**Supporting Statement – Part A**
**OMB Control Number –** 0579-XXXX

**Title:** Highly Pathogenic Avian Influenza (HPAI); Additional Testing and Reporting of HPAI in Livestock and Milk
**Date Prepared:** December 2024

## 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 is an emergency information collection request. The Animal and Plant Health Inspection Service (APHIS) is asking the Office of Management and Budget (OMB) to approve its use of several information collection activities: testing, reporting, and gathering epidemiological investigation data to verify compliance with a new APHIS Federal Order. The new order requires testing milk from U.S. dairy cattle to limit the spread of highly pathogenic avian influenza (HPAI) Influenza A virus.

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 required to prevent the spread of any livestock or poultry pest or disease. The AHPA is contained in Title X, Subtitle E, Sections 10401-18 of P.L. 107-171, May 13, 2002, the Farm Security and Rural Investment Act of 2002; 7 U.S.C. 8301, et. seq.

Part of the mission of APHIS' Veterinary Services (VS) business unit is preventing foreign animal disease outbreaks in the United States, and monitoring, controlling, and eliminating a disease outbreak should one occur.

HPAI is a contagious viral disease of domestic poultry and wild birds. HPAI is deadly to domestic poultry and can wipe out entire flocks within a matter of days. HPAI is a threat to the poultry industry, animal health, human health, trade, and the economy worldwide. In the United States, HPAI H5N1 has now been detected in dairy cattle. As of December 9, 2024, USDA has confirmed 720 HPAI H5N1 clade 2.3.4.4b virus detections in 15 States (California, Colorado, Kansas, Idaho, Iowa, Michigan, Minnesota, New Mexico, North Carolina, Ohio, Oklahoma, South Dakota, Texas, Utah, and Wyoming). APHIS has also confirmed - based on specific phylogenetic evidence and epidemiological information - that 42 commercial poultry premises (as well as 5 noncommercial and 12 nonpoultry premises reportable to the World Organization for Animal Health) have also been infected with the same HPAI H5N1 virus B3.13 genotype detected in dairy cattle.

The U.S. Department of Agriculture has already recognized HPAI as a threat, and APHIS already prohibits the interstate movement of animals infected with HPAI. See title 9, *Code of Federal Regulations* (9 CFR) 71.3(b). This distinct HPAI H5N1 virus genotype poses a continuing animal disease risk as it infects both cattle and poultry. The disease in cattle ranges from mild to moderate symptoms (significant milk loss, decreased appetite, fever, dehydration, etc.), and appears to resolve within a few weeks with palliative care. However, the phylogenetic and epidemiological data indicate spread between dairy premises and – concerningly, given the far more severe effects of the disease in poultry - from dairy premises to poultry premises. The mode of spread appears to be multifactorial. The virus is shed in milk at high concentrations. Anything that encounters unpasteurized milk, such as spilled milk, or milk residue, has the potential to spread the virus to humans or other animals, and can contaminate vehicles and other objects or materials. Spread has occurred via not only directly spilled milk but also from contaminated objects. These factors show that this outbreak is having a continuing sizeable economic impact.

On April 24, 2024, APHIS announced a Federal Order to assist with limiting the spread of H5N1 in dairy cattle. The Federal Order requires testing lactating dairy cattle prior to interstate movement and mandatory reporting from laboratories of positive Influenza A cases in livestock. The Federal Order also requires infected dairy cattle premises to not move lactating dairy cattle interstate for 30 days and to provide epidemiological information, including animal movement tracing, via a questionnaire. This Federal Order went into effect on April 29, 2024.

On December 6, 2024, APHIS announced a second Federal Order to help limit the spread of H5N1. This order specifically addresses the spread of the virus through raw milk and adds testing of raw (unpasteurized) milk to detect and provide data to control and eradicate HPAI. Samples will be collected at facilities that ship, receive, or transfer milk interstate. Laboratories and state veterinarians must report positive Influenza A nucleic acid detection results (e.g., polymerase chain reaction (PCR) or genetic sequencing) in diagnostic samples obtained from livestock, including raw (unpasteurized) milk, to APHIS. APHIS issued this second order because while movement controls implemented under the earlier Federal Order have reduced transmission across State lines, HPAI infections linger in States that have not been able to institute a widespread bulk milk testing program. Often these affected farms show no clinical signs. Supporting and requiring national level bulk milk testing will help States and producers identify areas where H5N1 is lingering. Owners of herds in which dairy cattle test positive for interstate movement, or herds identified through mandatory testing of raw (unpasteurized) milk for pasteurization will be required to provide epidemiological information, including animal movement tracing to State animal health officials for follow up.

The two Federal Orders are meant to supplement each other; OMB has already approved burden estimates for the April 2024 order under the approval number 0579-0494. The new order is an addendum to those activities and does not duplicate what is already approved. APHIS is using both orders to work with State and industry partners to encourage farmers and veterinarians to report cattle illnesses quickly so that APHIS can monitor new cases and minimize the impact to farmers, consumers, and other animals. APHIS will publish a 60-day notice for the new burden set forth in this collection and will ultimately combine it with the burden currently approved in 0579-0494.

**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.**

**(ADDITIONAL) Milk Sample Collection and Testing; (Both Federal Orders); (Business/State)**
Samples are collected by or under the supervision of an accredited veterinarian, or a State licensed veterinarian, or a sample collector approved by the appropriate State animal health official. Designated individuals on production sites can be trained to collect milk sample samples for diagnostic testing.

Owners of herds in which milk tests positive must provide epidemiological information, including animal movement information. APHIS has developed a questionnaire for this purpose, discussed below.

APHIS has prepared updated sampling instructions for use in connection with the silo submission form (see below) and silo monitoring. Each Grade A raw milk silo (a larger bulk tank) at each processing plant is to be tested at least 4 times every 6 months.

**(ADDITIONAL) HPAI H5N1 Milk Submission Form (NVSL Submission Form (VS 12-1)); (Both Federal Orders); (Business/State)**
This form is used to submit both individual and bulk milk samples directly to APHIS National Animal Health Laboratory Network laboratories and the National Veterinary Services Laboratories (NVSL) for HPAI (Influenza A) testing. (Bulk sampling is discussed further below.) The form is prepared by sample collectors (accredited veterinarians, State-approved collectors, producers) and captures all the information needed regarding purpose of submission, disposition of the animals, and source of the milk samples – single animal vs. bulk tank milk vs. string (i.e. in-line sampler) vs. tanker.

Milk sample collection and testing using the VS 12-1 and as described in the two above items is currently under the April 24, 2024 Federal Order as noted in 0579-0494. About 1500 premises and 52 State responders collect samples under that collection for a total number of responses of 7500 (business) and 750 (States) and 15,000 burden hours (business) and 1500 (States). The new collection will add another 1500 premises and 150 State responders (additional State personnel carrying out the work), another 7500 (business) and 750 (State) responses, and an additional 15,000 (business) and 1,500 (State) burden hours.

**(ADDITIONAL) Dairy Cattle Emerging Health Event: Epidemiological Questionnaire; (Both Federal Orders); (Business)**
This questionnaire gathers epidemiological information about HPAI-affected cattle. The questionnaire collects data from producers/cattle herd premises owners, premises employees caring for the animals and carrying out premises maintenance. and accredited veterinarians on daily farm activities, facility and premises practices, deliveries to the premises, and sick cattle to help APHIS address this health syndrome. The form references a 30-day period dating to the 30 days before the date clinical signs of disease were first observed on the premises. VS uses the information collected to further determine how the disease was introduced to a herd and the

associated risk factors, which helps premises and States prevent HPAI spread and potential infection of other animals and humans.

Use of the epidemiological questionnaire is also currently covered in 0579-0494, where it accounts for 600 responses from 600 premises/business respondents with a total burden estimate of 1,200 hours. The new collection will garner 600 additional responses from 600 additional responses at an additional burden hour estimate of 1,200 hours.

**(NEW) HPAI H5N1 Milk Silo Submission Form (National Surveillance) (VS 12-2); (December 6, 2024 Federal Order); (Business/State)**

This form is used to submit bulk milk samples collected at Grade A milk silos directly to NVSL for HPAI (Influenza A) testing. (Lower-level bulk sampling is discussed in the previous 0494 supporting statement for the April 24, 2024 Federal Order.) The form is prepared by sample collectors (State-approved collectors) and captures all the information needed regarding date collected, total number of samples collected, sample number with bar code and identification of the sample by the BTU numbers (bulk tank unit) which indicates the number of farms contributing to the silo sample. This new burden encompasses 1,500 business/premises respondents and 150 State-level respondents with 40,000 total annual responses from premises/businesses and 10,000 from State-level respondents for a total new burden estimate of 40,000 hours for business/premises respondents and 5,000 hours for State-level respondents.

**(NEW) Mandatory USDA Silo Monitoring Supply Order Form (VS 12-3); (December 6, 2024 Federal Order); (State)**

APHIS has prepared a new order form for processing plants to obtain materials for bulk milk testing. The form requires the contact name and shipping address and allows the plant contact to order testing supplies. This new burden encompasses 52 State-level respondents with 10 additional annual respondents for an additional burden of 5 hours.

**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.**

APHIS makes every effort to comply with the E-Government Act, 2002 (E-Gov) and to provide for alternative submission of information collections.

NAHLN laboratories already have reporting via electronic messaging in place (via the National Centers for Animal Health [NCAH] portal) with electronic messaging requirements provided by the NAHLN Program Office. All other laboratories testing samples from livestock for Influenza A virus must report all positive results regardless of the test method. Laboratories are required to report testing results and accompanying sample information weekly to APHIS by emailing a copy of a spreadsheet to HPAI.Results@usda.gov. Ordering supplies can also be done via the NCAH portal. APHIS has provided screenshots of the general NCAH portal submission process, which is the same for all forms (the form to be submitted is available on a drop-down menu). APHIS has not yet added the silo submission and supply ordering forms to the Portal.

The milk and silo submission form can be submitted in paper format, via the NCAH portal, or using the reporting tool listed below.

VS is working on a new system to accept test results. The Electronic Lab Reporting Tool (ELR) is a flexible, disease/test agnostic reporting tool that allows any laboratory (including NAHLN and private labs) across the nation to report any diagnostic results to the USDA. The ELR is currently under development. Expected time to completion and use is not known at this time. ELR is being designed to work within Veterinary Services Integrated Surveillance Modules, a USDA system that requires an E-Auth Level 1 or Level 2 account to access.

Epidemiological information is collected on a fillable PDF form that allows data to be electronically extracted.

APHIS estimates that 75 percent of the responses in this collection can be submitted electronically. 25 percent of the responses will use the HPAI.Results@USDA email address or, for the silo monitoring supply order form, NVSLShipping@usda.gov.

**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 and every effort has been made to avoid duplication. APHIS is the only Federal agency responsible for preventing the entry of exotic animal and poultry diseases into the United States.

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

APHIS estimates approximately 50 percent of the 1500 business respondents in this information collection (750) are small businesses. The information collected is the absolute minimum needed to prevent the spread of HPAI in all livestock.

**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.**

This is an ongoing information collection request. Responses are mandatory. If the information were conducted less frequently or not at all, APHIS would not be able to adequately protect producers and livestock owners against wider outbreaks of HPAI or mitigate risk to public health and the food supply. A lack of this information could undermine APHIS' ability to prevent or control further outbreaks, which may result in additional disease spread and greater producer hardship.

**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, such as:**

- **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;**

  The following activities encompass both above bullet points:
  - Test results as completed at NAHLN laboratories, at minimum weekly for non-NAHLN laboratories.
  - Epidemiological information as quickly as possible after disease detection.

- **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 other 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 has engaged in productive consultations with State animal health officials, accredited veterinarians, and producers to discuss how adding silo samples of milk testing will affect control of the ongoing dairy cattle event. They have taken recommendations on how to collect

the data as well as how the continuing event affects the collection of data. The consulted officials have agreed with the new Order and collection requirements.

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The Federal Register 60-day public comment requirement is postponed until after this request for emergency information collection is approved. Once the collection is approved, APHIS will publish the 60-day notice and, at the next renewal of the collection tied to the earlier Federal Order (0579-0494), will merge this emergency collection into 0579-0494.

**9. Explain any decision to provide any payment or gift to respondents, other than remuneration of contractors or grantees.**

APHIS will provide no direct 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.**

The epidemiological questionnaire states: "APHIS will safeguard study data as Confidential Business Information (CBI), as defined in 19 CFR 201.6, and we will use exemption 4 for any Freedom of Information Act (FOIA) (5 U.S. Code 552) requests for survey information associated with this study." No additional assurance of confidentiality is provided with this information collection. APHIS will comply with the Privacy Act of 1974. The APHIS Privacy Officer has reviewed this collection and APHIS is working with the Privacy Office to provide Privacy Act statements for the included forms as appropriate.

**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.**

**A) 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.**

APHIS is seeking approval for an estimated 1,650 respondents, (affected public: 1,500 Business; 150 State, Local, and Tribal governments), 58,860 total annual responses, and 62,705 total annual burden hours. Breakouts of the differences between these numbers and those previously approved under 0579-0494 are outlined in the responses to Q. 2 above.

Estimates were developed based on real-time use and discussions with dairy cattle producers, State and private laboratory staff, and State and accredited veterinarians.

**B) 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 is $3,801,959 computed by multiplying the estimated average hourly wage ($42.43) by the total number of burden hours needed to complete the work (62,705), and then multiplying the product ($2,660,573) by 1.429 to capture benefit costs. APHIS derived the estimated wage by averaging the following figures from the U.S. Department of Labor; Bureau of Labor Statistics website.

| Dept of Labor SOCC Code | Average Wage | Occupation Description |
|---|---|---|
| **11-9013** | $43.35 | Farmers, ranchers, and other agricultural managers |
| **19-1011** | $43.01 | Animal scientists |
| **29-1131** | $65.53 | Veterinarians |
| **45-2093** | $17.82 | Farmworkers, farm, ranch, and aquaculture animals |
| | **$42.43** | **Average Hourly Wage** |

According to DOL BLS news release USDL-24-0485, dated March 13, 2024, 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 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 79. The annualized cost to the Federal government is estimated at $1,468,964.

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

This is a new collection which will add 62,705 estimated total annual burden hours and 58,860 estimated total annual responses to APHIS' OMB inventory.

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

Diagnostic information, via sequencing, and associated epidemiological information have already been included in an NVSL publication. APHIS anticipates epidemiological summaries/briefs and publications as well, as outlined below.

APHIS and partners will summarize information collected during testing and epidemiological investigation immediately following the data collection and validation phases. APHIS employees will enter data into electronic databases and perform statistical calculations such as descriptive statistics including frequency distributions, prevalence, and odds ratios. Standard errors and point estimates will be published for aggregated statistical measures.

To disseminate findings and recommendations, APHIS and partners will provide study results in aggregate to the industry at national conferences and published in a scientific or trade journal. Because no personally identifiable information will be collected, survey respondents cannot be contacted to share study results directly. Study results will be shared at industry and other national meetings and published in a scientific or trade journal to disseminate findings. An info brief document for producers will also be published and be made publicly available on the APHIS News and Science Updates webpage.

**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 the OMB approval expiration date on the instruments.

**18. Explain each exception to the certification Statement in the "Certification for Paperwork Reduction Act."**

There are no exceptions to the certification requirement.