



UNITED STATES
DEPARTMENT OF
AGRICULTURE

ANIMAL AND PLANT HEALTH
INSPECTION SERVICE

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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
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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 Testing for and Reporting of Highly Pathogenic Avian Influenza (HPAI) in Livestock

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, Testing for and Reporting of Highly Pathogenic Avian Influenza (HPAI) in Livestock, 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, testing for and reporting of HPAI in livestock intended for interstate movement. I have further determined that the recent outbreak of HPAI in dairy cattle 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, as further delay would threaten to hasten the spread of the disease, multiplying the potential harm to livestock, poultry, the dairy industry, and, potentially, human health. The Animal and Plant Health Inspection Service (APHIS) requests a 6-month approval for this collection. This request includes both existing forms and activities repurposed for the current situation and new activities prepared as directed by Department officials.

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. In the United States, HPAI has now been detected in dairy cattle.

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 investigating the emergence of 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 May 15, 2024, USDA has confirmed HPAI H5N1 clade 2.3.4.4b virus detections on 49 dairy cattle premises in 9 states.

The detection of this new distinct HPAI H5N1 virus genotype in dairy cattle poses a new animal disease risk for dairy cattle - as well as an additional disease risk to domestic poultry farms - since this genotype can infect both cattle and poultry. This continued outbreak is likely to have an immediate, sizeable, and lingering economic impact for an extended period. It could disrupt domestic production of and traffic in and international exports of milk and dairy products as well as potentially beef and other cattle derivatives. The value of lost exports, to say nothing of lost domestic sales (due to both drops in demand and supply), would be a substantial detriment to the economy and would also affect interstate commerce. Farms would shut down, causing unemployment and costs both on-farm and in related sectors. In addition, the response effort involves direct costs for testing and investigation, depopulation, indemnity payments, animal disposal, disinfection, and movement control measures.

APHIS' 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 requiring mandatory testing for interstate movement of dairy cattle and mandatory reporting of positive Influenza A diagnostic testing results in livestock. Owners of herds in which dairy cattle test positive for interstate movement will be required to provide epidemiological information, including animal movement tracing. APHIS also anticipates using biosecurity and incident response and containment plans to monitor and control disease incidence, including epidemiological investigation, sampling, testing, tracking, risk surveys, and reporting of test administration and results.

Emergency approval for information collection in respect to disease monitoring and control is needed to prepare for an 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 is addressing an animal (and potential human) health emergency, and normal clearance processing time will prevent the rapid response that is



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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 May 28, 2024.

Thank you for your time and consideration.



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