Supporting Statement – Part A
OMB Control Number – 0579-0494

Title: Highly Pathogenic Avian Influenza (HPAI); Testing, Surveillance, and Reporting of HPAI in Livestock; Dairy Herd Certification
Date Prepared: December 2024

TERMS OF CLEARANCE: After the initial approval of this information collection APHIS will move the HPAI in dairy cattle burden for VS Forms 10-4 and 10-4A to 0579-0090 at its renewal. 0579-0090 will become the sole approved collection for all specimen submission. VS Forms 1-27 and 1-27A will be transferred to a new collection that will encompass all VS permitting burden

These actions will be taken at the renewal of 0579-0090, and completion and approval of a new permitting information collection.

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 a request for extension with change of an information collection request originally approved as an emergency request. The underlying situation continues. The Animal and Plant Health Inspection Service (APHIS) is asking the Office of Management and Budget (OMB) to approve, for an additional 3 years, its use of these information collection activities in connection with gathering all data associated with testing, surveillance, monitoring herd status, reporting, and epidemiological investigation/animal movement tracing to verify compliance with an APHIS Federal Order's requirements for moving dairy cattle within the United States 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 November 20, 2024, USDA has confirmed 616 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. Additionally, APHIS' National Veterinary Services Laboratories (NVSL) found HPAI in a lung tissue sample from an asymptomatic cull dairy cow that originated from an affected herd, and which did not enter the food supply.

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. APHIS is working 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. Along with the Federal Order, APHIS announced that it is reimbursing the National Animal Health Laboratory Network (NAHLN) for all pre-movement and other testing (asymptomatic herd testing and testing of suspect animals), as well as providing confirmatory testing at NVSL. APHIS is also supporting ongoing State surveillance strategies in addition to the ongoing herd surveillance through the HPAI Dairy Herd Status Program, both of which use bulk milk testing.

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.

Prior to interstate movement, lactating dairy cattle are required to receive a negative test for HPAI (Influenza A virus) at an approved NAHLN laboratory using a NAHLN-approved assay.

Sample Collection and Testing for Interstate Premovement Testing of Lactating Dairy Cattle; (Federal Order); (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 NVSL recommended sample types (e.g., milk samples, nasal swab, serum) for diagnostic testing.
- For groups/lots of 30 or fewer animals moving interstate, all animals being moved must be tested. If more than 30 animals are moving interstate, then only 30 animals total must be tested.
- Sample collection and testing must take place no more than 7 days prior to interstate movement.
- Samples are collected for the purpose of assessing disease status prior to movement.

For Cattle with Positive HPAI Test Results

- Lactating dairy cattle from herds which have tested positive for HPAI (Influenza A virus) are not eligible for interstate movement for 30 days from the most recent collection of any sample collected for non-research purposes that tests positive from any individual animal in the herd. After the 30-day period, animals must be tested again to evaluate disease status before movement.
- Owners of herds in which dairy cattle test positive must provide epidemiological information, including animal movement information. APHIS has developed a questionnaire for this purpose, discussed below.
- State animal health officials must discuss and reach agreement with APHIS on any specific circumstances for isolating test-positive cattle and moving them to another premises across State lines.

Cattle Moved Directly to Slaughter

- Nonclinical lactating dairy cattle moving interstate direct to slaughter, or intrastate to a sale barn and then interstate direct to slaughter, are not required to have a premovement test but must move on a certificate of veterinary inspection, or other documentation of movement, approved by and provided to both the sending and receiving State animal health officials.
- Clinical lactating dairy cattle are ineligible for interstate movement or movement to slaughter.

HPAI H5N1 Milk Submission Form (NVSL Submission Form (VS 12-1); (Federal Order); (Business/State)

This form is used to submit both individual and bulk milk samples directly to NAHLN laboratories and NVSL for HPAI (Influenza A) testing. (Bulk sampling is discussed further below in the dairy herd status program.) 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.

Sample Collection and Testing for Interstate Premovement Testing of Nonlactating Dairy Cattle; (Federal Order); (Business/State)

Although not required by the Federal Order, APHIS recommends premovement testing of nonlactating cattle. This testing at NAHLN laboratories, which follows the same process outlined above, is completed at no cost to the producer and documents absence of disease before movement.

Dairy Cattle Emerging Health Event: Epidemiological Questionnaire; (Federal Order); (Business)

This questionnaire gathers epidemiological information about HPAI-affected cattle. The questionnaire gathers information 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.

Certificates of Veterinary Inspection or Owner/Shipper Statement; (Federal Order); (Business/State)

The interstate movement of all lactating dairy cattle must be accompanied by a Certificate of Veterinary Inspection (CVI) or owner/shipper statement per 9 CFR Part 86, Animal Disease Traceability. The destination/receiving State(s) uses these documents to track the interstate movement of lactating dairy cattle.

- All cattle on the CVI or owner/shipper statement must have individual official identification.
- The individual official identification must be recorded on the CVI or owner/shipper statement.
- The CVI or owner/shipper statement. must include a statement that the cattle are both free from, and have not been exposed to, a known contagious and/or infectious disease.

In addition, the ICVI, completed by an accredited veterinarian from information the producer provides, documents that the veterinarian inspected the animals and found them free of reportable diseases. The ICVI must show:

- The species of animals covered by the certificate.
- The number of animals covered by the certificate.
- The purpose for which the animals are to be moved.
- The departure address.
- The destination address.
- The names and addresses of the consignor and the consignee (if different from the departure and destination addresses).

Unless APHIS' species-specific ICVI requirements provide an exception, the ICVI must list the official identification number of each animal, or group of animals, moved that must be officially identified. If an alternate form of identification has been agreed on by the sending and receiving States or tribes, the ICVI must include a record of that identification. A State representative, or an accredited veterinarian, issuing an ICVI must enter all the required information, retain a copy for their records, provide a copy to accompany the shipment, and forward a copy of the certificate to the State animal health official in the State of origin within 7 calendar days. The State of origin forwards a copy to the State of destination within 7 calendar days.

If cattle must be moved, APHIS strongly encourages extreme diligence by producers, veterinarians, and States to ensure only healthy cattle are moving and to ensure the validity of interstate health certificates. APHIS continues to stand ready to help State animal health officials develop language for interstate certificates of veterinary inspection or owner/shipper statements, as needed.

Biosecurity Plan; (Federal Order); (Business)

Dairy farms with positive animals should prepare a biosecurity plan. If the premises agrees to accept financial support (which APHIS offers and which is optional) for developing a plan, the premises must write a plan and make it available for review. Having and implementing a biosecurity plan is considered a best practice for all dairy farms. VS verifies the premises has a plan in place or develops a plan and uses this information to determine whether the premises is taking adequate steps to eliminate HPAI and prevent recurrence, so the disease does not infect other animals or humans.

The plan must include:

- Basic information about the premises, including:
  - National Premises Identification Number (PIN).
  - Premises address (a valid 911 address).
  - Premises GPS coordinates (latitude, longitude).
  - Animals on primary premises (all species and number).
  - Animal housing types (e.g., buildings, pastures, dry lots).
  - Other business operations on premises? If yes, what? (e.g., sale of milk/milk products, vegetable stand; sale of feed fertilizer or compost; hosting farm tours).
  - Secondary premises locations [list the PINs, 911 addresses, or GPS coordinates (latitude, longitude) where animals associated with this operation reside (e.g., dry cows off-site, heifers on pasture, steers)].
  - The name, address, and phone number of the designated biosecurity manager and their designee.
- Requirements that employees limit contact with cattle unless using appropriate personal protective equipment and limit exposure to other animals on the premises.
- Requirements that restrict access of other personnel/visitors to the premises; if access is necessary, limit contact with cattle and other animals onsite.
- An education and training program for company employees and contractors.
- Company veterinary infrastructure to ensure monitoring and disease diagnosis and control measures.

- Policies for managing vehicles and equipment used on the premises and to connect to other premises as needed.
- A labeled premises map including farm site requirements (location, layout, and construction).
- Pest management program (insect and rodent eradication and control).
- Cleaning and disinfection processes, including designation of a dedicated cleaning and disinfection station.
- Sanitation policies, including procedures for managing feed and water supplies.
- An Entry Logbook for caretaker/other personnel access to the premises.
- Contingency plans for interrupted animal movement (euthanasia and disposal of cull cattle; housing and feeding of other cattle).
- Processes for milk collection, including access points to the premises, truck/tanker cleaning, disinfection, and maintenance for leakage; whether trucks carry commingled loads from other operations; standard operating procedures for haulers and drivers regarding truck/tanker access, access to farm personnel and animals, loading, and use of personal protective equipment.
- Processes for feeding dairy products to calves (if present on the operation).
- Processes for milk disposal if raw milk cannot be moved off-farm.
- Whether dogs, cats, and other pets are allowed to roam between operations during an outbreak. On a positive premises, whether mitigations are or can be put in place to prevent dogs, cats, and other pets from roaming between operations.

Initial State Response and Containment Plan; (Federal Order); (State)

For owners within a State to be eligible for compensation for up to 100 percent of eligible testing and surveillance costs, the State in which the cattle reside must have an APHIS-approved initial state response and containment plan in place. VS uses this information to determine whether the State is taking adequate steps to eliminate HPAI on affected premises and prevent recurrence, so the disease does not infect other animals or humans.

This plan must include:

- Provisions for a standing emergency disease management committee, regular meetings, and exercises, including coordination with any affected Tribal governments.
- A minimum biosecurity plan followed by all producers.
- Provisions for adequate diagnostic resources.
- Detailed, specific procedures for initial handling and investigation of suspected cases of HPAI.
- Detailed, specific procedures for reporting test results to APHIS. These procedures must be developed after appropriate consultation with producers in the State and must provide for the reporting only of confirmed cases of HPAI in accordance with the Federal Order.
- Detailed, strict quarantine measures for presumptive and confirmed index cases.
- Provisions for developing herd plans for infected and exposed herds.
- Detailed plans for disposal of materials that encounter cattle or milk infected with or exposed to HPAI.
- If vaccination is considered as an option, a written plan for use in place with proper controls and provisions for APHIS approval of any use of vaccine.
- Plans for negative herds that provide for quarantine, testing, and controlled marketing.
- Public awareness and education programs regarding avian influenza.

HPAI Dairy Herd Status Program; (Federal Order); (Business/State)

APHIS' goal is to test bulk tank milk (BTM) samples from every dairy operation in the country (36,024 dairy farms according to the 2022 Census of Agriculture) to understand the prevalence of HPAI in the national dairy herd. Initially, APHIS piloted the program with seven States on a voluntary basis to interested producers. The pilot allowed APHIS to develop a robust program that was rolled out to all 50 States. APHIS reimburses costs to test bulk tank milk weekly, requiring 3 weeks of testing to develop individual herds' status and ongoing weekly testing for a herd to maintain Monitored Unaffected status.

Producers enroll their herd in the program, and the herd is designated as Provisional Enrolled Herd status. To become a Monitored Unaffected herd, the herd needs to test negative on three weekly BTM tests, and in the third week test negative via individual testing of all other lactating cows on the premises (hospital pen and cows not contributing to the bulk tank). Under this program, producers consent to weekly sampling of their BTM to confirm that their herd stays free of virus. As part of a Monitored Unaffected herd, dairy cattle in the herd are eligible to be shipped to any destination without the need to test individual animals or obtain a CVI for purposes of this Federal Order, subject to the other terms as further set out in this collection.

To participate, producers sign an HPAI Dairy Herd Monitoring Plan (hereafter referred to as a Herd Monitoring Plan), initiate weekly bulk milk testing, and arrange for testing of lactating animals not contributing to the bulk tank milk at the time of the third weekly BTM sample (i.e. milk from sick and recently freshened cows[1]). Under the HPAI Dairy Herd Status Program, individual lactating dairy cattle from a Monitored Unaffected herd are not required to receive a negative test for Influenza A Virus prior to interstate movement because APHIS has confidence the herd is unaffected based on the initial bulk milk testing and testing of all other lactating cows not contributing to the bulk tank on the premises combined with ongoing weekly bulk milk sample results to determine movement eligibility. This allows producers to schedule and plan for regular shipments of cattle, maintaining business continuity.

VS adopted bulk milk testing because while testing every animal individually one time provides confidence that the herd is unaffected, it is not practical for most U.S. dairy herds. It is much less labor intensive to the producer and less burden on the lab to test bulk milk samples over a 3-week period than to test every individual lactating animal on the premises. Serial testing over 3 weeks gives confidence a herd is truly unaffected from HPAI. A single positive test result tells APHIS the herd is affected by HPAI, but a series of negative test results are needed to have greater than 95 percent confidence the herd is negative.

Producers that do not wish to participate in the HPAI Dairy Herd Status Program will be obligated by the Federal Order to test individual animals before interstate movement and receive CVIs.

Provisional Herd Status

[1] A freshened cow is one that has recently given birth and begun producing milk.

Herds enrolled in the HPAI Dairy Herd Status Program in the first 3 weeks awaiting their official status.

Monitored Unaffected Herd Status
Herds enrolled in the HPAI Dairy Herd Status Program with 3 consecutive weeks of negative prescribed testing results. These herds commit to ongoing monitoring described in their HPAI Dairy Herd Monitoring Plan, which alleviates the need for premovement testing for animals moving interstate.

Monitored Affected Herd Status
Herds participating in the HPAI Dairy Herd Status Program and that have been identified as positive based on testing will not be allowed to move lactating dairy cattle until they follow the testing protocol outlined in the Herd Monitoring Plan. Herds may return to Monitored Unaffected Herd Status and unrestricted movement after completing the required testing.

Monitored Suspended Herd
A temporary status for herds in the HPAI Dairy Herd Status Program who have reached Monitored Unaffected status when test results have not been received or reviewed to confirm program requirements have been met to maintain Monitored Unaffected status. Monitored Unaffected status is regained once test results have been received and program requirements are confirmed to have been met.

Non-Enrolled Affected Herds
Herds not participating in the HPAI Dairy Herd Status Program and identified as positive based on testing are subject to the movement restrictions for lactating dairy cattle. Owners may elect to start the enrollment process to become a Monitored Herd while designated as an affected herd.

Non-Enrolled Herds
Herds not participating in the program, that are either unknown disease status or previously identified as positive and have not had any sample test positive from an individual animal for over 30 days. Individual lactating cattle must be tested prior to movement as stipulated in the Federal Order.

Maintaining monitored status requires ongoing weekly bulk milk samples. APHIS no longer requires testing of sick and fresh pen milk to maintain Monitored Unaffected status. Assessment of data has shown the sensitivity of 3 consecutive weeks of bulk tank milk testing representing the milking herd is high. Additional analyses have shown that positive results occur prior to widespread clinical illness in the herd. Therefore, it is unlikely that including milk from sick or newly freshened cows during the maintenance phase of the program would significantly increase the chance of detecting an affected herd. APHIS is continually assessing ways to reduce testing burden on producers while maintaining scientific integrity of the program.

If a herd gets a positive result, APHIS designates the herd as Monitored Affected. The herd/premises continues to undergo weekly bulk milk testing until it receives 2 negative tests for 2 consecutive weeks plus negative test results for the hospital and fresh pens in the second week.

Movement of lactating cattle will not be allowed while the herd is in Monitored Affected Herd status.

HPAI Dairy Herd Monitoring Plan; (Federal Order); (Business/State)
To enroll in the program, producers must sign an HPAI Dairy Herd Monitoring Plan. The plan outlines the sampling protocol, who is authorized to collect samples, biosecurity plan recommendations, precautions taken, and how to maintain status. Activities encompassed in the herd monitoring plan include developing and signing the plan, assisting with collecting and shipping samples, requesting test kits and other materials from NVSL, and biosecurity measures.

Statement of Services Performed (VS Form 8-18) Premises Support Agreement, Expense Tracker, and Financial Plan; (Federal Order); (State, Business)
VS Form 8-18 is included to compensate producers for activities associated with responding to HPAI in dairy cattle as described in a Detailed Financial Plan. VS also uses a Premises Support Agreement and Expense Tracker which align with the Financial Plan.

The Premises Support Agreement indicates which support options the producer would like to receive and what frequency of payments (every 30 days vs. one-time payment after 120 days). Producers must submit receipts and either fill out an Expense Tracker or other format to provide line-item expenses. The producer is not required to use the tracker document; they can submit the information in another format if they choose.

The tracker and forms are completed by either personnel from the State VS office or a Federal and State-approved appraiser (usually a Federal employee) with input from the producer.

VS provides financial support per premises for producers with affected herds for the following activities:

- Supplying personal protective equipment to employees and/or outerwear uniform laundering.
- Facilitating worker participation in public health monitoring.
- Developing biosecurity plans.
- Heat treating milk from sick cows to dispose of it in a bio secure fashion.
- Veterinary costs necessarily incurred for treating cattle infected with HPAI, as well as fees for veterinarians to collect samples for testing.
- Supplies and shipping costs for submitting samples to the NAHLN laboratories for testing.

VS provides financial support per premises for producers with non-affected herds for the following activities:

- Developing biosecurity plans.
- Fees for veterinarians to collect samples for testing.
- Supplies and shipping costs for submitting samples to the NAHLN laboratories for testing.

The VS Form 8-18 is signed by both the approving official and the owner and provides information about the service provider, the services provided, and the rate charged. For electronic payment processing, the claimant name on the VS 8-18 must be the same as the vendor name associated with the System for Award Management (SAM) number provided.

Owners may decline to be paid through SAM.gov and elect to be paid through Electronic Funds Transfer (EFT),

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.

The milk 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.

The Herd Status Program is managed in Surveillance Collaboration Services (SCS) HPAI instance to log the status of each herd in the database dependent on weekly test results, which are available electronically. State and Federal employees manage the program.

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

VS initiates the 8-18 and submits/receives the forms usually via email to/from the producer.

The following are not standardized forms, but customized documents tailored to specific purposes and situations. Currently, apart from the ICVIs (which most States accept electronically) they are not available for electronic retrieval and submission. Examples and modified documents serving as templates may be used with each requirement.

- Biosecurity plans.
- Initial state response and containment plans.

- Dairy Herd Monitoring Plans.
- Premises support agreements.
- Certificates of (interstate) movement.
- Agreements for owner participation in the financial support program.
- Expense Tracker and Financial Plan.

The Dairy Herd Monitoring Plan and premises support agreements require original signatures from the owners. These documents may be scanned and emailed; there is currently no direct electronic submission method.

APHIS estimates that 75 percent of the responses in this collection can be submitted electronically.

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 respondents in this information collection 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.
  - CVIs and movement permits as needed.
  - Epidemiological and animal movement tracing 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 the ongoing dairy cattle event has affected data requirements and data availability since the initial outbreak, as well as how the continuing event affects the collection, including frequency, of data collection. APHIS asked if the amount of data has changed and whether its collection, reporting, and recordkeeping methods have worked well for producers and other providers. The consulted officials reported no unusual issues.

Dr. Maggie Baldwin
State Veterinarian
Colorado Department of Agriculture
Animal Health Division
305 Interlocken Parkway
Broomfield, CO 80021
O: (303) 869-9130
F: (303) 466-8515
maggie.baldwin@state.co.us

Dr. Samantha Holeck
State Veterinarian
New Mexico Livestock Board
2105 Osuna NE, South Building
Albuquerque, NM 87113
O: (505) 841-6161
F: (505) 841-6160
samantha.holeck@nmlb.nm.gov

Dr. Annette Jones
State Veterinarian and Director
California Department of Food and Agriculture
Animal Health and Food Safety Services
2800 Gateway Oaks Drive
Sacramento, CA 95833
O: (916) 900-5000
F: (916) 900-5332
annette.jones@cdfa.ca.gov

On August 29, 2024, a notice was published in the Federal Register (89 FR 70162) providing a 60-day period for public comment on this renewal of an information collection request. We received five comments.

The first comment raised issues outside APHIS' jurisdiction.

The second comment pointed out that the terms of clearance required APHIS to remove the burden for VS forms 10-4, 10-4A, 1-27, and 1-27A and place them in separate dedicated collections. These actions will be taken at the renewal of 0579-0090, and completion and approval of a new permitting information collection.

The third comment expressed concern about measures APHIS is undertaking to prevent the spread between farms, with particular regard to worker biosecurity practices. APHIS assures the commenter that it is working with producers to increase the use of PPE etc.

The fourth comment relates HPAI H5N1's effect on the commenter's operations and the U.S. livestock industry in general, and expresses support for the collection.

The fifth comment supports the continuing collection of this information and offers several suggestions for expansion and interagency cooperation which APHIS is carefully considering. APHIS is evaluating whether the suggested activities may practically be added to the current program.

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 apart from financial support options, which requires the use of the VS Form 8-18. The biosecurity plan must be prepared and submitted for review if the producer opts to receive funding for having the plan. The information collected will otherwise inform best management practices to prevent disease occurrence and understand the burden of disease.

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.

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 6,052 respondents, (affected public: 6,000 Business; 52 State, Local, and Tribal; etc.); 104,504 total annual responses; and 503,000 total annual burden hours.

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 $30,498,132 computed by multiplying the estimated average hourly wage ($42.43) by the total number of burden hours needed to complete the work (503,000), and then multiplying the product ($21,342,290) 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 apart from the following: APHIS will reimburse for all interstate premovement testing at NAHLN laboratories; therefore, this testing at NAHLN laboratories will be completed at no cost to the producer/submitter. APHIS is reimbursing for sample collection and shipping through the premises support program. Producers with unaffected premises can claim up to $2,000 for veterinary costs related to sample submission and up to $100 per month for 4 months for shipping samples to the lab. APHIS is also supporting States' surveillance sampling through emergency cooperative agreements.

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 $13,270,139.

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	104,504	0	(32,000)	0	0	136,504
Annual Time Burden (Hours)	503,000	0	(15,066)	0	0	518,066

APHIS is seeking an extension of a currently approved information collection request. The currently approved burden for this request is an estimated 6,052 total annual respondents, 136,504 total annual responses, and 518,066 total annual burden hours. This request for renewal is for an estimated 6,052 respondents, 104,504 estimated responses and 503,000 estimated burden hours. The requests reflects no increase in respondents, merely a correction in reporting. Otherwise, the renewal reflects a decrease of 32,000 in estimated responses and a decrease of 15,066 hours of estimated burden from the previous renewal request, as further explained below. There are no third-party disclosure burden estimates. All of the changes are discretionary.

The Permit for Movement of Restricted Animals (VS Forms 1-27, 1-27A), and Specimen Submission Form (VS Forms 10-4, 10-4A) activities have been removed from this and placed in collections geared to animal permitting and sample collection, respectively. Removal of those items eliminates an estimated 32,000 responses and 15,066 response hours.

The HPAI Dairy Herd Status Program was also updated to reflect assessment of new data in the on-going event and updated understanding of the disease progression in dairy animals. This is an adjustment in procedure and added neither respondents nor response time.

The amount of time to complete the epidemiologic questionnaire was increased from 1.5 hours to 2.0 hours based on feedback from field responders over the previous 3 months. This increased the time for this burden from 900 hours to 1,200 hours, adding 300 hours of burden.

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 infobrief document for producers will also be published and be made publicly available.

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.