SUPPORTING STATEMENT
BLOOD AND TISSUE COLLECTION, AND RECORDKEEPING, AT SLAUGHTERING, RENDERING, AND APPROVED LIVESTOCK MARKETING ESTABLISHMENTS AND FACILITIES
OMB NO. 0579-0212

May 2020

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 U.S. Department of Agriculture (USDA) is authorized to prevent the interstate spread of livestock diseases and to eradicate such diseases from the United States when feasible under the Animal Health Protection Act (Title X, Subtitle E, Sections 10401-18 of P.L. 107-171, May 13, 2002, the Farm Security and Rural Investment Act of 2002). Under 7 U.S.C. 8301, the USDA, Animal and Plant Health Inspection Service (APHIS), carries out this prevention and eradication mission, and APHIS' Veterinary Services (VS) program conducts animal disease surveillance and testing using procedures and agreements prescribed in Title 9, *Code of Federal Regulations* (9 CFR) Part 71.

Disease prevention is the most effective method for maintaining a healthy animal population and for enhancing the United States' ability to compete in international animal and animal product trade. A key element of this approach is the restricted interstate movement of livestock within the United States to mitigate the spread of diseases, allowing APHIS to use livestock movement records to conduct disease surveillance to protect the health of livestock and poultry populations. Epidemiological data from blood and tissue sampling is used to assess the prevalence of disease and to identify its source. Coupled with animal identification, blood and tissue test results are used to trace the movement of an animal that tests positive and identify other animals it may have come into contact with that may also be diseased.

When a disease is suspected in a given area, sampling is 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 used to provide data for new or updated risk analyses in support of disease control programs, and, as required, opening international markets for animal products.

Regulations at 9 CFR 71.20 and 71.21 authorize APHIS to conduct disease surveillance and blood and tissue sampling activities using Livestock Facility Agreements and Listing Agreements between APHIS and owners and operators of slaughtering and rendering establishments and livestock marketing facilities. APHIS requires all livestock facilities that enter into Approval of Livestock Facility Agreements (which are voluntary) to record animal identification, make timely notifications, keep certain records, and take other actions that facilitate tracking animal movements and identifying possible disease occurrences. APHIS requires all slaughtering and rendering establishments that receive livestock or poultry interstate to enter Listing Agreements that permit

the Agency to conduct blood and tissue sampling at the facilities. The Agreements are critical during disease outbreaks as they reduce delays in assessments and, subsequently, disease spread.

APHIS is asking OMB to approve, for an additional 3 years, its use of these information collection activities in connection with its program to collect from animals blood and tissue samples, and trace their movements, as they move through slaughtering and rendering establishments and livestock marketing facilities.

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 approve and monitor the interstate movement of livestock as it pertains to disease control, and perform testing at slaughtering and rendering establishments to mitigate the spread of animal disease within the United States:

Agreement - Approved Livestock Facility for Handling Livestock Pursuant to Title 9 of the Code of Federal Records (9 CFR 71.20(a)) (State)(Business) - (hereafter called Agreement.) To obtain APHIS approval for handling animals in interstate commerce, the individual legally responsible for the day-to-day operation of a livestock facility must execute an approved livestock facility agreement with APHIS. The agreement allows VS to identify livestock movement nexus points for efficient livestock testing and monitoring for potential diseases. Agreements are completed for new markets and changes in existing livestock market facilities. VS officials prepare the document after obtaining from the facility owner or operator the name of the facility, its address, and a business telephone number. The owner or operator then indicates, by initialing the appropriate paragraphs of the agreement, the class or classes of livestock that will be handled at the facility. The owner or operator must sign the document agreeing to follow its requirements. APHIS also requires the State animal health official to sign the Agreement. The facility and State are provided copies with the original maintained at the VS District Office.

Schedule of Sales Days (9 CFR 71.20(a)) (Business) - Each Agreement requires the facility to provide timely schedules of sales days which indicate the types of animals that will be handled at the facility. The schedules allow accredited veterinarians, State representatives, and/or APHIS representatives to be on site to perform testing and monitoring. Schedules are usually included in the Agreement.

Diseased Animal Notification (9 CFR 71.20(a)) (Business) - Each Agreement requires facilities, or State representatives or accredited veterinarians if they are on site, to immediately notify APHIS when any livestock arrives and is known to be infected, exposed, high risk and scrapie-positive or suspect, or that shows signs of possibly being infected with any infectious, contagious, or communicable disease. Notification allows APHIS representatives to perform testing and monitoring in a timely manner.

Quarantine Signs (9 CFR 71.20(a)) (Business) (Third Party Disclosure) - Agreements require quarantine pens to be posted with quarantine signs alerting people of the presence of potentially infected animals.

Request for Appeal of Denial of Agreement (9 CFR 71.20(b)(1)) (Business) - If APHIS denies an Agreement, the owner or operator of the establishment may appeal the denial in writing within 10 days after receiving notification. The appeal must include all of the facts and reasons on which the owner or operator relies to show that the establishment was wrongfully denied the Agreement. The Administrator will grant or deny the appeal, in writing, as promptly as circumstances permit, stating the reason for his or 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 Agreement (9 CFR 71.20(b)(2)) (Business) - If APHIS withdraws an Agreement, the owner or operator of the establishment may appeal the withdrawal in writing within 10 days after receiving notification. The appeal must include all of the facts and reasons on which the owner or operator relies to show that the establishment was wrongfully denied the Agreement. The Administrator will grant or deny the appeal, in writing, as promptly as circumstances permit, stating the reason for his or 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 Livestock Facility Agreement (9 CFR 71.20(b)(3)) (Business) - The Administrator will automatically withdraw the approval of an establishment to handle livestock for blood and tissue collection if the operator of the establishment notifies the Administrator, in writing, that the establishment no longer handles livestock moved interstate, or that the person who signed the Agreement is no longer responsible for the day-to-day operations of the establishment.

Recordkeeping (9 CFR 71.20(a)) (General; 2-Year Requirement; 5-Year Requirement) (Business) - Approved livestock marketing facilities are required to maintain records that trace the movement of livestock. Records include weight tickets, sales slips, and records of origin, identification, and destination related to livestock that are in, or that have been in, the facility. For poultry and swine, such documents must be kept for at least 2 years, and for cattle and bison, sheep and goats, cervids, and equines, for at least 5 years. These retention periods allow APHIS to trace the movements of diseased livestock or poultry farther into the past than current records allow and facilitate finding potentially infected or exposed livestock or poultry that might otherwise remain unidentified.

Listing Agreement for a Slaughter or Rendering Establishment Handling Livestock, Poultry, or Carcasses in Interstate Commerce Pursuant to Title 9, Code of Federal Regulations (VS Forms 10-6A and 6B) (9 CFR 71.21(a)) (Business) - 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 and tissue samples at slaughter at different times, and under different circumstances. To accommodate these activities, APHIS requires slaughtering or rendering facilities to enter into a Listing Agreement with APHIS. Agreements are completed for new plants or when they have significant changes in operations. Through the Agreements, plants authorize APHIS to collect blood and tissue samples on their premises without cost to the United States and allow VS or its representatives to record all internal and external animal identification devices for animals from which blood and tissue samples are collected. The Agreement contains the name, address, and telephone number of the facility and lists the type of animal carcasses handled at the

facility. After authorized business representatives sign and date the Agreement, copies are provided, and the original maintained at the nearest VS field office. VS also enters the information from the listing agreement into its Emergency Management and Response System database.

USDA Listed Slaughter or Rendering Facility Inspection Report (VS Form 10-5) (9 CFR 71.21(b)) (Business) - The Administrator will list a slaughtering or rendering establishment after determining it meets the facility and access requirements of 9 CFR 71.21(b). Determination is made by inspection using VS Form 10-5 (USDA Listed Slaughter or Rendering Facility Inspection Report) that includes basic contact and production information provided by the facility. A copy of the results is provided to the facility once signed by a VS official; the original is maintained at the VS District Office.

Request for Appeal of Denial of Listing (9 CFR 71.21(d)(1)) (Business) - If APHIS denies the listing of an establishment, the owner or operator of the establishment may appeal the denial in writing within 10 days after receiving notification. The appeal must include all of the facts and reasons on 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 or 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 (9 CFR 71.21(d)(2)) (Business) - If APHIS withdraws listing approval from an establishment, the establishment owner or operator may appeal the withdrawal in writing within 10 days after receiving notification. The appeal must include all of the facts and reasons on 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 or 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.

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.

Approved Livestock Facility Agreements, and Listing Agreements for a Slaughter or Rendering Establishment (VS Forms 10-6A and VS Forms 10-6B), may be prepared electronically but they require original signatures to be valid. Original signatures may be pen-and-ink or digital. APHIS enters information from these forms into its EMRS database. It does not currently have an electronic submittal system for these forms but is always working to improve its digital processes.

VS Form 10-5 (Facility Inspection Report) is completed by VS personnel. A copy of the report becomes part of the Listing Agreement.

Appeals and requests for withdrawal may be submitted to VS in any format but the documents must have original signatures to be valid.

Changes to schedules of sales days may be provided to VS by facility representatives in any format suitable to both parties. This includes telephone call or email.

Notifying officials of suspected diseased animals may be done via telephone call or email.

Quarantine signs must be physically affixed to the holding pens containing suspected diseased animals.

The media for storing livestock records are at the discretion of facility owners. At a minimum, the following information must be maintained and made available when requested by VS: Name and address of the individual from whom an animal was purchased; the animal's sex, age, and breed; date the animal entered the facility; and the animal's final disposition. Facilities are encouraged to store this information electronically when possible.

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.

APHIS is the only Federal agency responsible for detecting and controlling contagious animal diseases in the United States. The information that APHIS collects 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.

Approximately 98 percent of the business respondents are small entities. The information APHIS collects is the minimum needed to conduct its test-at-slaughter surveillance program and implement its animal disease surveillance program. Most of the non-recordkeeping paperwork in this information collection is prepared by VS personnel for respondent signature or is infrequently required.

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 require recordkeeping would make it impossible for APHIS to effectively operate its disease surveillance programs. The agency's ability to detect disease in the United States animal population, prevent disease spread within the country, and ultimately eliminate certain animal diseases from the United States, would be severely hampered. Failure to detect and eliminate a contagious livestock disease before it is transmitted to another herd or flock may result in multimillion-dollar economic losses for meat producers, and impact the supply and prices of meats for U.S. consumers.

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;**

As part of its agreement with USDA, livestock facilities are required to provide APHIS representatives schedules and notices of sale days, and to report receipt of suspected diseased animals when they are discovered. Notices from the same facility may occur days or weeks apart.

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

If APHIS denies or withdraws an Approved Facility Agreement or a Listing Agreement, the establishment owner or operator may appeal the action 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, governmental contract, grant-in-aid, or tax records for more than 3 years;**

Animal diseases are traced to transmitting animals using certain livestock records. Some diseases, such as scrapie in sheep, have long incubation periods and may not appear in a live animal until 5 years or more after exposure. Therefore, to facilitate traces when they are needed, certain livestock records must be accessible for a minimum of 5 years after the death of an animal or the departure of an animal from a livestock facility.

- **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 statue 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 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 publications in the Federal Register of the agency's notice, soliciting comments on the information collection prior to submission to OMB.

APHIS consulted with the following by email and phone to discuss the information APHIS collects to administer its livestock market and disease sampling regulations. The discussions were about how we 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.

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On Thursday, June 25, 2020, pages 38108-38109, Vol. 85, No. 123, 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. No comments were received from the public during that time; however, a comment was received for the 30-day notice which was posted on Friday, November 6, 2020, page 71047, Vol. 85, No. 216. The comment had no relevance to this information 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 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.

•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.

•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 $67,755.20. APHIS arrived at this figure by multiplying the hours of estimated response time (1,111 hours) by the estimated average hourly wage of the above respondents ($41.47) and then multiplying the result ($46,073.17) by 1.4706 to capture benefit costs.

According to DOL BLS news release USDL-18-1499, dated September 18, 2018 (see https://www.bls.gov/news.release/pdf/ecec.pdf), benefits account for 32 percent of employee costs, and wages account for the remaining 68 percent. Mathematically, total costs can be calculated as a function of wages using a multiplier of 1.4706."

Respondents are: (1) State animal health officials, (2) accredited veterinarians, and (3) livestock marketing, slaughtering, and rendering establishment owners and employees. The average hourly wage was derived from U.S. Department of Labor Bureau of Labor Statistics website at https://www.bls.gov/news.release/pdf/ocwage.pdf. Wages used are for State animal health authorities [11-0000 Management Occupations] ($58.88); veterinarians ($50.39); agricultural inspectors ($22.67); owners or operators of livestock facilities [General and Operations Managers] ($59.15); and miscellaneous production workers [Production Workers, All Others] ($16.26).

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.

See APHIS Form 79. The estimated annualized cost to the Federal Government is $134,125.29.

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

ICR Summary of Burden:

	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	6,635	0	0	-7,375	0	14,010
Annual Time Burden (Hr)	1,111	0	0	-1,360	0	2,471
Annual Cost Burden ($)		0	0	0	0	0

There is an adjustment decrease of -2,080 respondents and -7,375 responses resulting in a decrease of -1,360 burden hours. The decrease is due to fewer slaughter and rendering establishments requested or required listing agreements and inspection reports than during the previous renewal.

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 has no plans to seek approval for not displaying the OMB expiration date on the forms in this information collection.

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.