

12 September, 2016

Mr. William Kelley
Supervisory Management and Program Analyst
Center for Epidemiology and Animal Health
Animal and Plant Health Inspection Service
2150 Centre Avenue, Building B, MS 2E6
Fort Collins, CO 80526

Re: Notice of Request for Approval of an Information Collection; National Animal Health Monitoring System; Antimicrobial Use Studies (Docket No. APHIS-2016-0023)

The undersigned environmental, health, consumer, and veterinary groups offer the following comments on the Animal and Plant Health Inspection Service's (APHIS) request for approval to collect antimicrobial use data from beef and pork producers via the National Animal Health Monitoring Service (NAHMS) survey program. Collectively, our organizations represent millions of people across the United States. Our organizations have consistently called for stronger action from government agencies to collect quantitative, reliable, farm-level data on antimicrobial use in animals raised for food. APHIS' proposal to conduct annual surveys of beef and pork producers for a period of 3 years is one potential mechanism to improve our understanding of antimicrobial use patterns in agriculture and develop a robust strategy for achieving the reductions in use necessary to protect public and animal health.

We provide the following input in the areas posed by the Agency in its notification to the public of the request:

1) Comments on request for input on evaluating whether the collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility;

The collection of quantitative, on-farm antimicrobial use data is critical for achieving reductions in agricultural use of antimicrobials to protect both human and animal health. Reducing antimicrobial use will protect public health from resistant bacteria, promote the overall health and welfare conditions of animals raised for food, and improve the sustainability of animal agriculture in the U.S. And without use data, we're limited in our ability to monitor how use may be leading to the emergence, spread, or increase of resistant pathogens. Collection of use data, therefore, has practical utility and is within the purview of APHIS to coordinate.

The goal of data collection strategies should work toward the goal of identifying avenues for reducing use of all antibiotics in agriculture. As Beth Bell, Director of the National Center for Emerging and Zoonotic Infectious Diseases (NCEZID) at the Centers for Disease Control and Prevention (CDC) stated, on-farm use data are vital underpinnings for effective action, and the how, where, and why are essential to stewardship and identifying where intervention is needed.¹

Accurate information concerning actual use of antibiotics is necessary to assess the current landscape of antibiotic use and formulate a plan of action to curb overuse of antibiotics. Quantitative, granular, farm-level use data will facilitate identifying large or high-risk uses or patterns of use that should be focal points for future outreach, education, or other intervention efforts; enable researchers to effectively compare antimicrobial use patterns with antibiotic resistance data ; assist with corroborating other state and national data collection efforts (e.g., sales data); and support development of an accurate understanding of species-specific or geographic variation in antimicrobial use practices so that guidance and interventions can be tailored and so that we learn from model practitioners for each species.

As stated in the notice for the September 2015 public meeting held by USDA, FDA, and CDC, usage data are needed to help government and stakeholders: “1) Assess the rate of adoption of changes outlined in the Food and Drug Administration's (FDA) Guidance For Industry #213; 2) help gauge the success of antibiotic stewardship efforts and guide their continued evolution and optimization; and 3) assess associations between antibiotic use practices and resistance.”² An effective data collection system could also help to identify emerging problems, increase consumer confidence in the safety of food, and guide regulation of antimicrobial drugs.

2) Comments on request for input on evaluating the accuracy of our estimate of the burden of the collection of information, including the validity of the methodology and assumptions used;

APHIS’ estimated burden of collection on respondents is sound, and sufficiently demonstrates that the survey program will not represent an unreasonable request of producers. First, APHIS has extensive experience via NAHMS with surveying livestock producers in order to accurately estimate the time requirement for respondents. Second,

¹ Statements by Beth Bell, Centers for Disease Control and Prevention, at the Data Collection Public Meeting, U.S. Department of Agriculture Jefferson Auditorium, Washington, D.C. (September 30, 2015).

² “Collecting On-Farm Antimicrobial Use and Resistance Data; Public Meeting; Request for Comments,” Federal Register Vol. 80, No. 161 (Thursday, August 20, 2015), 50638-50639, at 50639.

most producers already keep accurate records on medicated feeds and, as such, would have ready access to the information necessary to complete the surveys efficiently. For example, previous NAHMS surveys have found that over two-thirds of all pork producers keep records on drug usage as part of the Pork Quality Assurance program, and nearly 100% of large sites and 90% of medium sites maintain such records.³ Of the large sites that used antibiotics in grower/finisher pigs, three-quarters recorded drug names, treatment dates, and doses.⁴ Last, the estimated burden of just over 0.5 hours per year⁵ for respondents is unlikely to have significant impact on the producers or their ability to operate.

3) Comments on request for input on enhancing the quality, utility, and clarity of the information collected; and

Quantitative data is needed, and must be reported by the specific drugs used, dosages, frequencies, durations, and purposes in order to provide the information required to effect change and achieve nationwide reductions in agricultural uses of antibiotics.

Many of our groups have pointed out shortcomings in previous NAHMS farm surveys, including their infrequency, their failure to provide data on actual amounts of antibiotics used, and their dependence on voluntary submissions. This proposed collection strategy improves the first two shortcomings by surveying producers annually for a period of 3 years and collecting data on actual, on-farm use. APHIS should address the remaining shortcoming to ensure its program's success. In order to avoid selection bias and prevent certain producers, such as intensive users of antimicrobials, from opting out, and thereby skewing survey results, participation in these surveys cannot be voluntary. The overall goal should be to provide sufficient, accurate information to link FDA's data on overall sales and distribution of antibiotics to species-specific changes on farm.

To adequately fulfill the need for useful, accurate data, APHIS' collection program should emphasize:

1. Quantitative Data – Information on the actual amounts administered and the number of animals for each antibiotic used for each indication is needed to fully identify use patterns. Quantitative data is necessary to gauge the progress of current efforts to reduce antimicrobial use in food animals, to

³ USDA Animal and Plant Health Inspection Service Veterinary Services. *Info Sheet—Pork Quality Assurance* (2003).

⁴ Ibid.

⁵ APHIS estimates 0.4276 hours per response and that respondents will complete 1.5 responses per year, calculating to an annual burden from completing the surveys of 0.6414 hours. "Collecting On-Farm Antimicrobial Use and Resistance Data; Public Meeting; Request for Comments," Federal Register Vol. 80, No. 161 (Thursday, August 20, 2015), 50638-50639, at 50639.

identify high risk use patterns, to effectively compare use patterns with antibiotic resistance data, and to develop an accurate picture of species-specific or geographic variations in use practices.

2. **Comprehensiveness** – The survey program should elicit data from a representative sample of producers and production classes (e.g., weaners and finishers), and must include the following information: duration of use, species and production class of animals receiving antibiotic, number of animals receiving antibiotic, total number of animals raised at the facility, indication, and dose.
3. **Ongoing Collection** – APHIS should consider extending the survey program beyond the proposed 3-year timeline to allow for a more robust trend analysis, to better identify emerging problems, and to link with ongoing data on resistance collected through the National Antimicrobial Resistance Monitoring Service (NARMS).
4. **Mandatory Participation** – Data collection should not be based on voluntary participation, in order to avoid selection bias, when heavy antibiotic users opt out.
5. **Transparency** – Data collected under this program must be made publicly available and accessible in a timely manner. Both ease of access to the relevant documents and presenting the data in a manner that can be easily interpreted is fundamental to the success of tackling antibiotic resistance. Transparency regarding the mechanisms for data collection to be implemented, the metrics to be used, and the actual data collected, is necessary for public stakeholders to verify that data are valid and reductions are achieved.
6. **Locally Specific Data** – Understanding the need to protect producer privacy, we urge APHIS to provide as much specific detail as possible when presenting data on antimicrobial use. If the Agency determines that aggregating data is necessary to protect confidential business information, the highest level of aggregation must be at the county level, as is done for most categories of animal production in the USDA Census of Agriculture. This will provide for accurate assessments of regional variations in antibiotic use practices.

Additionally, antimicrobial use studies must not be limited to the beef and pork industries. To date, no NAHMS studies have examined antimicrobial use in these industries. The absence of quantitative, granular, farm-level usage data for chickens and turkeys omits a substantial number of food-producing animals that may routinely be administered antimicrobials. APHIS must expand the scope of these studies to include all major food-producing species. This is necessary to develop a comprehensive, accurate picture of antimicrobial use in food animals.

4) Comments on request for input on minimizing the burden of the collection of information on those who are to respond, through use, as appropriate, of automated, electronic, mechanical, and other collection technologies; e.g., permitting electronic submission of responses.

As stated earlier, producer participation should not be voluntary in order to eliminate selection bias and ensure data collected are representative of the industry nationwide. Providing multiple avenues by which producers can complete and submit responses would make mandatory participation more feasible. For those producers with greater technological capacity, the ability to submit responses electronically may alleviate some of the perceived burden. In September 2015, James McDonald of the USDA Economic Research Service (ERS) acknowledged a key barrier to antimicrobial use data collection among hog producers based on ERS' experience: larger farmers are less likely to respond to ERS surveys.⁶ As such, all necessary steps must be taken by the Agency to better guarantee participation by large producers, including allowing for a variety of response platforms.

Other avenues for participation, such as by physical mail and telephone, must continue to be available to ensure that producers without easy access to electronic resources (who are likely operating at smaller scales), are not unduly burdened. In addition, APHIS should ensure that the survey responses are solicited from the correct individual or operator. Mr. McDonald's presentation in September 2015 also noted that contract hog producers often do not know the contents of their animal feed. To minimize the burden and ensure complete information for contract growers, APHIS must also survey and require the participation of the corporate owners for which the contract producers are raising animals.

We appreciate APHIS' initiative to begin collecting annual on-farm use data from beef and pork producers. A comprehensive data collection strategy cannot rely on one mechanism. Multiple existing and yet to be developed avenues must be utilized in order to best reach a wide sample of U.S. producers and provide an accurate picture of antibiotic use in U.S.

⁶ James McDonald, "Using ARMS Data for Analyses of Antibiotics Use in Livestock," *Presentation at the Data Collection Public Meeting, Washington, D.C.* (September 30, 2015), available at <http://www.fda.gov/AnimalVeterinary/NewsEvents/WorkshopsConferencesMeetings/ucm456380.htm>.

agriculture. This will have the added benefit of dividing the resource burden among agencies/sub-agencies.

Thank you for the opportunity to provide comment.

Respectfully submitted,

Center for Food Safety

Consumer Federation of America

Food Animals Concerns Trust

Antibiotic Resistance Action Center, Milken Institute School of Public Health, George Washington University

U.S. Public Interest Research Group (U.S.PIRG)

Keep Antibiotics Working

Food and Water Watch

Consumers Union

Humane Society of the United States

Humane Society Veterinary Medical Association

Natural Resources Defense Council