Supporting Statement – Part A OMB Control Number: 0579-0481

Title: Center for Epidemiology and Animal Health (CEAH), National Animal Health Monitoring System (NAHMS), On-Farm Monitoring of Antimicrobial Use and Resistance in U.S. Broiler Production Study **Date Prepared:** November 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 is a request for extension without change of an information collection request. APHIS is asking the Office of Management and Budget (OMB) to approve this request for 3 years.

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. APHIS' National Animal Health Monitoring System (NAHMS) 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 continue 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-NAHMS through a cooperative agreement with the University of Minnesota. The Food and Drug Administration (FDA) awarded a cooperative agreement to the University of Minnesota for piloting of methodologies to collect on-farm antimicrobial use (AMU) data (for chickens, turkeys, and swine) beginning in September 2016 and lasting for five years. Due to COVID-19-related delays in 2020, this award was extended through July 2022. The FDA cooperative agreement work did not include collection of antimicrobial resistance data. Starting in Fiscal Year 2017, or FY17 (October 2017-September 2018), APHIS-NAHMS entered into a cooperative agreement with the University of Minnesota to gather AMU and antimicrobial resistance (AMR) data on broiler farms under a longitudinal study design to investigate the relationships between them.

Under the terms of the previous cooperative agreements, the cooperator provided quarterly progress reports as well as an annual report. The main interest of the cooperator was to produce

manuscripts based on the data collected. APHIS-NAHMS received aggregated data in the reports and did not have access to record-level data. These quarterly reports included aggregate summary results describing the presence or absence of *Salmonella*, *E. coli* and *Campylobacter*, *Salmonella* serotype and *Campylobacter* species distributions, and antimicrobial susceptibility profiles for the *Salmonella* and *Campylobacter* isolates tested during the quarter.

The annual report described the overall methodology utilized in the project and the scope of the annual sampling. Annual prevalence for *Salmonella* and *Campylobacter* in the samples was reported. *Salmonella* serotypes and *Campylobacter* genus information for the isolates collected were reported. Finally, the aggregate antibiotic usage information was described. Manuscripts for peer-reviewed publication were prepared during the year, and progress of these manuscripts was described in the report. All results in this report and manuscript were aggregated so that individual producers are kept anonymous and their individual data confidential.

Not having access to record-level data made it difficult for APHIS-NAHMS to produce reports which meet NAHMS' standards. These standards ensure that reports include percentages at both the animal and site or operation level and also include standard errors so differences can be detected. Therefore, beginning with the FY22 (October 2022-September 2023) cooperative agreement, APHIS-NAHMS required the cooperator to make the non-identified (unique farm ID only identifying the operation, no names) record-level data available for analysis and reporting. This change better leveraged APHIS-NAHMS' and the University of Minnesota's shared expertise. All samples taken are pooled and are representative of an entire house, so results will be reported at the site level since animal level results are not available. This longitudinal study will continue the monitoring of 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 will accomplish this by collecting survey data and litter samples over time from the same broiler 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-Resistant Bacteria (2015 and 2020) and the USDA AMR National Action Plan (2014). Additionally, this information is an essential component in accomplishing APHIS' second strategic goal, to safeguard American agriculture. Specifically, this collection will directly support objective 2.2.¹

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

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

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

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.

This study provides U.S. broiler 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. APHIS-NAHMS is developing a dashboard as well as a descriptive report and several information briefs based on the data received from the University of Minnesota. All of these data products are in the draft stage and are anticipated to be released on the NAHMS website later in calendar year 2024.

<u>On-Farm Monitoring of Antimicrobial Use and Resistance in U.S. Broiler Production –</u> <u>Informed Consent (NAHMS 470); 7 U.S.C. 391; Business</u>

Both APHIS-NAHMS and the University of Minnesota are committed to safeguarding participant's confidential business information. This form increases the participant's understanding of the study focus, highlights confidentiality safeguards, and explains participation processes and the benefits of participation. A University of Minnesota data collector reviews the form with the producer/company contact, and if the producer/company contact wishes to participate, the data collector will sign the form and give the original to the producer/company contact. Copies are retained by the University of Minnesota grantee.

<u>On-Farm Monitoring of Antimicrobial Use and Resistance in U.S. Broiler Production</u> <u>Survey (NAHMS 471); 7 U.S.C. 391; Business</u>

The University of Minnesota grantee assigns each company, complex, and farm a unique identification number for participating producers and then mails a paper survey to the participants. The producer/company contact completes the survey every quarter, collects litter (bedding) materials if they choose to do so, and ships these to the research team at the University of Minnesota.

APHIS-NAHMS produces reports and dashboards on the APHIS website and collaborates on manuscripts written by the cooperator. APHIS-NAHMS has been addressing AMR in the agricultural production environment through multiple initiatives for decades including studies conducted by APHIS-NAHMS and as an active participant in national planning, including the National Action Plan for Combating Antibiotic-Resistant Bacteria (NAP-CARB, 2015 and 2020) and the USDA AMR Action Plan (2014). Information from this study provides information about the relationship between AMU, AMR, animal health and production, and changes in each over time. This benefits U.S. broiler producers, other federal agencies, animal health professionals, stakeholders, academicians, and the general public. APHIS-NAHMS has no regulatory authority over AMU and AMR (FDA does) but provides this information as a service through the APHIS-NAHMS program. FDA has expressed to APHIS in the past that they rely on the NAHMS program to provide data on on-farm antimicrobial use because FDA does not have the staff or authority to collect these data on farms. 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.

Surveys are administered via paper format, and completed surveys are returned via mail, email or fax. 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.

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.

Every effort has been made to avoid duplication. APHIS-NAHMS and University of Minnesota conducted literature searches of all known sources for existing data relevant to the study. These sources included private industry and professional publications, other Federal and State agencies, and universities. APHIS-NAHMS and the University of Minnesota also 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.

The primary information collected on AMU in the U.S. is sales data collected by FDA, who produce annual reports on these data. The challenge with sales data, though, is that they are not indicative of actual antimicrobial use practices; rather, they represent a summary of the volume of product sold or distributed through various outlets by antimicrobial drug manufacturers, not the volume of product ultimately purchased by the end user for administration to animals in a particular year. In addition, sales data lack the granularity to determine the reason for antimicrobial administration and other details such as age at administration, dose, route and duration. There have been some studies on AMU conducted on subsets of farms, but the intent of this longitudinal study is to provide national estimates of AMU and AMR on broiler farms.

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-NAHMS monitoring needs. USDA and APHIS-NAHMS need current AMU and AMR information to make effective decisions in this area of animal health and welfare.

On January 1, 2017, the FDA instituted policy changes in the use of medically important antibiotics in livestock and poultry feed such that a veterinary feed directive administered by a veterinarian is now needed to use these antibiotics. Prior to this date, antibiotics used in feed were available over-the-counter, and veterinary involvement was unnecessary. Because of these regulatory changes, antibiotic use practices in feed have changed for both livestock and poultry.

Historical data prior to 2017 would not serve as a good baseline due to the changes in use practices that occurred in 2017 and subsequent years.

In addition, over the past several years, due to increased concern from consumers on use of antibiotics in livestock and poultry, many companies began raising broilers that never received antibiotics under a "no antibiotics ever" marketing strategy. Approximately half the broilers in the U.S. are currently raised under a "no antibiotics ever" strategy. These newer market-driven influences have led to newer practices that are not comparable to historical antibiotic use practices. The changes in antibiotic use practices due to the regulatory changes begun in January 2017 and the adoption of "no antibiotics ever" strategies make historical antibiotic use data unsuitable for our monitoring needs. Data are needed that reflect these new changes in antibiotic use practices.

5. Describe the impact to small businesses. If the collection of information impacts small businesses or other small entities (Item 5 of OMB Form 83-I), describe any methods used to minimize burden.

APHIS-NAHMS estimates there are no small entities impacted by this request as no small businesses will be selected for participation. This study surveys some of the largest broiler chicken companies in the United States as identified from the WATT list of top broiler producer companies². The smallest company listed reports producing 1.03 million pounds, liveweight, weekly and employing 325 staff. Overall, companies on the list have production numbers ranging from 1.03 million to 248.90 million pounds, liveweight, weekly and employee numbers ranging from 325 to 139,000.

APHIS-NAHMS minimizes the impact to producers by allowing producers 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).

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. Responses are voluntary.

Without this survey, the U.S. Government has limited information by which to make decisions related to AMU and AMR as they relate to the U.S. broiler industry.

The United States requires the ability to understand trends in AMU, AMR, animal health, and production in the broiler industry to make effective animal health and welfare decisions. This

² List of top U.S. broiler producer companies available here:

https://www.wattpoultryusa-digital.com/wattpoultryusa/march_april_2024/MobilePagedArticle.action? articleId=1959948#articleId1959948.

purposive data collection generates data that will enable USDA, state animal health entities, the U.S. broiler industry, and individual producers to make these decisions.

APHIS-NAHMS generates 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 have the adequate statistical power we prefer. Our traditional studies have longer inter-study intervals and cross-sectional study designs than this longitudinal broiler study, making trends estimates subject to higher variance with the inability 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.

Previous NAHMS studies that have collected data on AMU were typically collected at 5-10 year intervals depending on the commodity. These AMU data were population-based and represented national estimates. This longitudinal broiler study is the first in which NAHMS has collected AMU data in broilers. When NAHMS has collected antimicrobial resistance (AMR) information, that has been on a subset of operations, usually 100-200, and the data were not intended to be nationally representative but were instead a cross-sectional snapshot of antimicrobial resistance in a subset of operations.

This collection with repeated sample collections over subsequent years from the same complexes provides a more robust method for assessing the association between AMU and AMR. The target population is the top broiler producer companies in the United States and the broilers they raise, as published by WATT Global Media. These companies account for greater than 99 percent of the total live weight of slaughtered broilers (61,935,120,000 lb. from the WATT list compared to 62,215,158,000 lb. reported from USDA-NASS³ in 2023). They also account for greater than 98 percent of young chickens slaughtered in 2023 (calculated 9,439,514,289 head slaughtered from the WATT list compared to 9,501,611,000 head reported from USDA-NASS). Because these companies represent the majority of commercial broiler production in the U.S., APHIS-NAHMS is comfortable describing the target population as the principal commercial broiler producers in the U.S.

APHIS-NAHMS does not perform statistical survey analysis techniques to extrapolate results from this study to the U.S. broiler industry. Results from this study cannot be considered representative of all broiler producers in the U.S. because companies not on the WATT list have no ability to participate. Even though the sample is not a probability sample below the level of company, this study is the most comprehensive study investigating AMU and AMR in U.S. broiler production.

Using the projected sample size, APHIS-NAHMS estimated sample sizes based on the number of anticipated samples that would yield positive isolates for *Salmonella* and *Campylobacter*. Based on work performed in previous iterations of the study, we anticipate house-level prevalence values for *Salmonella* and *Campylobacter* to be approximately 40 percent and 50 percent for the organisms, respectively. Assuming these prevalence values, and assuming that

³ From the NASS Poultry Slaughter 2023 Annual Summary:

https://downloads.usda.library.cornell.edu/usda-esmis/files/pg15bd88s/q524m975v/zs25zx570/pslaan24.pdf.

measurements of flocks within house are independent, we estimate standard errors of farm-level prevalence estimates to be approximately 0.022 in any given year using a partial dependence model. To estimate presence of resistance within each isolate of the pathogens of interest, assuming that 1.5 isolates are found in each positive sample and resistance is found in approximately 50 percent of isolates, the standard error of the prevalence of resistance is estimated to be approximately 0.060 with a partial dependence model.

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 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;

The focus of the study is on longitudinal AMU and AMR effects at the broiler complex level (see Justification B). The study does 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 is not done on a random basis. 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-NAHMS 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 top broiler-producing companies in the U.S., and these companies produce the majority (over 99 percent) of live weight slaughtered in the U.S. (see Section B.1 of this justification for additional details).

- 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-NAHMS does not utilize a pledge of confidentiality to collect these data. The University of Minnesota maintains the contact information for participants and provides only de-identified data to APHIS-NAHMS. Once APHIS-NAHMS receives the deidentified data, we consider the data protected as confidential business information, and it is managed in the same manner as APHIS-NAHMS manages data protected by CIPSEA. APHIS-NAHMS, the University of Minnesota, and the broiler industry all believe that the information the participants provide is confidential business information and manages data and 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 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-NAHMS 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 that from industry and producers were used to develop the survey questionnaire to ensure the information collected is relevant and timely.

Ken Opengart, DVM, PhD, DACPV Consulting Poultry Veterinarian 3 Birds Consulting 7565 Harrier Hill Road Signal Mountain, TN, 37377

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

Suzanne Dougherty DVM, MAM, MS, DACPV AAAP Executive Vice President American Association of Avian Pathologists 23696 Piney Creek Drive Athens, Alabama 35613 Dr. Suzanne Dougherty 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. Mark Burleson, DVM, MS, DACPV Wayne Sanderson 4110 Continental Drive Oakwood, GA 30566

Dr. Mark Burleson has considerable knowledge of this program and has helped design its current format. He has provided input on approaches for data collection to gather relevant information while reducing the burden on the producer. He also assisted with strategies for participant recruitment.

USDA National Agricultural Statistics Service (NASS) reviewed this request and provided recommendations which were incorporated into Part A of the supporting statement.

On July 2, 2024, a notice was published in the Federal Register (89 FR 54764) providing a 60day period for public comment on this renewal of an information collection request. We received one comment from a citizen who was generally opposed to the study and APHIS as a regulatory agency. The comment had no impact on the study objectives.

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

Neither APHIS-NAHMS nor University of Minnesota provide any direct payments or gifts to respondents. The biological sampling of litter (bedding) samples does have a monetary value which we estimate 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 is used for statistical purposes only. Information collected by the University of Minnesota on behalf of APHIS-NAHMS is not protected by The Confidential Information Protection and Statistical Efficiency Act (CIPSEA). However, APHIS-NAHMS, the University of Minnesota, and the broiler producers all consider the provided information to be confidential business information (CBI) 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-NAHMS and the University of Minnesota protect this information from Freedom of Information Act (FOIA) requests under

Exemption 4.

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

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

All forms and data refer to the respondent by the unique code only. University of Minnesota conducts the testing of biological samples. Additionally, it encrypts and securely stores all completed survey forms and laboratory test results. Finally, the University of Minnesota securely sends APHIS-NAHMS a dataset, containing no PII, which is stored on a secure, limited access folder on an APHIS-NAHMS server.

APHIS-NAHMS and University of Minnesota 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. 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.

The collection is based off the WATT Global Media list of top U.S. broiler producers. The number on the list varies but typically includes the largest ~30 companies. Of these companies, the University of Minnesota will attempt to contact approximately 75 percent of the companies on the list (or about 25 companies using the most recent list), accounting for at least 85 percent of live weight slaughtered in the U.S., to invite to participate in the study. From those, we expect 12 companies will agree to participate and will sign the informed consent form, indicating their willingness to continue in the study, resulting in a 48 percent response rate at the company level. There will be approximately 36 complexes sampled from those 12 companies. From the complexes, approximately 4 (between 4 and 8, depending on complex enrollment) farms will be selected from each complex, quarterly. From each farm, one broiler house will be selected, and survey information and biological sample collection will be performed. This means there will be approximately 36 (complexes from the 12 companies) x 4 (farms sampled) x 4 (sample events occurring quarterly) = 576total farms providing information annually. These numbers are presented at the company level, assuming that for the 12 companies expected to enroll, all of the complexes and farms within them will complete the data collection, congruent with previous iterations of the study.

We anticipate approximately 606 annual responses with 21 responses per respondent (company), accounting for 869 total burden hours. For more specific information, please see the enclosed APHIS 71 Form.

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

APHIS-NAHMS estimates the annual respondent cost for the study is \$81,352. This estimate is calculated by multiplying the estimated burden hours (869) times the average hourly wage for a veterinarian (BLS SOCC 29-1131, \$65.53), and then multiplying the product by 1.4286 to capture benefit costs.

The SOCC and wage is obtained from the Bureau of Labor Statistics webpage https://www.bls.gov/oes/current/oes_nat.htm#00-0000.

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, resulting in a multiplier of 1.4286.

13. Provide an estimate 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 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.

We estimate it will cost the Federal Government \$437,210 annually to administer the study. Over the course of three years, the total cost would be \$1,311,630. This assumes a 7 percent yearly increase in costs. For more specific information, please see the enclosed APHIS 79 form.

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	606	588	0	0	18	0
Annual Time Burden (Hr)	869	866	0	0	3	0

APHIS-NAHMS estimates this renewal request has 30 respondents, 606 annual responses, and 869 hours of burden.

Company counts fluctuate over time. The number of companies listed on the WATT Global Media list of top U.S. broiler producers changes over time. Some companies may reach a point where they no longer want to participate in the study, or companies can merge or split, causing the number of companies invited or that participate in the study to fluctuate, even if participation has not changed. At least 10 companies have participated in the study to date, and the study team wants a minimum of 10 companies to remain in the study. If the number of participating companies drops below 10, the University of Minnesota collaborator will attempt to enroll more companies and will track limited responses from the complexes and will educate the personnel on these complexes on the importance of supplying complete samples and questionnaires. Also, even though it would be ideal to have all companies listed on the WATT Global Media list of top U.S. broiler producers be invited and participate in the study, logistical and other issues result in some of the companies not responding or not being able to be contacted. Several of the companies on the list are relatively small, niche companies that represent a small proportion of

the broilers produced by those on the list, and participation by these companies is not as important as the very large companies on the list. Over the course of the study, new or uncontacted companies could be contacted and invited to participate in the study, up to the number listed on the WATT Global Media list of top U.S. broiler producers at the time.

No other program changes or adjustments have been made for the project.

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

This information collection is a collaborative effort between APHIS-NAHMS and the University of Minnesota. Both parties jointly summarize the data following data collection, validation, editing, and analysis of the data. Both parties 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 calculate variance measures and confidence intervals for the point estimates as appropriate. Additionally, we conduct analytics that account for the longitudinal study design over a prolonged period.

APHIS-NAHMS produces reports and dashboards on the APHIS website and collaborates on manuscripts written by the cooperator. APHIS-NAHMS is preparing an annual report which details the descriptive and inferential analysis results as described in Section B.2 of this submission. APHIS-NAHMS publishes this report under the "Antimicrobial Use and Resistance" link at http://www.aphis.usda.gov/nahms. APHIS-NAHMS and the University of Minnesota also create and submit manuscripts for peer-reviewed publications.

APHIS-NAHMS' electronic summaries of results from the study are made available to producers, universities, researchers, practitioners, animal health related industries, Federal agencies, legislators, and any other interested party on the APHIS website.

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 forms.

18. Explain each exception to the certification statement identified in the "Certification for Paperwork Reduction Act."

APHIS can certify compliance with all provisions of the Act.