementation is late 2020.

The VS Form 6-35 is available electronically on the VS TB website.

VS Forms 10-4 and 10-7 are available online in fillable PDF format but require original signatures and must be printed to accompany samples sent to Federal laboratories. They are not candidates for electronic submission. They may be downloaded at https://www.aphis.usda.gov/aphis/resources/forms/ct_vs_forms.

VS Forms 6-2, 6-4, 6-4A, 6-4B, 6-22A, 6-22C, and 6-38 are available in PDF format but are not fillable. Because they also require original signatures, they are not currently candidates for electronic submission.

VS Forms 1-23, 1-24, 1-27, 1-27A, 6-22, 6-22B, 6-22D, and NVSL shipping labels are multi-part paper forms, continuation sheets, or self-adhesive labels. They require original signatures or are otherwise not suitable for electronic submission at this time.

The following are not standardized forms but customized documents tailored to specific purposes and situations, and require original signatures. Currently, they are not available for electronic retrieval and submission. Examples and modified documents serving as templates may be used with each requirement.

- Requests for State or zone status
- Memoranda of Understanding (MOU) for split-State recognition
- Epidemiological reviews of zone testing
- TB management plans
- Accredited herd plans
- Wildlife risk surveys
- TB test records, gamma
- Affected herd data and affected herd testing results
- Approved herd plans (depopulation and repopulation, and test-and-remove agreements)
- Requests for 15-day extensions
- Certificates of (interstate) movement
- Commuter herd agreements
- Inspection results of feedlot records
- Agreements for owner participation in projects evaluating new TB tests

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 TB from the United States. All burden within this collection is focused on specific aspects of the TB Surveillance and Eradication Program.

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

APHIS estimates that 20 percent of the respondents for this information collection are small businesses. The information collected is the absolute minimum needed to initiate and maintain an effective bovine TB surveillance, containment, and eradication program in the United States.

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 operate an effective bovine TB surveillance, containment, and eradication program. Consequently, TB would likely spread to areas of the United States that are currently not affected.

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**

To support a State's formal request for zone status (Epidemiological Review of Zone Testing), APHIS requires that the State's designated TB epidemiologist review reports of all testing for each zone within the State within 30 days of the testing.

APHIS requires that each State prepare a report of tuberculosis eradication (VS Form 6-2) within 30 days of the end of each month for the entire State or for each zone within a State covering the tuberculin testing that took place during the month and the reasons for the testing.

- **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;**

Approved feedlot owners must keep records for 5 years of all livestock identification, inventory, changes in inventory, and the origin and destination of all livestock moved into and out of approved facilities. APHIS requires the 5-year retention to align with traceability regulation requirements and to facilitate disease tracking and eradication.

- **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 other special circumstances exist that would require this information 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 individuals outside the agency to obtain their views on the availability of data, frequency of collection, the clarity of instructions and record-keeping, 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 engaged in productive consultations with the following individuals regarding the bovine tuberculosis program:

Dr. Susan Keller
North Dakota State Veterinarian
State Board of Animal Health
600 E Boulevard Ave. Dept. 602
Bismarck, ND 58505-0020
P: 701-328-2655
F: 701-328-4567
Email: doa-bah@nd.gov

Dr. Mendal Miller
Assistant State Veterinarian
South Dakota Animal Industry Board
411 South Fort Street
Pierre, SD 57501
P: 605-773-3321
F: 605-773-5459

Dr. Anita Edmondson
Supervising Veterinarian, Animal Health Branch
California Department of Food and Agriculture
2800 Gateway Oaks Drive, Sacramento, CA 95833
P: 916-900-5002
F: 916-900-5333
Email: ahbfeedback@cdfa.ca.gov

APHIS contacted these respondents by email and phone to discuss the information APHIS collects to administer its bovine TB surveillance, containment, and eradication program. We discussed with them how we and they obtain the necessary data and how frequently; how much data is available; the convenience and clarity of reporting formats and other collection instruments; and the clarity of, and

necessity for, any recordkeeping requirements. The respondents stated via email or phone that they had no concerns with any of these items and had no further recommendations.

On Monday, August 5, 2019, APHIS published a 60-day notice on pages 37986 and 37987 of the Federal Register (84 FR 37986) seeking public comment on its plans to request renewal of this collection of information. No comments 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.

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 individuals from whom the information is requested, and any steps to be taken to obtain their consent.

This information collection activity asks 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.

See APHIS Form 71. APHIS estimates there are 4,914 respondents -- 4,864 businesses and 50 State, local, and tribal entities. Response and burden estimates were developed using historical data, calculations, and discussions with field and industry personnel.

APHIS estimates the total annualized cost to the above respondents to be \$1,626,840, and arrived at this figure by multiplying the 27,830 hours of estimated response time by the respondents' estimated average hourly wage of \$39.75, and then multiplying the result by 1.4706 to capture benefit costs.

The average hourly wage for State animal health officials, producers and owners (including feedlot owners), accredited veterinarians, professional appraisers, and laboratory technicians was obtained from the U.S. Department of Labor, Bureau of Labor Statistics May 2018 Report - Occupational Employment and Wages in the United States. According to DOL BLS news release USDL-18-1499, (dated 09/18/2018, www.bls.gov/news.release/pdf/ecec.pdf), benefits account for 32% of employee costs, and wages account for the remaining 68%. Mathematically, total costs can be calculated as a function of wages, resulting in a multiplier of 1.4706.

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 startup cost component annualized over its expected useful life; and (b) a total operation, 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. The estimated annualized cost to the Federal Government is \$1,204,604.

15. Explain the reasons for any program changes or adjustments reported in Items 13 or 14 of the OMB Form 83-1.

	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	89,325	0	0	(1,128)	0	90,453
Annual Time Burden (Hours)	27,830	0	0	(1,685)	0	29,515

This request for renewal includes 4,914 respondents, 89,325 annual responses, and 27,830 hours of burden. There is an increase of 340 respondents but a decrease of 1,128 responses and 1,685 hours of burden from the previous request. All changes are based on estimate adjustments, primarily in projected responses.

A summary of these changes is shown in the two tables below.

Changes in Responses

<u>REGS</u>	<u>REASON</u>	<u>PREVIOUS RESPONSES</u>	<u>NEW RESPONSES</u>	<u>DIFFERENCE</u>	<u>TYPE OF CHANGE</u>
77.1	Accredited Herd Plan	11	16	5	Adjustment
77.4	Wildlife Risk Survey	301	1,095	794	Adjustment
77.7 et al	VS 6-2	60	24	(36)	Adjustment
77.7 et al	VS 10-4	15,360	19,875	4,515	Adjustment
77.7 et al	VS 10-7	630	900	270	Adjustment
77.1	VS 6-22, 6-22B	15,000	11,000	(4,000)	Adjustment
77.7 et al	VS 6-22C	560	800	240	Adjustment
77.1 et al	VS 6-22D	560	800	240	Adjustment
77.1	Affected Herd Data	1	2	1	Adjustment
77.1	Affected Herd Testing	12	6	(6)	Adjustment
77.1	Test and Remove Plan	2	11	9	Adjustment
77.7 et al	Depop / Repop Agreemnt	6	3	(3)	Adjustment
77.7 et al	VS 6-22A	1	4	3	Adjustment
77.7 et al	VS 6-4B	2,500	800	(1,700)	Adjustment
50.7	15-Day Extension	1,500	25	(1,475)	Adjustment
77.7 et al	VS 1-24	10	25	15	Adjustment
77.33	Apply Label to Shipment	775	775	0	Adjustment
		36,514	35,386	(1,128)	

Changes in Burden

<u>REGS</u>	<u>REASON</u>	<u>PREVIOUS HOURS</u>	<u>NEW HOURS</u>	<u>DIFFERENCE</u>	<u>TYPE OF CHANGE</u>
77.1	Accredited Herd Plan	25	56	31	Adjustment
77.4	Wildlife Risk Survey	602	2,190	1,588	Adjustment
77.7 et al	VS 6-2	30	12	(18)	Adjustment
77.7 et al	VS 10-4	2,458	3,180	722	Adjustment
77.7 et al	VS 10-7	101	144	43	Adjustment
77.1	VS 6-22, 6-22B	7,500	5,500	(2,000)	Adjustment
77.7 et al	VS 6-22C	235	336	101	Adjustment
77.1 et al	VS 6-22D	235	336	101	Adjustment
77.1	Affected Herd Data	20	40	20	Adjustment
77.1	Affected Herd Testing	48	24	(24)	Adjustment
77.1	Test and Remove Plan	50	230	180	Adjustment
77.7 et al	Depop / Repop Agrmnt	240	120	(120)	Adjustment
77.7 et al	VS 6-22A	4	14	10	Adjustment
77.7 et al	VS 6-4B	3,750	1,200	(2,550)	Adjustment
50.7	15-Day Extension	375	6	(369)	Adjustment
77.7 et al	VS 1-24	400	1,000	600	Adjustment
77.33	Apply Label to Shipment	7	7	0	Adjustment
		16,080	14,395	(1,685)	

16. For collections of information whose results are planned to be published, outline plans for tabulation and publication.

APHIS has no plans to publish the 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.

The VS Form 1-23 is used in eight collections; the VS Form 1-24 is used in two collections; the VS Form 1-27 and 1-27A are used in six collections; the VS Form 6-22 is used in two collections; and the VS Form 10-4 is used in six collections. It is not practical to include an OMB expiration date on these forms because of the various expiration dates for each collection. APHIS is seeking approval to not display the OMB expiration date on these forms.

18. Explain each exception to the certification statement identified in “Certification for Paperwork Reduction Act.”

APHIS can certify compliance with all the provisions in the Act.

B. Collections of Information Employing Statistical Methods

Statistical methods are not used in this information collection.