

## **Supporting Statement – Part A**

**Docket APHIS-2023-0088**

**OMB Control No.** - 0579-XXXX associated with RIN 0579-AE79, Interim Rule, Payment of Indemnity and Compensation for Highly Pathogenic Avian Influenza

**Title:** Payment of Indemnity and Compensation for Highly Pathogenic Avian Influenza

**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 information collection is associated with rulemaking, specifically an interim final rule amending the regulations pertaining to conditions for payment of indemnity for highly pathogenic avian influenza (HPAI).

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 necessary 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. APHIS is the Federal agency charged with carrying out the AHPA.

Highly pathogenic avian influenza (HPAI) is an extremely infectious and fatal form of avian influenza in poultry. An HPAI outbreak can have significant consequences for the poultry industry, wildlife, and producers' livelihoods, as well as significant impacts on international trade in poultry and poultry products. Certain strains of avian influenza have the potential to affect humans. An HPAI outbreak in poultry in the United States is declared when the first case in domestic poultry meets the case definition of HPAI as defined in the Animal and Plant Health Inspection Service's (APHIS') National List of Reportable Animal Diseases (<https://www.aphis.usda.gov/sites/default/files/avian-influenza-case-definition.pdf>). Per World Organization for Animal Health (WOAH) standards, a national HPAI outbreak ends when the United States declares freedom from HPAI in poultry by providing evidence demonstrating that the requirements for the disease status have been met in accordance with WOAH standards. Specifically, an outbreak ends when the country provides scientific data that explains the epidemiology of avian influenza in the region concerned and demonstrates how all the risk factors are managed. This includes proof of effective surveillance strategies that mitigate the introduction of HPAI.

The U.S. poultry industry experienced a severe outbreak of HPAI in 2015. The outbreak was discovered in December 2014 in backyard flocks in the Pacific Northwest, and in two commercial turkey and chicken flocks in California. Eventually 21 States reported a total of 337

HPAI detections in backyard flocks, commercial premises, captive wild birds, and wild birds. There were additional detections of HPAI in 2016, 2017, and 2020. In January 2016, HPAI virus was detected in a commercial turkey flock in Indiana. In March 2017, HPAI was detected in two commercial chicken breeder flocks in Tennessee. In March 2020, HPAI was detected in a commercial turkey farm in South Carolina.

Established U.S. animal health policy calls for control, containment, and elimination of the virus when detected in poultry flocks. When HPAI is identified, APHIS works with State and local animal health officials to euthanize poultry, clean and disinfect premises and equipment, and test for elimination of the virus to ensure that farms can be safely restocked.

The 2014-2015 outbreak was unprecedented in magnitude and scope. The final cost associated with the 2014-2015 outbreak was nearly \$1 billion. The cost obligated for response activities totaled \$650 million and indemnity payments totaled \$200 million, and an additional \$100 million was made available for further preparedness activities. Poor biosecurity practices led to HPAI introduction and spread to several commercial poultry facilities. Biosecurity practices are aimed at evaluating a premises for possible introduction of disease onto the premises and taking appropriate mitigations to address these possible sources of introduction and to limit the spread of disease if introduced. During the 2014-2015 outbreak, APHIS initially paid full indemnity to bird owners of poultry infected with HPAI, regardless of whether the owners had a plan for biosecurity practices in place at their facilities at the time of introduction.

In 2016, because of the 2015 HPAI outbreak, APHIS (through the work of the National Poultry Improvement Plan (NPIP) General Conference Committee), developed and passed the NPIP Program Standards and amended its regulations. Consequently, APHIS began requiring poultry operations to develop a biosecurity plan compliant with principles outlined in the NPIP Program Standards (i.e., to prevent the introduction of and spread of HPAI) and to have those plans audited every 2 years. Producers were given a 2-year grace period to comply with the NPIP Program Standards. Since 2018, APHIS has denied indemnity claims for destruction of animals and eggs due to HPAI if the poultry operation, unless exempted, did not have a biosecurity plan in place at the time of HPAI detection.

The U.S. poultry industry is currently experiencing a more severe outbreak of HPAI that began in 2022. As of November 2024, the costs associated with the ongoing outbreak have exceeded \$1.4 billion, including \$1.25 billion in indemnity and compensation payments. Since 2022, APHIS has spent approximately \$296 million on indemnity payments to premises that have been infected multiple times. A total of 67 unique commercial poultry premises have been infected at least twice with HPAI during the current outbreak, including 19 premises that have been infected 3 or more times. The current outbreak surpassed the 2014-2015 outbreak as the largest animal health emergency in U.S. history and APHIS' experiences to date indicate that reintroduction of HPAI onto previously affected premises persists.

In March 2024, the detection of HPAI in dairy cattle – a species in which HPAI had not previously been detected, caused by the lateral spread of HPAI – further underscored APHIS' need to revise its HPAI regulations. By early April, commercial poultry premises in the same county as affected dairy premises in Michigan were confirmed with HPAI. More than 30 poultry premises have been infected with the same genotype circulating on dairy premises.

Epidemiological investigations identified the potential factors for the transmission as shared personnel and vehicles between dairy and poultry premises and frequent visitors to the poultry premises. Additionally, several workers on affected dairy premises have become infected with HPAI.

During the current outbreak APHIS learned that, for premises in control areas and premises that have had previous introductions of HPAI within the same outbreak, biennial paper-based audits are insufficient to determine whether a premises has enough biosecurity measures in place to reduce the risk of HPAI introduction or reintroduction. APHIS' experiences show that a biosecurity plan's effectiveness is determined not only by its provisions, but also by how well the plan is implemented. APHIS has also found that it must visually inspect premises to see how well they implement their biosecurity plans. To help address spread of HPAI by verifying that commercial premises have biosecurity plans with appropriate mitigations that are being implemented and maintained, APHIS is amending the regulations to require biosecurity audits for two statuses of premises as conditions for HPAI indemnity. One audit is for HPAI-infected premises that intend to restock and wish to be eligible to receive subsequent indemnity payments during an outbreak. The other is for premises in the buffer zone of a control area that intend to move poultry from outside of or within the buffer zone and wish to be eligible to receive indemnity payments for poultry that have been moved onto the premises. (The buffer zone, which undergoes periodic surveillance, is an uninfected area situated 3-10 km around an infected premises. Premises in the buffer zone are usually notified of this status by the State animal health official, although within this rule we are making allowance for notification by APHIS instead).

APHIS plans to allow remote biosecurity audits of buffer zone premises because, while the premises are at risk of becoming affected with HPAI, they are, by definition, currently unaffected. They are in proximity to affected premises, however, and premises in the buffer zone undergo periodic surveillance. Because premises in control areas are at a higher risk of being infected with HPAI, adequate biosecurity measures need to be implemented on these premises to prevent the introduction and spread of HPAI from premises to premises within the control area, and from premises within the control area to premises outside the control area. For these reasons, virtual visual inspection should usually suffice. Conversely, previously affected premises will be audited in person (absent extenuating circumstances or a State animal health official's request) to ensure that reintroduction risks are being effectively mitigated. APHIS' goal is to reduce the risk that a producer becomes inclined to disregard biosecurity because they believe that APHIS will continue to cover the costs associated with damages related to an HPAI outbreak through indemnity payments regardless of their biosecurity status.

APHIS is asking the Office of Management and Budget (OMB) to approve its use of the information collection activities outlined below in connection with poultry producers' HPAI-related losses and expenses. The information collected will inform planning to minimize outbreaks of avian influenza and aid in developing control options.

**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.**

APHIS uses the following activities to collect information necessary to determine appropriate indemnity payments for HPAI depopulation in the United States:

**APHIS Biosecurity Audit; (9 CFR 53.10(g), 53.11(e)(2), 53.11(f)(2)); (Business, State)**

Buffer zone premises can be audited virtually unless the animal health official in the premises State requests an in-person audit. Previously affected premises will be audited in-person, absent extenuating circumstances, unless the State animal health official requests a virtual audit. All previously infected premises must pass an additional biosecurity audit before moving poultry onto the premises and every 6 months thereafter, until the State in which the premises is located declares freedom from HPAI. Producers may use successful biosecurity audits completed within the preceding 6 months, otherwise a new biosecurity audit must be conducted.

If premises in a buffer zone change their biosecurity plan, biosecurity coordinator, ownership, or infrastructure during the 6-month period, they are required to pass a new biosecurity audit in accordance with 9 CFR 53.11(f)(1)(i) before moving poultry onto the premises.

A premises will pass an audit if the audit team determines, through visual verification and review of documentation, that sufficient biosecurity is in place at the facility, and that the facility complies with any other applicable Federal regulations or orders related to HPAI. Further, the premises passes if the auditor determines that the minimum requirements are met for all biosecurity audit criteria in the biosecurity audit tool. If the auditor/team identifies deficiencies, it will communicate the identified deficiencies to producers and collaborate, where appropriate, to identify solutions to resolve the deficiencies identified. Producers may ask clarifying questions about the nature of the deficiencies and/or provide additional documentation to remediate the identified deficiency. The auditor may revise the audit results based on the additional information provided. If the producer needs further guidance on addressing a deficiency that goes beyond the auditor's training, the request should go to the audit reviewer and if needed the BCAP Program Manager. Producers must provide auditors with timelines to remediate identified deficiencies. Once the audit process concludes, the auditor will submit the audit package to a reviewer based in the State where the premises is located.

**Biosecurity Audit Tool; (9 CFR 53.10(g), 53.11(e)); (Business, State)**

Claims for HPAI indemnity, unless exempted, require producers to have a plan meeting the biosecurity principles in the NPIP Program Standards. Biosecurity plans support continuity of business and are specific to the premises and its operational procedures. The NPIP Program Standards describe the 14 biosecurity principles that must be included in the biosecurity plan. These principles can be found through viewing:

<http://poultryimprovement.org/documents/StandardE-BiosecurityPrinciples.pdf> and include:

1. Biosecurity Responsibility
2. Training
3. Line of Separation
4. Perimeter Buffer Area
5. Personnel
6. Wild Bird, Rodent, and Insect Management

7. Equipment and Vehicles
8. Mortality Disposal
9. Manure and Litter Management
10. Replacement Poultry
11. Water Supplies
12. Feed and Replacement Litter
13. Reporting of Morbidity and Mortality
14. Auditing

APHIS developed the Biosecurity Compliance Audit Program (BCAP) to administer the audits. The BCAP administration includes a BCAP Manager within APHIS' Veterinary Services program, and local auditing teams composed of an auditor and reviewer. Members of the audit team may be required to fill more than one role; however, the auditor and reviewer will be different individuals. All biosecurity auditors and audit reviewers will undergo an APHIS-led training program before joining a team. The reviewer will always be an APHIS employee because a final audit determination is an Agency decision that affects the eligibility of the producer to receive future indemnity payments for poultry destroyed due to HPAI.

To conduct the audits further described above, the BCAP members will use a biosecurity audit tool APHIS developed with State and industry input. The tool allows auditors to evaluate the premises' biosecurity plan against the 14 NPIP biosecurity principles and to document (and receive documentation) that the plan is being implemented. The tool also includes visual verification of perimeter buffer areas; line of separation procedures for personnel, visitors, equipment, and vehicles; and on-premises rodent and wildlife mitigations. Use of the tool will ensure consistency in reviewing premises and identifying biosecurity deficiencies. The tool may be revised as audits are conducted and additional data is gathered, as updated epidemiological information becomes available, or as other advancements in technology and production practices occur. To that end, the BCAP Manager will review the tool at least annually. Changes to the tool will be published in a Federal Register notice inviting public comment. APHIS may use an intermediate process to update the tool if the Administrator determines that the biosecurity tool is no longer sufficient for auditors to use to conduct biosecurity audits pursuant to 9 CFR 53.11(f)(1)(i) or (ii). APHIS will update the audit tool and subsequently publish a notice in the Federal Register advising the public of the revisions and the reasons for the revisions, providing an effective date for the revisions, and providing for a public comment period.

**Reconsideration Process for Audit Results; (9 CFR 53.11(f)(3); (Business)**

If a producer disagrees with deficiencies identified by an auditor, a reviewer will review these deficiencies and communicate their judgment in the matter to the producer. If this does not resolve the matter, a producer may request reconsideration of the outcome of the audit to the BCAP Program Manager through email or by postal mail to the addresses listed in the regulations. The request for reconsideration must be in writing, must state the material facts on which the producer considers the deficiencies identified by the auditor and reviewer to be in error, and be submitted within 14 calendar days of communication of the reviewer's results. After receipt of the reconsideration request, the BCAP Program Manager will review the reconsideration request, the audit package prepared by the auditor, and the reviewer's final audit determination. If the BCAP Program Manager disagrees with the reviewer's final determination

the results of the biosecurity audit become a pass; if the BCAP Program Manager agrees that a biosecurity deficiency exists, the reconsideration request proceeds to panel review. A panel consisting of the State animal health official of the State where the premises is located, the APHIS Area Veterinarian in Charge, and the BCAP Program Manager will review the reconsideration request, the audit package prepared by the auditor, and the reviewer's final audit determination. The panel's decision is final and the outcome of the reconsideration process will be communicated to the producer, by the auditor, as promptly as circumstances allow and will state, in writing, the reasons for the decision.

**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 E-Government Act, 2002 (E-Gov) and to provide for alternative submission of information collections.

As described above, APHIS has developed the BCAP and the biosecurity audit tool to implement the audit processes. The biosecurity audit tool is a fillable portable document format (pdf). The audits will be recorded electronically and stored in the USDA Emergency Management Response System (EMRS).

Requests for reconsideration and responses will be in writing. While these may be transmitted via email, APHIS does not have nor expects to have an automated electronic system set up for this purpose.

**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 in connection with this program is not available from any other source. APHIS is the only Federal agency responsible for preventing, detecting, controlling, and eliminating diseases of poultry from 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 85 percent of the respondents in this information collection are small businesses. The information collected is the absolute minimum needed to ensure the implementation of minimum biosecurity practices on poultry premises to prevent the introduction and spread of HPAI.

**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. The information collection is voluntary, however providing the information is mandatory to initiate and collect indemnity and compensation from the government. If the information were collected less frequently or not at all, APHIS would not know if producers are implementing sufficient biosecurity practices on their premises to prevent the introduction and spread of HPAI. Further, APHIS has paid – multiple times - producers who did not implement sufficient biosecurity measures and sustained reintroductions of HPAI on their premises. Lack of this information could undermine APHIS’ ability to provide indemnity in a cost-efficient manner and prevent the introduction and spread of HPAI to additional poultry premises, which may lead to greater hardship for producers.

**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;**
- **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 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 engaged in productive consultations with the following individuals outside the agency to gather feedback on the feasibility of implementing the biosecurity audit tool criteria and executing the BCAP, and to gather information on whether producers could comply with, and state auditors could enforce the BCAP. The respondents stated via email, phone or virtual meeting that they had concerns regarding the enforcement of the biosecurity audit criteria. Specifically, their concerns were with the consistency of the auditors conducting the audits and identifying deficiencies in biosecurity across the various poultry production categories. They did not have any further recommendations on the biosecurity audit tool or the logistical feasibility of the BCAP implementation plan. APHIS will work with stakeholders to refine the BCAP during implementation to address these concerns.

Dr. Shauna Voss  
Senior Veterinarian  
Minnesota Board of Animal Health  
P.O. Box 126  
622 Business Hwy 71 NE  
Willmar, MN 56201  
Direct: 320-441-4055  
Cell: 651-247-0255  
Email: shauna.voss@state.mn.us

Beth S. Thompson, JD, DVM  
State Veterinarian | Executive Secretary  
South Dakota Animal Industry Board  
411 S. Fort Street  
Pierre, SD 57501  
Office: 605-773-3321  
Cell: 507-272-6254  
Email: Beth.Thompson@state.sd.us

Lindy Chiaia, Ph.D.  
Vice President of Scientific and Regulatory Affairs  
National Turkey Federation  
1225 New York Avenue NW, Suite 400



Washington, D.C. 20005  
Cell: 936-671-0322  
Email: LChiaia@turkeyfed.org

On December 31, 2024, APHIS published in the Federal Register (89 FR 106981) a notice of interim final rule, RIN 0579-AE 79, Payment of Indemnity and Compensation for Highly Pathogenic Avian Influenza (HPAI), amending the regulations. The amendments are effective December 31, 2024, but the notice includes a 60-day period for receiving public comments through March 3, 2025. Any changes to this information collection request resulting from public comments will be implemented in the collection's revision.

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

This information collection activity involves no 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.**

No additional assurance of confidentiality is provided with this information collection. Any and all information obtained in this collection shall not be disclosed except in accordance with 5 U.S.C. 552a.

**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 request 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 525 respondents, (affected public: 473 Business; 52 State, Local, and Tribal), 1,302 total annual responses and 5,652 total annual burden hours.

Burden estimates breakouts were developed on real-time use and discussions with commercial poultry farm owners and managers; private veterinarians; poultry agencies and organizations; and State animal health officials and laboratory personnel. There are no third-party disclosure burden estimates.

See APHIS Form 71 for hour burden estimates.

- **Provide estimates of annualized cost to respondents for the hour burdens for collections of information, identifying and using appropriate wage rate categories.**

The total annualized cost to respondents is \$286,723.13, computed by multiplying the estimated average hourly wage (\$35.50) by the total number of burden hours (5,652) needed to complete the work, and then multiplying the result (\$200,646) by 1.429 to capture benefit costs.

Dept of Labor SOCC Code	Average Wage	Occupation Description
11-9013	\$ 43.35	Ranchers
29-1131	\$ 65.53	Veterinarians
45-2021	\$ 25.73	Animal breeders
45-2093	\$ 17.82	Ranch farmworkers
45-2011	\$ 25.08	Agricultural inspectors
	<b>\$ 35.50</b>	<b>Average Hourly Wage</b>

The average hourly rates used to calculate the estimate are for ranchers (SOCC 11-9013, \$43.35); veterinarians (SOCC 29-1131, \$65.53); animal breeders (SOCC 45-2021, \$25.73); ranch farmworkers (SOCC 45-2093, \$17.82); and agricultural inspectors (SOCC 45-2011, \$25.08), using information found at the U.S. DOL Bureau of Labor Statistics occupational employment statistics website.

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 \$251,367.

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

	Total Requested	Previously Approved	Change Due to New Statute	Change Due to Agency Discretion	Change due to Adjustment in Estimate	Change Due to Potential Violation of the PRA
Annual Number of Responses	1,302	0	0	1,302	0	0
Annual Time Burden (Hr)	5,652	0	0	5,652	0	0

This is a new collection. It has an estimated 525 respondents, 1,302 annual responses, and 5,652 annual burden hours. The estimated number of responses per respondent is 2.48, and estimated burden per response is 4.34 hours.

The Agency estimates there will be 52 State and 473 business respondents affected by the three new information collections in this rule. For the APHIS Biosecurity Audit information collection, it estimates there will be 104 State and 473 business responses, with 624 total annual burden hours for State respondents and total annual 2,728 burden hours for business. For the Biosecurity Audit Tool information collection, it estimates there will be 52 State and 473 business responses, with total burden hours of 208 for State respondents and 1,892 for business respondents. For the Reconsideration Process for Audit Results information collection, it estimates there will be 200 business responses and 200 hours of burden annually.

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

APHIS has no plans to publish information it collects in connection with this program.

**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 is not seeking an exemption.

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

APHIS can certify compliance with all provisions under the Act.