According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0579-0481. The time required to complete this information collection is estimated to average 10 minutes per response, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collected. Send comments regarding this burden statement or any other aspect of this information collection, including suggestions for reducing this burden, to APHIS.PRA@usda.gov.

OMB Approved 0579-0481 EXP: XX/XXXX

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE
VETERINARY SERVICES
NATIONAL ANIMAL HEALTH MONITORING SYSTEM
2150 CENTRE AVE, BLDG B
FORT COLLINS, CO 80526

On-farm Monitoring of Antimicrobial Use and Resistance in U.S. Broiler Production - Informed Consent

Instructions to the data collector:

Review this page with the producer, answering any questions. Make sure the producer understands that participation is voluntary. After signatures, give the original to the producer, send one copy to NAHMS, and retain the final copy at the University of Minnesota.

Background

USDA's Animal and Plant Health Inspection Service (APHIS) is collecting information on antimicrobial use and resistance in the U.S. broiler industry through the National Animal Monitoring System (NAHMS). This information will be used to describe current antimicrobial use and resistance, help policymakers and industry make informed decisions, assist researchers and private enterprise in identifying and focusing on vital issues related to antimicrobial use and resistance, and facilitate education of future producers and veterinarians. Participation is voluntary and you may decline to participate. Your participation is vital and will help APHIS develop antimicrobial use and resistance national estimates in the broiler industry. We ask that you provide accurate information regarding your facility's antimicrobial use; however, you retain the right to refuse to answer any or all questions.

Confidentiality

APHIS will not apply the Confidential Information Protection provision of Title V, Subtitle A, Public Law 107-347 (CIPSEA) for this information collection. However both APHIS and the University of Minnesota will keep the information you provide as part of this study confidential and will only use it for statistical purposes. We recognize that the information collected is not typically shared publicly and will consider it as Confidential Business Information (CBI), as defined in the U.S. Code of Federal Regulations (CFR) 19 CFR 201.6. As CBI, we will utilize exemption 4 for any Freedom of Information Act (FOIA) (5 U.S. Code 552) requests for your information. Exemption 4 of the FOIA U.S. Code 552 (b) (4) (2012 & Supp., V 2017) states that "trade secrets and commercial or financial information from a person is privileged or confidential." Exception from FOIA prevents your information from being released to the press, the public, or other non-federal government agencies. Exemption 4 of U.S. Code 552 does not exempt CBI from subpoenas from other federal agencies. Please see the CBI document provided for more information.

The Data Collector will keep the origin of the data confidential by recording the data stored at the University of Minnesota with the Producer's unique code number only. The Data Collector will deliver data to APHIS with no identifying information of any company, complex, or farm. The Data Collector will manage identifying information via a key kept separate from other data, and will not keep any key after the completion of the study. The Data Collector and all other project personnel acknowledge that the Producer is providing information and samples that he/she does not customarily share and is providing them with the expectation that they are and will be managed as Confidential Business Information (CBI) by APHIS and the University of Minnesota.

Once any physical and electronic data that are collected by the data collector are received by NAHMS, they will be stored in the NAHMS laboratory, which is an access-controlled environment specifically used for housing and managing controlled data. Your responses will be kept confidential and will not be disclosed in identifiable form.

Maintaining confidentiality and protection of Producer data is important to APHIS. Therefore, no identifying information such as personal or company name, or contact information, will be transferred from the University of Minnesota to USDA, and no data will be reported in a way that could reveal the identity of a participant. In reports derived from the data, all results are presented only in aggregated summaries or analyses.

Process of Collection

The University of Minnesota, the "Data Collector", will provide tools for the Producer to collect survey data at the farm level and litter samples at a single poultry house per selected farm. The Data Collector and the Producer will participate together in implementing a plan for the Producer to conduct site visits and data collection designed to monitor the use of antimicrobials and occurrence of antimicrobial resistance in selected bacteria on U.S. broiler farms.

The Producer will assist the Data Collector and APHIS by completing surveys for approximately four (between four and eight, depending on complex enrollment and as agreed upon by the Data Collector and the Producer) farms per sampled complex on a quarterly basis and, if elected, collecting of litter samples from broiler houses. The Producer retains the right to refuse to answer any questions or to allow sampling.

Use of Information

All APHIS-NAHMS studies are voluntary and nonregulatory and therefore, data and samples collected by APHIS-NAHMS or the Data Collector will not be used for regulatory purposes.

APHIS or the University of Minnesota may publish aggregate (summary) findings for the benefit of the poultry industry, allied private industries, and other interested groups. Neither the Data Collector or APHIS will publish, or authorize others to publish, individual questionnaire responses or sampling results. APHIS or the University of Minnesota will conduct testing in accordance with the Statement of Work associated with the study, which is available to all participants. APHIS or the University of Minnesota may perform additional testing, or authorize others to perform additional testing, of samples collected through the study, for the benefit of the poultry industry.

Continued on next page with biological testing.		
/date		
University of Minnesota – Data Collector	Producer ID	

To prevent NAHMS from gaining access to producer information, please do not initial, rather place an 'X' under the requested choices.

Biologic Sampling by Data Collector for Fecal Pathogens, Antimicrobial Susceptibility and Antimicrobial Resistance Genes	I WISH to participate	I DO NOT WISH to participate
Producer consents and authorizes the Data Collector or a mutually agreed upon designate to collect two composite litter samples from four to eight broiler farms from each enrolled complex each quarter.		
All litter samples will be cultured for <i>Salmonella</i> , <i>E. coli</i> , <i>Campylobacter</i> , and <i>Enterococcus</i> at the University of Minnesota. The Producer will receive results as a positive/negative and serotype or speciation, usually within 3 months of collection.		
Salmonella isolates will be tested for serotyping. Campylobacter and Enterococcus isolates will be speciated.		
All bacterial isolates will be tested for antimicrobial susceptibility.		
(Agent to initial the correct column based on producer's choice.)		