



UNITED STATES
DEPARTMENT OF
AGRICULTURE

ANIMAL AND PLANT HEALTH
INSPECTION SERVICE

1400 INDEPENDENCE AVE
WASHINGTON, DC 20250

TO: Dominic Mancini
Deputy Director
Office of Information and Regulatory Affairs
Office of Management and Budget

THROUGH: Levi S. Harrell
Departmental Clearance Officer
Information Management Division
Office of the Chief Information Officer

FROM: Jennifer Lester Moffitt
Under Secretary
Marketing and Regulatory Programs

Michael Watson
Administrator
Animal and Plant Health Inspection Service

Rosemary Sifford
Deputy Administrator
Veterinary Services

SUBJECT: Request for Emergency Approval of a New Information Collection for Additional Testing for and Reporting of Highly Pathogenic Avian Influenza (HPAI) in Livestock and Milk

SUMMARY: Pursuant to Office of Management and Budget (OMB) procedures established at 5 CFR Part 1320, *Controlling Paperwork Burdens on the Public*, I request that the proposed information collection project, Additional Testing for and Reporting of Highly Pathogenic Avian Influenza (HPAI) in Livestock and Milk, be processed in accordance with section 1320.13, Emergency Processing.

I have determined that this information must be collected prior to the expiration of time periods established under Part 1320, and this information is essential for activities connected to the control of highly pathogenic avian influenza (HPAI), in particular bulk testing for HPAI in raw (unpasteurized) milk for pasteurization as well as livestock intended for interstate movement. I have further determined that the ongoing outbreak of HPAI in dairy cattle and the finding of and resulting spread of HPAI virus in and through raw milk meets the requirements for emergency processing outlined in 5 CFR 1320.13(a) as needed immediately, essential to the Agency's mission, and likely to result in public harm. Further delay will hasten the spread of the disease, multiplying the potential harm to livestock, poultry, the dairy industry, and, potentially, human health. As the background section will subsequently describe, since March 25, 2024, and as of December 5, there have been 718 confirmed cases of HPAI in dairy cattle across 15 States; in the last 30 days there have been 273 new confirmed cases across 2 States. This represents a 38% increase in cases in the last month, which is indicative of the need for a national testing strategy to identify and quickly respond to virus detections. Moreover, USDA

has precedent with successful bulk milk testing approaches, including the use of bulk milk testing to eradicate brucellosis from dairy herds. Testing which facilitates the adoption of enhanced biosecurity measures and animal movement restrictions has been demonstrated to be effective in eliminating the virus from affected States. To better understand its national prevalence and ensure immediate response to detections, preventing further spread, APHIS is now moving to a national surveillance strategy focused on testing unpasteurized milk, because it has the potential to harbor the virus, causing livestock disease and serving as a potential pathway for further transmitting the virus. Furthermore, there is growing scientific evidence that H5N1 can be detected in milk prior to cows showing symptoms, increasing the urgency for approval for this request.

The Animal and Plant Health Inspection Service (APHIS) requests a 6-month approval for this collection. This request covers new forms that will gather information related to bulk milk testing, an expansion of current milk testing which requires slightly different information fields on forms related to testing supply requests, sample collection, and testing submissions. APHIS has prepared a new form for increased bulk milk testing and is preparing additional monitoring.

APHIS' primary mission is to protect the health of U.S. agriculture and natural resources against invasive pests and diseases. This includes the prevention, control, and eradication of animal diseases to safeguard animal health. Disease prevention is the most effective method for maintaining a healthy animal population and for enhancing the United States' ability to compete globally in animal and animal product trade.

BACKGROUND: 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. Since late March 2024, the U.S. Department of Agriculture, Food and Drug Administration, Centers for Disease Control and Prevention, State veterinary and public health officials and the National Animal Health Laboratory Network (NAHLN) laboratories have been responding to the HPAI H5N1 virus in dairy cows. The NAHLN is a nationally coordinated network and partnership of Federal, State, and university-associated animal diagnostic laboratories. The laboratories are trained and proficiency tested by USDA's National Veterinary Services Laboratories (NVSL) to perform official Federal animal health testing; the network provides ongoing disease surveillance, responds quickly to disease events, communicates diagnostic outcomes to decision makers, and has the capability and capacity to meet diagnostic needs during animal disease outbreaks.

As of December 5, 2024, USDA has confirmed 718 HPAI H5N1 clade 2.3.4.4b virus detections in 15 States. Moreover, data collected over the past 8 months indicates the virus can be transmitted on equipment, people, or other items that move from farm to farm, including between dairies and poultry facilities. Evidence has shown that raw (unpasteurized) milk is a vehicle for the spread of the H5N1 virus, and subject to measures to detect disease in accordance with APHIS' authority. Specifically, laboratory testing has confirmed high quantities of the HPAI H5N1 virus in raw milk, creating opportunities for transmission within herds when animals have contact with raw milk. Even small amounts of raw milk from affected animals can harbor high levels of virus and can be easily spread among dairy farms and between dairy and poultry farms through the movements of people, vehicles, trucks, and other animals. Expanded disease surveillance provides more data to detect disease and inform focused response efforts.



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APHIS' continuing goals are to (1) detect, control, and contain HPAI in dairy cattle and other livestock as quickly as possible; and (2) provide science- and risk-based approaches and systems to facilitate continuity of business for non-infected animals and non-contaminated animal products. Achieving these goals will allow individual livestock facilities, States, Tribes, regions, and industries to resume normal production as quickly as possible. APHIS intends to accomplish these goals by adding mandatory testing of raw (unpasteurized) milk for pasteurization to the current testing of dairy cattle for interstate movement and mandatory reporting of positive Influenza A diagnostic testing results in raw milk as well as livestock. Owners of herds in which dairy cattle test positive for interstate movement will be required to provide epidemiological information, including animal movement tracing. The epidemiological information will be collected via a questionnaire approved under information collection 0579-0494; Expiration Date: 12/31/2024, and according to the April 24 Federal Order. APHIS has also prepared a new silo submission form to track milk samples collected from large repositories and documents to monitor submissions and submitting premises using the new Federal Order as a basis.

Emergency approval for this information collection is needed to continue APHIS' efficient and effective response to the spread of HPAI into nonpoultry species in the United States. APHIS cannot reasonably comply with the normal clearance given the fact that this outbreak response addresses an expanding animal (and potential human) health emergency, and normal clearance processing time will prevent the rapid response that is warranted during an outbreak investigation. APHIS believes this situation will persist for the foreseeable future. It therefore plans to issue 60- and 30-day notices in the Federal Register and to submit information collection requests under the Paperwork Reduction Act's non emergency procedures to seek OMB approval to continue to collect the necessary data.

Please provide an approval/disapproval determination of this request to collect information under an emergency clearance by close of business December 5, 2024.

Thank you for your time and consideration.



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