October 2020

SUPPORTING STATEMENT
PART A
SARS-CoV-2 TESTING IN ANIMALS REPORTING ACTIVITIES
OMB NO. 0579-XXXX

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.

This submission is a request for emergency approval to gather data on the emerging Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2), the animal virus known as COVID-19 in humans, and part of an ongoing global pandemic. Data collection will occur by the National Animal Health Reporting System[1] (NAHRS) staff. The NAHRS program was designed to provide summary information on the presence or absence of reportable animal diseases in the U.S. The program collects data from participant States on the presence of listed diseases in livestock, poultry, and aquaculture species that have been observed in the State with a high level of certainty. SARS CoV-2 is currently on the list of reportable diseases which State officials report each month. NVSL will collect from private laboratories additional data regarding SARS-CoV-2 testing of animals.

The main objectives behind collecting additional SARS-CoV-2 data through the NAHRS system are to further our understanding of the disease in animals while meeting our World Organization of Animal Health (OIE) reporting obligations. As the COVID-19 pandemic continues to spread worldwide in humans, confirmed cases of SARS-CoV-2 are also occurring in several animal species. There is limited research available at this time concerning the susceptibility and impact of SARS-CoV-2 infections in animals. We currently know that the virus is zoonotic and does appear to spread from humans to animals in some situations.[2] The OIE notes that, "[i]nfection of animals with SARS-CoV-2 may have implications for animal and human health, animal welfare, for wildlife conservation, and for biomedical research."[3] With these widespread concerns in mind, the OIE has asked member countries like the United States to report any disease detections of SARS-CoV-2 in animals as they would for other OIE-listed diseases.

Reports of emerging and OIE-listed diseases occurring in the United States are required for membership in the OIE and meet international trade reporting requirements for animal health. The data collected from member countries are available at the OIE website World

[1] See the homepage for the NAHRS program: https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/monitoring-and-surveillance/sa_disease_reporting/ct_info_for_participants.
[2] https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/SA_One_Health/sars-cov-2-animals-us
[3] https://mailchi.mp/oie.int/the-oies-role-in-global-efforts-to-combat-covid-19

Animal Health Information Database (WAHIS)[4] . Information about SARS-CoV-2 and other emerging diseases is used by OIE member and nonmember countries to better understand the disease and enhance the world's capacity for response to such crises.[5]

Furthermore, because SARS-CoV-2 is a zoonoses, the United States Department of Agriculture (USDA) has a duty under Section 8319 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 to collaborate and coordinate with Department of Health and Human Services (HHS) partners in its surveillance.[6] Collection and dissemination of animal and poultry health data and information is mandated by 7 U.S.C. 391, the Animal Industry Act of 1884, which established the precursor of the APHIS, Veterinary Services, Bureau of Animal Industry. Legal requirements for examining and reporting on animal disease control methods were further mandated by 21 U.S.C. 119, "Agents to Examine and Report on Methods of Treatment of Animals, and Means for Suppression of Diseases," amended February 7, 1928.

Collection, analysis, and dissemination of animal and poultry health information is consistent with the APHIS mission of protecting and improving American agriculture's productivity and competitiveness. APHIS is collecting and disseminating SARS-CoV-2 information, by means of the NAHRS system, that is not available from any other source on the emergence, prevalence, epidemiology and economic importance of this disease in livestock, poultry and other animals. The NAHRS facilitates standardization of disease information throughout the United States and provides a central point for the collection of national data. It is anticipated that many, if not all, participating States will make reporting these data a requirement in their State for laboratories offering diagnostic services to producers.

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.

On a monthly basis, the chief State Animal Health Official (State Veterinarian) in each of the 50 States will be asked to review a list of SARS-CoV-2 laboratory testing submissions from his/her state and provide additional epidemiological data on these cases, when available. The form requesting additional SARS-CoV-2 testing data collects primarily qualitative data (i.e. checking box/es next to prescribed answer/s for a corresponding question). Some questions will also allow a respondent to provide free-form answers to a question, if no prescribed answer fits or more detail is desired. Disease information from State Animal Health Officials will be submitted through the secure web NAHRS reporting system, utilizing E-Authentication verification technology.
On a monthly basis, private commercial, public and private university laboratories, and state and local government laboratories who perform SARS-CoV-2 testing animal testing

[4] More information on the World Animal Health reporting may be found at the OIE's website: https://www.oie.int/wahis_2/public/wahid.php/Wahidhome/Home
[5] https://mailchi.mp/oie.int/the-oies-role-in-global-efforts-to-combat-covid-19
[6] https://uscode.house.gov/statviewer.htm?volume=116&page=674

will be asked to complete an excel workbook requesting data regarding clinical signs and specific testing data.

SARs-CoV-2 animal testing data will be used to make decisions about individual animal and population disease management and public health responses. It may also provide further knowledge on transmission of the virus. Specifically, the information collected by APHIS will be used for three main reporting purposes[7]:

- **Summary Reports -** These reports will summarize SARS-CoV-2 disease prevalence data in animals within the United States. Information will be regularly shared with other Federal partners, such as agencies in HHS. It will also be made publically available on the Center for Epidemiology and Animal Health (CEAH) website found at https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/program-overview/ceah.

- **Trend Reports –** These reports will highlight commonalities noted in SARS-CoV-2 epidemiological data that could help to better understand the disease and/or control its spread. A specific trend report may not be published, but could be shared with other Federal partners, such as agencies in HHS and/or State Animal and Public Health partners.

- **OIE Emerging Disease Reports –** These reports notify the OIE about emerging diseases of concern that occur within the U.S. and are required by the OIE to maintain membership. The reports will list confirmed positive cases of SARS-CoV-2 in animals and the pertinent epidemiological and disease response data related to such cases.

The Agency will use the following instruments to collect information related to the SARS CoV-2 in animals:

Emerging Disease Reporting Form (NAHRS-2); (21 U.S.C. 119); (States)
This form is used by the State Animal Health Official to report additional data related to laboratory testing results for SARS-CoV-2 submissions originating from his/her State. Most data provided to the State Animal Health Official will be epidemiological information further clarifying the circumstances for submission of SARS-CoV-2 test samples.

The form asks a series of 13 questions: eight questions have yes-no-unknown answer options; five questions offer other prescribed answer options; and two questions request a brief free-form answer response. There is a header at the top of the form indicating the animal identified by a submitted sample, the laboratory where the SARS-CoV-2 testing occurred and the sample submission details (State where the sample was collected and dates of sample collection, receipt at the lab, and testing). This header information will

[7] For examples of APHIS' use of these data please see:

OIE reports: https://www.oie.int/wahis_2/public/wahid.php/Wahidhome/Home
Trend reports: http://www.usaha.org/animal-health-surveillance-and-information

assist the State Animal Health Official in correctly reporting any additional epidemiological data specific to the described SARS-CoV-2 sample and testing. The State Animal Health Official completes one form concerning each animal tested for SARS-CoV-2 from his/her State. The form/s are submitted online in conjunction with monthly NAHRS disease reporting by the State Animal Health Official.

Request for Information for U.S. Laboratories Engaged in the Testing of Animals for SARS CoV-2 (NVSL-200); (21 U.S.C. 119); (Private)
This is a letter sent to laboratories that may be performing testing requesting they utilize the Excel workbook and report the data to NVSL on a monthly basis.

SARS CoV-2 Testing Data from Testing Laboratories (NVSL-201); (21 U.S.C. 119); (Private)
NVSL 201 is an Excel workbook recording the name of the testing lab, test purpose, lab accession number, species, barcode or specimen ID, animal ID, specimen, submission reason, clinical signs, date collected, date specimen received, date tested, test type, PCR CT value, test result interpretation, premises state, submitter and owner information, and an option for comments. The form will be delivered electronically to NVSL each month when positive tests deem it appropriate.

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 NAHRS-2 Emerging Disease Testing Form will be web-based and completed on a permissions-restricted, secure-submission site, open only to approved data providers. Completed forms will be submitted electronically via the internet. To reduce the burden of providing SARS CoV-2 information, the form will be added directly to the NAHRS reporting system. Respondents will be able to enter data at the same time they report other monthly disease trends in their States.

Submissions of the NVSL-2 Testing Data from Testing Laboratories Excel workbook will be emailed electronically to one point of contact at NVSL.

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 collecting and disseminating animal and poultry

health data as well as monitoring and reporting OIE notifiable and emerging diseases within the U.S.

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

This collection of information has no economic impact on small entities. The NVSL 201 has been designed to collect only the minimum amount of data required to understand the prevalence and spread of SARS-CoV-2 in animals, compile the OIE emerging disease reports, and meet other reporting duties.

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.

Monitoring the health status of U.S. commodities and submitting emerging disease reports to OIE is required for the United States to maintain OIE membership. The type, quantity, and frequency of data collected on the Emerging Disease Testing Form is unique in the U.S. No other source/entity is collecting data of this nature or can be used to collect these data. With the form embedded in the NAHRS system, collection of the requested SARS-CoV-2 testing information is streamlined with other monthly disease reporting submissions from State Animal Health Officials. The single location for all monthly disease reporting allows for less burden and better data accuracy from submitters. Not collecting this type of information will cripple the U.S.' ability to respond to the worldwide COVID-19 pandemic and severely jeopardize the health of both humans and animals.

7. Explain any special circumstances that require the collection to be conducted in a manner inconsistent with the general information collection guidelines in 5 CFR 1320.5.

This information collection is consistent with guidelines established in 5 CFR 1320.5.

8. Describe efforts to consult with persons outside the agency to obtain their views on the availability of data, frequency of collection, the clarity of instructions and recordkeeping, disclosure, or reporting form, and on the data elements to be recorded, disclosed, or reported. If applicable, provide a copy and identify the date and page number of publication in the Federal Register of the agency's notice, soliciting comments on the information collection prior to submission to OMB.

Improving our understanding of the SARS-CoV-2 virus and how it spreads among people and animals is a joint effort of the USDA-APHIS and HHS partners, Centers for Disease Control and Prevention (CDC) and Food and Drug Administration (FDA). APHIS is engaging in productive collaborations and consultations with the individuals below. APHIS discussed with them the importance of gathering SARS-CoV-2 animal testing data, the usefulness of having an electronic means for State Animal Health Officials to submit their reports about such testing and continued support for SARS-CoV-2 control and prevention. Their suggestions were instrumental in developing the NAHRS-2 and NVSL-201.

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9. Explain any decision to provide any payment or gifts to respondents, other than reenumeration of contractors or grantees.

There will be no payments or gifts provided to respondents.

10. Describe any assurance of confidentiality provided to respondents and the basis for the assurance in statute, regulation, or agency policy.

Confidentiality is strictly maintained for States participating in the NAHRS and access to data is limited. The Emerging Disease Testing Form will only be accessible from the NAHRS platform. Currently, only the APHIS-VS-CEAH representative compiling/ analyzing these data has knowledge of the State's identity. No individual owner or animal location is collected on the NARHS monthly reporting form or SARS-CoV-2 form, and no State level data is publically released unless authorized by the State. There is no Personally Identifiable Information (PII) or premises information of any kind collected in the NAHRS or the SARS-CoV-2 Form. The owners name and state are asked on the NVSL SARS-CoV-2 testing data form and are both clearly stated as optional. The workbook is sent to one point of contact and owner info is never released. While every effort is made to keep responses confidential, certain non-sensitive details could be released as required by a Freedom of Information Act (FOIA) request. All confidential information from the Emerging Disease Testing Form will be stored in secure electronic databases with permissions-restricted accounts only open to APHIS-VS-CEAH and APHIS-VS-NVSL analysts. The reporting forms are permissions-restricted only to data reporters and analysts.

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.

There are no questions of a sensitive nature used in this collection activity.

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 83-1.**

  See APHIS Form 71. APHIS estimates there are 77 respondents providing a total of 949 responses per year, or 1,626 hours of burden. There are an average of 12 responses per respondent, taking approximately 1.713 hours each to complete.

- **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 the respondents to be $96,845. It arrived at this figure by multiplying the hours of estimated response time (1,626 hours) by the estimated average hourly wage of the respondents ($41.68) and then multiplying the result by 1.429 to capture benefit costs.

The hourly rate is derived from the U.S. Department of Labor, Bureau of Labor Statistics May 2018 Report − Occupational Employment and Wages in the United States, found at http://www.bls.gov/news.release/pdf/ocwage.pdf: veterinarians (SOCC 29-1131), $50.39; and animal scientists (SOCC 19-1011), $32.96.

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.

There are no capital/start up costs or ongoing operations and maintenance costs associated with this information collection.

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 79. The estimated cost to the Federal Government is $123,740.

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	949		949	0		0
Annual Time Burden (Hr)	1,626		1,626	0		0

This is an emergency request for a new ICR related to the SAR CoV-2 and COVID-19 virus pandemic. It has 77 respondents, 949 responses, and 1,626 hours of burden. All of the activities are discretionary.

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

Information from these studies will be tallied immediately following each monthly data collection phase to provide descriptive information regarding the presence of notifiable diseases as a report on the status of U.S. animal health. Results will appear in monthly and semi-annual OIE reports that indicate the presence of these diseases within the U.S. The results will also appear in trends reports and annual NAHRS reports, as described in Item 2.

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 will display OMB approval expiration date on the forms.

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

APHIS is able to certify compliance with all provisions of the Act.