

Supporting Statement
Case-Control Study on Highly Pathogenic Avian Influenza in Poultry 2022
OMB Control Number 0579-XXXX

Part A

A. Justification

1. Explain the circumstances that make the collection of information necessary. Identify any legal or administrative requirements that necessitate the collection of information.

The Animal and Plant Health Inspection Service (APHIS) is requesting approval for information collection request for a Case Control Study on highly pathogenic avian influenza (HPAI) in commercial table egg flocks, hereafter referred to as the Study.

In 2015, the United States experienced an outbreak of HPAI that has been described as the worst animal health event in U.S. history, requiring over \$950,000,000 in federal expenditures and a loss of nearly 50 million birds. At that time, in Iowa alone, more than 30 million table egg layers and pullets were lost to infection or depopulation. This represented a loss of 52% of the Iowa table egg layer inventory.

Since that time, Federal, State, and industry groups have promoted biosecurity and preparedness efforts and engaged in research that has guided prevention work to minimize future outbreaks. Though the 2022 outbreak of HPAI has a wider geographic distribution, the impacts have been lessened. However, these effects are still devastating. As of the end of May 2022, nearly \$800 million in federal expenditures has been authorized. Over 40 million birds have been lost to infection or depopulation, and over 30 million of these birds are commercial table egg layers, pullets, and breeder birds.

The strain of HPAI that caused the outbreak in 2015 was different than the strain causing the outbreak in 2022. Avian influenza viruses vary in transmissibility and ability to cause disease symptoms. Evidence suggests that the predominance of infections in 2022 were due to independent wild bird introductions, whereas lateral spread from farm to farm was more common in 2015, therefore, updated information on factors associated with HPAI infection is needed. As the fall season of wild bird migration approaches and the risk of a resurgence of new infections increases, it is critical to identify current risk factors to mitigate future outbreaks.

This study will generate up-to-date information needed to determine current risk factors for infection with this environmentally hardy foreign animal disease pathogen. Current information on risk factors is critical for science-based updates to prevention and control recommendations.

APHIS will solicit study participation from affected and unaffected producers collected from the Emergency Management Response System. Having accurate farm data in EMRS prior to an incident significantly facilitates response efforts and allows resources to be devoted to other critical information management tasks during an outbreak. As part of surveillance for HPAI, we

monitor uninfected farms to test for infection. This is captured in EMRS. APHIS will collect data via in-person surveys with commercial table egg layer, pullet, and breeder producers. Face-to-face surveys offer advantages in data quality and ensure respondents remain focused and engaged while completing the survey. Additionally, if we are to compare results from the 2015 survey to the current survey, it would be considered best practice to administer the survey in 2022 the same way it was administered in 2015.

This survey is voluntary. This data collection supports the following study objectives:

- Identify current risk factors for the development of HPAI and biosecurity challenges
- Refine biosecurity recommendations to prevent HPAI in commercial table egg flocks^{1,2}
- Where feasible, compare biosecurity practices of commercial table egg producers in 2015 and 2022 to determine areas of improvement and additional opportunities for improvement

Collection and dissemination of animal health data and information is mandated by 7 U.S.C. § 391, the Animal Industry Act of 1884, which established the precursor of the APHIS, Veterinary Services, the Bureau of Animal Industry. Legal requirements for examining and reporting on animal disease control methods were further mandated by 7 U.S.C. § 8308 of the Animal Health Protection Act, “Detection, Control, and Eradication of Diseases and Pests,” May 13, 2002. This collection of commercial table egg flock data is consistent with the APHIS mission of protecting and improving American agriculture’s productivity and competitiveness.

As an ongoing disease threat with significant economic impacts to affected producers, updated information on the sources, impacts, and spread of this disease is critical for informing prevention and response efforts, including biosecurity measures. The epidemiology of highly pathogenic avian influenza in commercial layers is complex. Many U.S. trading partners will not accept poultry or poultry products from countries affected with HPAI. The U.S. poultry export market is approximately \$4.25 billion annually. Determining current and complex risk factors for HPAI and developing science-based mitigation strategies to address these risks, is the best option APHIS has to minimize the domestic and export-related effects of the pathogen on the United States poultry industry.

2. Indicate how, by whom, 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.

Results of a similar study conducted in 2015 were widely utilized by producer groups, academicians, and extension specialists, state and federal animal health officials, and veterinarians. The data collected, analyzed, and interpreted will be disseminated to a wide variety of stakeholders. Producers can utilize the study findings to update flock and barn biosecurity practices to reduce the risk from avian influenza. Producer groups, academicians and extension

¹ https://www.aphis.usda.gov/animal_health/emergency_management/downloads/hpai/2015-hpai-final-report.pdf , p. 9.

² <https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/animal-disease-information/avian/defend-the-flock-program/df-biosecurity/bird-biosecurity>

specialists, state and federal animal health officials, and veterinarians will use summary estimates of disease and associated operation characteristics to improve health management, disease prevention measures, disease response measures, and information outreach efforts. State and Federal officials responsible for regulatory veterinary medicine will use estimates reflecting disease and disease prevention to gain a more complete picture of animal health as a basis for program planning and funding. Research scientists will also use summary point estimates to design their research efforts. Veterinary and agricultural students in universities will use the reports for training in health management and other agriculturally based careers. Additionally, students will participate in the data collection and analysis process, furthering their training.

APHIS will use the data collected from the study to address the following goals:

- Identify current risk factors for the development of HPAI and biosecurity challenges
- Refine biosecurity recommendations to prevent HPAI in commercial table egg flocks
- Where feasible, compare biosecurity practices of commercial table egg producers in 2015 and 2022 to determine areas of improvement and additional opportunities for improvement

The questionnaire includes questions on-farm practices including current biosecurity practices, ecology and wild birds/wildlife, farm worker practices, equipment, egg handling, dead bird handling, and barn-level parameters. All of these topics are potentially associated with risk for HPAI, however, it is not known which of these may be most relevant for the current outbreak. The case-control approach allows comparison of practices and parameters for affected and unaffected farms. This information can support informed decision-making for producers seeking to protect themselves against future infection. In the case of ecological differences between case farms and control farms, findings can support seasonal decision-making such as heightened biosecurity during wild bird migration seasons. Changing practices can be resource-intensive for producers, therefore, current epidemiologic information is needed for informed decision-making.

Additionally, as a member in good standing of the World Organisation for Animal Health (WOAH), it is incumbent upon the United States to provide scientific data to explain the epidemiology of avian influenza within U.S. borders. This requirement is stated in WOAH Terrestrial Code Chapter 10.4, article 10.4.26. WOAH is the international regulatory body for animal health. Its role is mandated by the World Trade Organization.

Commercial Table Egg Flock Case Control Survey; (State, Business)

A survey that participating table egg layer producers will complete in person with an enumerator from APHIS VS or a state department of agriculture. Enumerators will return questionnaires to the APHIS study team. Survey data will be stored and maintained on secure a USDA network. No personally identifiable information are included with the survey data.

The potential respondent universe for the Highly Pathogenic Avian Influenza Virus (HPAI) Commercial Table Egg Flocks Case Control study are all commercial table egg layer, pullet, and breeder operations located in the 10 States where positive commercial table egg premises have been detected, as listed in the APHIS Emergency Response Management System (EMRS). All

26 commercial table-egg producers affected by HPAI in 2022 will be contacted and asked to participate in the survey.

The maximum number of survey participants is 78 (26 case premises + 52 control premises). All participating producers will receive the same questionnaire.

Case Control Study Screening Responses for Controls: (Business)

To account for nonresponse, up to 5 potential control table egg operations will be contacted for every control operation that participates in the study, therefore an estimated 260 contacts of 10 minutes each are included in APHIS Form 71 (5 x 52).

Contact information for case and control farms will be obtained from the USDA VS Emergency Management Response System, and, if needed, from shared company records, or by information provided by the State agricultural flock data base.

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 will administer the study to participating producers in person at a mutually agreed location off-site from the farm premises. Screening will take place via phone call or email.

4. Describe efforts to identify duplication. Show specifically why any similar information already available cannot be used or modified for use for the purpose(s) described in item 2 above.

APHIS staff performed literature searches for existing data relevant to the Study. Available data were reviewed and compiled from all known sources. Sources reviewed include a wide variety of research publications. APHIS staff consulted employees from federal agencies, industry representatives, and academicians to identify areas of potential duplication. Based on this effort, APHIS is convinced that no other entity/source is collecting and analyzing this type of nationally representative information regarding highly pathogenic avian influenza impacts to the U.S. commercial table egg layer industry with publicly available results.

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

APHIS is minimizing burden by prefilling questionnaires with data already provided by case operations, reaching out to the minimum number of operations to meet needs of 2 controls per case operation, only asking questions relevant to the objectives of the study, and only including operations with 50,000 or more birds. All case farms had 50,000 or more birds; no small entities are involved. Smaller farms are not included so that the control population is appropriately matched to the case population, and they tend to have practices that are different than larger

farms solely due to scale. The Study is designed to collect data from selected producers who are willing to participate and thus not burden producers who feel they do not have the time to participate, which will minimize potential impacts on business operations. Industry and producer input into the survey has been solicited to ensure that information collected is relevant, timely, and of appropriate complexity. Response to any portion of the Study is voluntary.

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.

The rapid spread of HPAI in commercial table egg layer flocks has resulted in significant economic losses for producers. Without information on the most likely routes of disease introduction, flock managers are unable to implement updated science-informed approaches to preventing infection and/or spread. Because infection results in depopulation of affected flocks and widespread trade restrictions, the lack of rapid prevention and control measures will have significant economic impacts to the commercial table egg layer industry.

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

- **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;**

Both the screening and the survey will take place in fewer than 30 days after first contact, however, a prepared written response is not required of respondents.

- **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.

The following people were consulted during planning and development of the Study:

- Dr. Elliott Dennis, agricultural economist and extension specialist, 208A Filley Hall, University of Nebraska Lincoln, Lincoln, NE 68583

Dr. Dennis was consulted on the value of the study and the general approach, as well as the potential for economic analysis work utilizing data collected.

- Dr. David Halvorson, avian health specialist, 144 Veterinary Science Building, 1971 Commonwealth Avenue, Saint Paul, MN 55108

Dr. Halvorson was a collaborator in development of the draft survey tool as well as seeking buy-in from industry veterinarians.

- Dr. Jennifer Burroughs, veterinary medical officer, Pennsylvania Department of Agriculture 2301 N. Cameron St., Harrisburg PA 17110
Dr. Burroughs was consulted on the value of the study, consideration of types of commercial layer premises to include, and the development of the draft survey tool.

This is an emergency information collection request (ICR) and the Federal Register notice for public comment will be published after approval but before renewal.

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. The information collected will be valuable to 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.

APHIS will protect the data from this study as Confidential Business Information (CBI) as defined in 19 CFR 201.6. Respondent information will be protected by ensuring that no identifying information is linked to the data.

Only summary estimates based upon the inference population will be reported. While every effort will be made to ensure respondent confidentiality, it is possible that information could be released as required by a Freedom of Information Act, or in the case of required disease reporting. However, names, addresses, and personal information will not be linked with survey.

11. Provide additional justification for any questions of a sensitive nature, such as sexual behavior and 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.

There are no questions of a sensitive nature used in this collection activity.

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. 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.**

A total of 155 annual burden hours are needed to complete the Study over the collection period for this information collection. A detailed burden estimate has been included on the enclosed APHIS Form 71.

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

The total annualized cost to respondents is \$8,063, computed by multiplying the estimated average hourly wage (\$35.90) by the total number of burden hours (155), and then multiplying the product (\$5,564.50) by 1.449 to capture benefit costs.

The average hourly rates used to calculate the estimate are \$34.09 for State agricultural officials (news release USDL-22-0469 obtained from the U.S. Department of Labor Bureau of Labor Statistics website https://www.bls.gov/news.release/archives/ecec_03182022.htm) and \$37.71 for farmers (BLS SOCC 11-9013 obtained from the U.S. DOL Bureau of Labor Statistics website at http://www.bls.gov/current/oes_stru.htm).

According to DOL BLS news release USDL-22-0469, employee benefits account for 31 percent of employee costs, and wages account for the remaining 69 percent. Total costs can be calculated as a function of wages using a multiplier of 1.449.

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 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.

There are no capital/startup costs or ongoing operations and maintenance costs for respondents or record keepers associated with this information collection. Questions in this study may reference operation records, but APHIS does not require producers to maintain or provide these records to answer questions.

14. Provide estimates of annualized cost 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.

The estimated cost for the Federal Government is \$32,244 (see APHIS Form 79).

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

This is a new information collection request.

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

APHIS and partners will summarize information from this survey 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.

The OMB approval expiration date will be displayed on the survey.

18. Explain each exception to the certification statement identified in the “certification for paperwork reduction act.”

APHIS is able to certify compliance with all provisions in the Paperwork Reduction Act.