SUPPORTING STATEMENT ON-FARM MONITORING OF ANTIMICROBIAL USE AND RESISTANCE IN U.S. BROILER PRODUCTION OMB NUMBER 0579-XXXX

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 pertinent section of each statute and regulation mandating or authorizing the collection of information.

7 U.S.C. § 391, the Animal Industry Act of 1884, directs USDA to collect and disseminate animal health data and information. 7 U.S.C. § 8308 of the Animal Health Protection Act, "Detection, Control, and Eradication of Diseases and Pests," May 13, 2002, further directs USDA to examine and report on animal disease control methods.

APHIS's mission is to protect and improve American agriculture's productivity and competitiveness. Realizing this mission relies, in large part, on collecting, analyzing, and disseminating livestock and poultry health information. The APHIS-NAHMS program conducts studies to investigate current issues and examine general health and management practices used on farms and provides this information to the public. Industry and stakeholder interest drives these studies. The information collected is not available from any other source.

APHIS is making this submission to initiate the National Animal Health Monitoring System's (NAHMS') On-farm Monitoring of Antimicrobial Use and Resistance in U.S. Broiler Production study. This study is an information collection conducted by APHIS through a cooperative agreement with the University of Minnesota. University of Minnesota completed previous work for APHIS under a different cooperative agreement in which APHIS received reports and completed analyses but not farm-level data. Now, however, APHIS desires access to the non-identified farm-level data. This change will better leverage APHIS and the University of Minnesota's shared expertise.

This longitudinal study will monitor U.S. broiler chicken operations for antimicrobial use (AMU), antimicrobial resistance (AMR), animal health and production practices, and the relationship between them and changes over time. We plan to accomplish this by collecting survey data and litter samples over time from the same poultry complexes and examining AMR in bacteria such as *Salmonella* and *Campylobacter*. This study meets objectives for both the U.S. National Action Plan for Combating Antibiotic Resistance (2015) and the USDA AMR National Action Plan (2013). Additionally, this information is an essential component in accomplishing APHIS' second strategic goal, to safeguard American agriculture. Specifically, this collection will directly support objective 2.2¹.

¹ See <u>https://www.aphis.usda.gov/about_aphis/downloads/aphis-strategic-plan.pdf</u>.

APHIS and the University of Minnesota will analyze and organize the information into one or more descriptive reports and scientific manuscripts. For important or special topics, APHIS will develop and disseminate targeted information sheets to producers, stakeholders, academicians, veterinarians, and any other interested parties. This information benefits the poultry industry by supplying scientific estimates of AMU and stewardship by poultry producers and the influence of these and other management practices on AMR.

Participation in this survey is voluntary. Selected producers will decide whether to participate and may leave the study when they wish.

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.

This study provides U.S. poultry producers and animal health professionals information about the relationship between AMU, AMR, animal health and production, and changes in each over time. This information is essential for effectively responding to the global health threat posed to animals and humans of increasing antimicrobial resistance. This is a new data collection by APHIS.

<u>On-Farm Monitoring of Antimicrobial Use and Resistance in U.S. Broiler Production</u> <u>Survey (NAHMS 471), (Business)</u>

The University of Minnesota grantee will assign each company, complex, and farm a unique identification number for participating producers and then mail a paper survey to the participants. The producer/company contact will complete it every quarter and collect litter materials if they choose to do so. The complete survey and littler samples are then shipped to the research team at the University of Minnesota.

<u>On-Farm Monitoring of Antimicrobial Use and Resistance in U.S. Broiler Production –</u> <u>Informed Consent (NAHMS 470), (Business)</u>

Both APHIS-NAHMS and the University of Minnesota are committed to safeguarding participant's confidential business information. This form will increase the participant's understanding of the study focus, highlight confidentiality safeguards, explain participation processes, and the benefits of participation. A University of Minnesota data collector will review the form with the producer/company contact and if after reviewing the document the producer/company contact. Copies will be retained by the University of Minnesota grantee and APHIS-NAHMS. The consent is valid for one year and will be renewed each year of the study.

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.

The small size of the survey group does not warrant the time or costs to produce or train on the use of an information system. Completed surveys may be returned via email or fax.

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.

APHIS and University of Minnesota conducted literature searches of all known sources for existing data relevant to the study. These sources include private industry and professional publications, other Federal and State agencies, and universities. APHIS and University of Minnesota consulted experts from other Federal agencies and academia to identify any potential duplication. We found no other entity/source collecting and analyzing this type of information to obtain comparable estimates.

AMU and AMR in food animals are changing rapidly due to regulatory and private market influences. Therefore, historical information does not fulfill USDA and APHIS monitoring needs. USDA and APHIS need current AMU and AMR information to make effective decisions in this area of animal health and welfare.

5. If the collection of information impacts small businesses or other small entities, describe any methods used to minimize burden. Include the percentage of respondents contacted that are small entities.

APHIS estimates there are no small entities impacted by this request as no small businesses will be selected for participation. We are using the Small Business Administration's criteria (grossing less than \$1 million annually) for small businesses as the definition of these entities². This study will survey some of the largest broiler chicken companies in the United States, as identified from the Watt poultry list³. The smallest company listed reported producing 0.19 million head and employing 325 staff. Overall, companies on the list had production numbers ranging from 0.19 to 38.30 million birds and employee numbers ranging from 325 to 52,700.

APHIS will minimize the impact to producers by allowing produces to provide data when it is convenient for them. There is reasonable time built into the study in which to take samples (21 days to slaughter age).

² See: <u>https://www.ecfr.gov/cgi-bin/text-idx?</u>

SID=0ff5f0839abff4eec707b4478ed733c6&mc=true&node=pt13.1.121&rgn=div5#se13.1.121_1101.

³ List of top 30 U.S. broiler producer companies available here: <u>https://www.wattglobalproducts.com/products/top-us-broiler-producers-of-2019</u>.

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.

Without this survey, APHIS will have limited information by which to make decisions related to AMU and AMR as they relate to the U.S. poultry industry.

The United States requires the ability to understand trends in AMU, AMR, animal health, and production in the poultry industry to make effective animal health and welfare decisions. The information generated from this purposive data collection will enable USDA, state animal health entities, the U.S. poultry industry, and individual producers to make these decisions.

APHIS-NAHMS has generated national estimates of some on-farm AMU measures and AMR in selected bacteria from traditional commodity studies conducted in species other than poultry. Not all these studies had the adequate statistical power we desired. While we have had success with measuring the relationship between AMU and AMR, as well as between AMU, AMR, stewardship, animal health and production, there are limits on these data.

Our traditional studies have longer inter-study intervals and cross-sectional study designs than the study we are proposing. Therefore, trends estimates are subject to higher variance and are unable to adequately assess correlation. This study, conducted with repeated sample collections from the same complexes, provides the most robust method for reducing the variability to discern relationships between factors.

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 than quarterly
- Requiring respondents to prepare a written response to a collection of information in fewer that 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;

The focus of the study is on longitudinal AMU and AMR effects at the poultry complex level. The study will not conduct a strict probability sample at levels below the company. For example, the selection of complexes within company, farms within complex, and houses within farm. Our purpose for this is to maintain a low enough burden on companies in order to encourage and maintain participation over time.

Even though the sample is not a probability sample, APHIS believes that this study is the most comprehensive study investigating AMU and AMR in U.S. broiler production. We believe this because we are targeting the 30 top broiler-producing companies in the U.S, The companies produce the majority (approximately 95%) of live weight slaughtered and young chickens slaughtered in the U.S. (see Section B.1 of this justification for additional details).

APHIS and the University of Minnesota post-stratify estimates as appropriate. This effort will use population-level information such as slaughter estimates and antimicrobial use policies in U.S. broiler production.

- 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

APHIS will not utilize a pledge of confidentially to collect these data. The University of Minnesota will maintain the contact information for participants. It will provide only deidentified data to APHIS. Once APHIS receives the de-identified data, we will consider the data protected as confidential business information, and it will be managed in the same manner as APHIS manages data protected by CIPSEA. This means it will be maintained in the NAHMS data lab, which is an access-controlled room with a dedicated air-gapped network used for managing controlled data. APHIS, the University of Minnesota, and the poultry industry all believe that the information the participants provide is confidential business information products accordingly.

• 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, other than those addressed in the item above, 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 record keeping, 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 and the University of Minnesota consulted the following people during the study planning and development to gather input on feasibility, burden and need for the data collection. Their input as well as other from industry and producers were used to develop the survey questionnaire to ensure the information collected is relevant and timely.

Ashley Peterson, Ph.D. Senior Vice President of Scientific and Regulatory Affairs National Chicken Council 1152 Fifteenth Street, NW Suite 430, Washington, DC 20005

Dr. Ashley Peterson provided input on approaches for data collection to gather relevant information while reducing the burden on the producer. She also assisted with strategies for participant recruitment.

Denise Heard, DVM, MAM, ACPV Director, Research Programs U.S. Poultry & Egg Association 1530 Cooledge Road Tucker, GA 30084-7303

Dr. Denise Heard (and others at USPOULTRY) provided input on approaches for data collection to gather relevant information while reducing the burden on the producer. She also assisted with strategies for participant recruitment.

Charles Hofacre, DVM, MAM, PhD President, Southern Poultry Research Group 1061 Hale Road Watkinsville, GA. 30677

Dr. Charles Hofacre helped create this program in 2014 and provided input on approaches for data collection and participant recruitment.

USDA NASS reviewed the packet and provided one recommendation which was incorporated into Part B of the supporting statement.

On March 16, 2021, a notice was published in the Federal Register (86 FR 14404) providing a 60-day period for public comment on this information collection request. Three comments were received but had no impact on the action.

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

Neither APHIS nor University of Minnesota will provide any direct payments or gifts to respondents. The biological sampling of litter samples does have a monetary value. We estimate the value at approximately \$285 per farm. This sampling provides pathogen presence and prevalence information. Additionally, it enables us to evaluate antibiotic resistance metrics that cannot be provided through other means. Producers may consider this sampling an incentive to participate. The information provided back to the producer can be used to gain a better understanding of pathogen presence and their antimicrobial susceptibility. Therefore, producers can use his information to inform management decisions, such as medication use.

10. Describe any assurance of confidentiality provided to respondents and the basis for the assurance in statute, regulation, or agency policy.

All information acquired from study respondents will be used for statistical purposes only. Information collected by the University of Minnesota on behalf of APHIS will not be protected by The Confidential Information Protection and Statistical Efficiency Act, (CIPSEA). However, APHIS, the University of Minnesota, and the poultry producers all consider the provided information to be confidential business information in accordance with 19 CFR 201.6 and Section 777(b) of the Tariff Act of 1930 (19 U.S.C. 1677f(b)). The information provided by producers is not customarily shared publicly. APHIS and the University of Minnesota will protected this information from Freedom of Information Act (FOIA) requests under exemption 4.

The University of Minnesota will provide respondents confidentiality information as part of the enrollment process using NAHMS 470 and a CBI explanation document.

University of Minnesota will assign unique respondent ID codes to sampled complexes and farms. Only the University of Minnesota will know the participating company's identity. It will manage this connection using a confidential key containing the company information and assigned unique ID. The University of Minnesota will destroy this key once data collection, entry, validation, and report dissemination are complete.

All forms and data will refer to the respondent by the unique code only. University of Minnesota will conduct the biological sample testing. Additionally, it will encrypt and securely store all completed survey forms and laboratory test results. Finally, the University of Minnesota will securely send APHIS a dataset ,containing no PII, which will be stored on an APHIS server in a secure, limited access data lab.

APHIS and University of Minnesota will report only summary estimates and results of analyses to protect the privacy and confidentiality of individual companies and producers. Furthermore, once data are published, individuals are generally limited to the use of aggregate data files. Access to individual data files is restricted to maintain respondent confidentiality.

Several additional U.S. Codes apply to data collected by APHIS-NAHMS:

- Title 7, Section 2276 Confidentiality of Information.
- Title 18, Section 1902 Disclosure of Crop Information and Speculation Thereon.
- Title 18, Section 1905 Disclosure of Confidential Information Generally.
- Section 1619 of the 2008 Farm Bill.
- 19 CFR 201.6 Definition of Confidential Business Information.

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.

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.

• 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.

See APHIS 71.

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

APHIS estimates the annual respondent cost for the study is \$65,364. This estimate was calculated by multiplying the estimated burden hours (866) times the average wage for a veterinarian (BLS SOCC 29-1131, \$52.09), and then multiplying the product by 1.449 to capture benefit costs.

The SOCC and wage was obtained from the Bureau of Labor Statistics webpage https://www.bls.gov/oes/current/oes291131.htm.

According to DOL BLS news release USDL-21-0437, dated March 18, 2021, employee benefits account for 31% of employee costs, and wages account for the remaining 69%.

Mathematically, we can calculate total wage cost as a function of the published wages using a multiplier of 1.449.

13. Provide estimates of the total annual cost burden to respondents or record keepers 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 startup cost component annualized over its expected useful life; and (b) a total operation and maintenance and purchase of services component.

There are no capital/start-up costs or ongoing operations and maintenance costs associated with this information collection.

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. We estimate the cost to the Federal Government will be \$391,085 annually.

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. APHIS estimates there will be 30 respondents, 588 responses, and 866 hours of burden annually.

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

This information collection is a collaborative effort between APHIS and the University of Minnesota. Both parties will jointly summarize the data following data collection, validation, editing, and analysis of the data. Both parties will also enter data into database management systems, and perform statistical calculations, e.g., descriptive statistics including frequency distribution, prevalence, and ratio estimates. In order to describe the precision of the estimates, we will calculate variance measures and confidence intervals for the point estimates as appropriate. Additionally, we will conduct analytics that account for the longitudinal study design over a prolonged period.

APHIS will prepare an annual report which will detail the descriptive and inferential analysis results as described in Section B.2 of this submission. APHIS will publish this report under the "Antimicrobial Use and Resistance" link at <u>http://www.aphis.usda.gov/nahms</u>. APHIS and the University of Minnesota will create and submit manuscripts for peer-reviewed publications.

APHIS electronic summaries of results from the study will be made available to producers, universities, researchers, practitioners, animal health related industries, Federal agencies, legislators, and any other interested party.

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 to display the OMB approval expiration date.

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.