SUPPORTING STATEMENT FOR INFORMATION COLLECTION
PART A

UNITED STATES DEPARTMENT OF AGRICULTURE (USDA)

ANIMAL AND PLANT HEALTH INSPECTION SERVICE (APHIS)

VETERINARY SERVICES (VS)

THE CENTERS FOR EPIDEMIOLOGY AND ANIMAL HEALTH (CEAH),

NATIONAL ANIMAL HEALTH MONITORING SYSTEM (NAHMS)

NAHMS SWINE 2012 STUDY

SUPPORTING STATEMENT FOR INFORMATION COLLECTION BY THE CENTERS FOR EPIDEMIOLOGY AND ANIMAL HEALTH (CEAH), NATIONAL ANIMAL HEALTH MONITORING SYSTEM (NAHMS)
OMB NUMBER 0579-0315
NAHMS SWINE 2012 STUDY

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A. JUSTIFICATION

This submission is a request for approval to initiate the National Animal Health Monitoring System's (NAHMS') Swine 2012 Study, an information collection by the Animal and Plant Health Inspection Service (APHIS). This study will consist of two levels of data collection. Selected operations in 31 States[1] with less than 100 head will receive a mail in questionnaire that may alternatively be completed via a phone interview. Selected operations in the top 13 pork producing States[2] with 100 head or more will receive a mail in questionnaire with a telephone follow-up or a personal interview on-farm. Initial contacts will be performed by National Agricultural Statistics Service (NASS) telephone and personal interviewers and subsequent consenting producers will be contacted by APHIS data collectors who will administer questionnaires and perform biologic sampling. The collection will support the following objectives:

1) Describe current U.S. swine production practices including general management practices, housing practices, productivity, disease prevention and mortality for five phases of production: gestation, farrowing, nursery, grow/finish and wean-to-finish;

2) Describe trends in swine health and management practices.

3) Determine the prevalence and associated risk factors for select respiratory, neurologic, gastrointestinal, systemic and food-borne pathogens found in weaned market hogs;

4) Describe antibiotic usage patterns in weaned market hogs to control and treat disease and promote growth;

5) Evaluate presence of or exposure to select pathogens and characterize isolated organisms from the collection of biological specimens (feces, sera, saliva);

6) Estimate the economic cost of a selected respiratory, neurologic, gastrointestinal, systemic, or food-borne pathogen found in commercial swine herds.

The information collected through the Swine 2012 study will be analyzed and organized into descriptive reports. Several information sheets will be derived from these descriptive reports and will be disseminated by APHIS to the producers, stakeholders, academia, veterinarians, and any

[1] Alabama, Arizona, Arkansas, California, Colorado, Florida, Georgia, Hawaii, Illinois, Indiana, Iowa, Kansas, Louisiana, Michigan, Minnesota, Mississippi, Missouri, Nebraska, New Jersey, New Mexico, New York, North Carolina, Ohio, Oklahoma, Pennsylvania, South Carolina, South Dakota, Tennessee, Texas and Washington.

[2] Illinois, Indiana, Iowa, Kansas, Minnesota, Missouri, Nebraska, North Carolina, Ohio, Oklahoma, Pennsylvania, South Dakota and Texas.

other interested parties. The benefits to the Swine industry from the Swine 2012 study include scientifically valid national estimates of health and management practices of the nation's swine industry. The data collected will also be used to measure change over time from the previous NAHMS' Swine studies. Participation in this survey is voluntary. It is up to the individual producer to decide whether or not it is desirable to participate.

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.

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 swine data is consistent with the APHIS mission of protecting and improving American agriculture's productivity and competitiveness. APHIS is collecting information that is not available from any other source on the general health and management practices.

Collection, analysis, and dissemination of livestock and poultry health information on a national basis are consistent with the APHIS mission of protecting and improving American agriculture's productivity and competitiveness. In connection with this mission, the NAHMS program includes periodic national commodity studies to investigate current issues and examine general productivity, health, and management practices used on farms and their economic impact. These studies are driven by industry and stakeholder interest, and collect information that is not available from any other source. Without this study, APHIS would be unable to continue the trends analysis that began with the Swine 1990 study that various parts of the industry as well as many Federal and State partners have come to rely on. Additional reliance is placed on NAHMS national (population) estimates by researchers to create their own sample sizes for targeted studies. Many industry stakeholders require current information on select swine diseases and pathogens to assess efforts to combat them and keep export markets open. Finally, when economic analysis is performed upon estimates of swine disease or syndromes more accurate assessment of costs of intervention or eradication is available. This assists business owners and policy makers alike.

NAHMS will initiate the fifth national data collection of swine through Swine 2012. NAHMS' employees have completed a needs assessment which was a collaborative effort with producers, industry, extension specialists, Federal and State employees, and university researchers. Information gathered through this needs assessment was used to determine the study objectives.

National Surveys Providing Baseline Information

Swine 2012 is part of an ongoing series of NAHMS' studies on the U.S. swine population[3]. The first NAHMS' swine study was conducted in 1990, which provided a baseline for the 2012 study. The National Swine Survey of 1990 was the first statistically-valid national on-farm data collection by NAHMS. The objectives of the study were to provide information on the production and health levels of the United States' swine herd(s), and to suggest factors that may affect preweaning morbidity and mortality. Ultimately, this project provided baseline information on U.S. swine/pork productivity, water quality in farrowing facilities, health of farrowing sows and piglets from birth to weaning, and prevalence of transmissible gastroenteritis, swine influenza, and other swine pathogens which were economically significant to the industry at the time. The study represented 81% of the U.S. swine herd.

Swine '95: Grower/Finisher began NAHMS' second national on-farm monitoring activity. Data was collected from operations in 16 of the largest swine-producing States. Most of the data collected from this study was compared with data collected during the 1990 National Swine Survey to determine industry trends and detect changes in management practices and animal health. Swine '95 obtained baseline information on all phases of swine production as well as an in-depth focus on grower/finisher productivity and management. The sub-sampling phase of Swine '95 collected fecal and blood samples which were tested for the presence of Porcine Reproductive and Respiratory Syndrome virus, *Salmonella*, *E. coli*, and other swine pathogens which have an economic impact on swine operations. The study represented 91% of the U.S. swine herd.

The Swine 2000 Study gathered information that described changes in management practices and animal health in swine operations from 1990 and 1995 to 2000. Data was collected from operations in 17 States to describe management practices in swine operations that are associated with respiratory disease in market hogs. Swine 2000 also identified factors associated with shedding of specific food-borne pathogens, described antimicrobial usage, and described animal health management practices and their relationships to swine health. Almost 95% of the U.S. swine herd(s) was represented in the study.

The Swine 2006 Study followed the Swine 2000 study closely in methodology and type of information collected. Sampling was again done for operations in 17 States representing approximately 94% of the U.S. swine herd(s) to describe health status and management practices in swine operations. Swine 2006 provided the last chance for the industry to document levels and risk factors for Porcine Circovirus Associated Diseases (PCVAD) before new vaccines to reduce impact became widely available.

In 2007 the first study of swine operations with less than 100 animals, Small-Enterprise Swine 2007 was conducted. The study occurred in States that participated in previous national swine studies plus those States considered at risk for exposure to feral swine and transmission of

[3] Additional information and publications resulting from previous studies are available at: http://www.aphis.usda.gov/vs/ceah/ncahs/nahms/swine/.

classical swine fever (CSF) and pseudorabies (PRV). Estimates of productivity and farm practices from this previously un-surveyed population of producers provided insight into the modern “family” farm.

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.

Data collected, analyzed, and interpreted is disseminated to a wide variety of constituents. Producers will use the information to compare their operation’s animal health and productivity with other herds regionally and nationally. Producer groups and veterinarians will use information derived from analyses to improve preventive measures and information outreach efforts. Pharmaceutical and biologics companies will use the information to plan and develop research and marketing strategies for their products. Extension specialists will use the information to identify diseases and disease trends. State and Federal officials responsible for regulatory veterinary medicine will use the information to gain a more complete picture of animal health as a basis for program planning and to direct funding. State and Federal officials will use the data to show the scientifically based information used to make decisions. Research scientists will use the information to define current and future animal health issues and direct research funding. Veterinary and agricultural students in universities in the U.S. will use the reports for training in health management, animal welfare, nutrition, and other agriculturally based careers.

APHIS will use the data collected from the Swine 2012 study to:

- Predict or detect national and regional trends in disease emergence and movement such as the expansion or contraction of the incidence of Porcine Reproductive and Respiratory Syndrome (PRRS) and Swine Influenza in pigs.

- Provide factual information on volatile issues such as antimicrobial resistance among isolates obtained from feces

- Examine the economic impact of health management practices such as antimicrobial and vaccine practices.

- Update national and regional production measures (such as average farrowing rate) for producer, veterinary, and industry reference.

- Provide assistance to researchers and the industry in evaluating the utility of new pathogen collection methods such as ropes to test saliva.

Swine 2012 Study Data Collection Forms

NAHMS-287, Small Swine Operation Questionnaire (CATI) – will be sent out to participants via U.S. Mail. If a response is not received two weeks after the initial mailing, a NASS data collector will call the producer to administer the questionnaire via Computer Assisted Telephone Interview (CATI). Approximately 5-10 calls will be made to attempt to administer the questionnaire (more if response rates are low and time is available), if no contact is made after sufficient attempts, the respondent will be coded as inaccessible. There will not be any attempt to convert refusals other than a clear explanation of the importance of their voluntary participation in the initial phone call. Data from all completed mail questionnaires will be entered in a database by NASS. The CATI responses will be directly incorporated into the same database and no hard copy record will be available. Edit/validation specifications will be prepared by APHIS and incorporated by NASS.

NAHMS-288, General Swine Farm Questionnaire (Enumerator) – will be administered by a National Agricultural Statistics Service (NASS) enumerator to collect data on the producer's swine inventory, management practices and preventive care practices.

NAHMS-289, General Swine Farm Questionnaire (CATI) – will be sent out to participants via U.S. Mail. If a response is not received two weeks after the initial mailing, a NASS data collector will call the producer to administer the questionnaire via Computer Assisted Telephone Interview (CATI). Approximately 5-10 calls will be made to attempt to administer the questionnaire (more if response rates are low and time is available), if no contact is made after sufficient attempts, the respondent will be coded as inaccessible. There will not be any attempt to convert refusals other than a clear explanation of the importance of their voluntary participation in the initial phone call. Data from all completed mail questionnaires will be entered in a database by NASS. The CATI responses will be directly incorporated into the same database and no hard copy record will be available. Edit/validation specifications will be prepared by APHIS and incorporated by NASS.

NAHMS-290, Producer Agreement – is the first form that is presented to the participant by the APHIS designated data collector. This form helps NAHMS track the number of participants, and is designed to increase the participant's understanding of the study focus, highlight confidentiality safeguards, and explain participation requirements. After completing the form with the participant, the data collector will review the form with the participant. The form will then be signed by the participant and the data collector. One copy of this agreement is left with the participant and one copy is retained by the data collector.

NAHMS-291, VS Initial Visit Questionnaire – will be administered by an APHIS designated data collector to collect data on inventory numbers, vaccination practices, antibiotic usage, and management practices. Upon completion, the form (without producer contact information) is returned via U.S. Mail to NAHMS in Fort Collins Colorado, for data entry and validation, and a copy is retained by the data collector to facilitate validation.

NAHMS-292, Blood Collection Form – will be used by the Federal VMO to collect blood samples from late finisher pigs (over twenty weeks of age and breeding females), and collect

information on the general health of the animals being bled. The blood samples will be sent to the National Veterinary Services Laboratory for analysis. Test results will be returned to the NAHMS and will be added to the farm record.

NAHMS-293, Fecal Collection Form– will be used by the Federal VMO to collect fecal samples from late finisher pigs (over twenty weeks of age). The samples will be sent to the National Agriculture Research Service Laboratory in Atlanta, Georgia for analysis. Test results will be returned to the NAHMS and will be added to the farm record.

NAHMS-294, Saliva Collection Form– will be used by the Federal VMO to collect saliva of weaned market pigs. The samples will be sent to the University of Minnesota Veterinary Diagnostic Laboratory for analysis. Test results will be returned to the NAHMS and will be added to the farm record.

NAHMS-295, Nasal Swab Collection Form– will be used by the Federal VMO to collect nasal swabs of weaned market pigs. The samples will be sent to the University of Minnesota Veterinary Diagnostic Laboratory for analysis. Test results will be returned to the NAHMS and will be added to the farm record.

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.

No automated, electronic, or mechanical techniques will be used to collect information for the General Swine Farm Questionnaire (enumerator) of the Swine 2012 study. Since biological specimens are collected, an on-farm visit is required and provides an opportunity for a data collector to administer the questionnaire. Approximately 5-10 calls will be made to all mail non respondents of the CATI questionnaires and interview results entered directly into a computerized database.

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

Literature searches for existing data relevant to of the Swine 2012 study have been performed. Available data was reviewed and compiled from all known sources. Sources reviewed include; cooperative state research, private industry and professional publications, diagnostic laboratories, other Federal and State agencies, the National Pork Board, the National Pork Producers Council, and universities. Employees from Federal agencies and academia were consulted in their area of expertise to identify areas of potential duplication. No other entity/source is collecting and analyzing this type of information on the health of the U.S. swine industry.

5. If the collection of information impacts small businesses or other small entities (Item 5 of OMB 83-1), describe any methods used to minimize burden.

The Swine 2012 study is designed to collect the minimum amount of data required from a minimum number of swine producers to ensure statistically and scientifically valid data. Sixty-two percent of the participants will be small businesses. Industry and producer input is solicited to ensure that information collected is relevant and timely. This is a voluntary program; it is at the discretion of the individual swine producer to decide whether or not it is desirable for them to participate.

6. Describe the consequences 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 status of the U.S. swine industry has been examined in 1990, 1995, 2000, 2006, and must continue with the collection of data regarding the health and management of swine sites in 2012; such as the average level of production, prevailing production practices, biosecurity and movement practices, and frequency of health problems. In addition, it is imperative that APHIS continues to track disease levels through biologic sample testing, and maintain a bank of sera to preserve the capability to retrospectively examine the U.S. swine population. The type, quality, and frequency of data collected by the NAHMS through national on-farm collections is unique. No other entity is collecting this type of information in the U.S or has ever done so.

Without this type of national data, the U.S.' ability to detect trends in management, production, and health status that increases/decreases farm economy either directly or indirectly would be reduced or nonexistent. The possibility of assessing the reduction of risk to human health from *E. coli*, *Salmonella*, or Campylobacter due to management changes based on NAHMS data would also be nonexistent. Furthermore, the ability to respond to international trade issues involving the health status of the U.S. swine population would be severely reduced, jeopardizing the global marketability of meat and byproducts.

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 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 three 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 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 forms, and on the data elements to be recorded, disclosed, ore 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 Agency's notice of information collection activity was announced in the Federal Register on Tuesday, August 23, 2011, pages 52633-52634. No comments were received. A copy of the Federal Register notice is attached.

Consultants used for the Swine 2012 study are:

Dr. Liz Wagstrom
National Pork Producer's Council
Chief Veterinarian
National Pork Board
122 C Street N.W. Suite 875
Washington D.C. 20001
(202) 347-3600.

Dr. Harry Snelson
Director of Communications
American Association of Swine Veterinarians
830 26th Street
Perry, IA 50220
(515) 465-5255.

Dr. Mark Engle
PIC
812 Concord Church Road
Scottsville, KY 42164
(270) 622-6812

The NAHMS staff is responsible for developing the basic content of the questions and a reasonable flow through the questionnaire. Upon much iteration a draft is sent to NASS who assumes responsibility for the questionnaire thereafter. This includes review and editing for reasonable content, formatting questions into useable, producer and enumerator friendly terms and arranging questions for the best flow of the interview. Several exchanges of version development occur via Word software and then NASS enters the questionnaire into their QRS system which further standardizes the product. Many conference calls are completed between NAHMS staff and NASS in going over the various versions of the questionnaire.

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

There will be no payments or gifts provided to respondents.

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

Only summary estimates based upon the inference population will be reported within APHIS. Only the NASS designated data collector collecting on-farm data will have knowledge of the participant's identity. All forms, data, and reports will refer to the respondent by a numeric code, which is assigned by NASS. This link between participant and numeric code will be destroyed once data collection, entry, validation and report dissemination are complete (except in those cases where the producer indicated interest in further study). All completed survey forms will be stored securely in a limited access records room. While every effort will be made to ensure respondent confidentiality, certain information could be released as required by a Freedom of Information Act request. However, names, addresses, and personal information will not be collected and therefore no connection can be made between a completed questionnaire or laboratory results and the respondent's information.

NASS has statutory protection that allows them to keep on-farm data (such as producer name and address information) confidential. Several U.S. Codes apply to data collected by NASS:

- 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.

There are also additional protections available through the Confidential Information Protection and Statistical Efficiency Act (CIPSEA):

- Title V of E-Government Act of 2002, Public Law 107-347, Section 513. Fines and Penalties.
- Title V of E-Government Act of 2002, Public Law 107-347, Section 512. Limitations on Use and Disclosure of Data and Information.

Every NASS and APHIS employee or other individual that may handle a questionnaire, or data coming from a completed questionnaire, is required to sign a form governing Certification and Restrictions on use of Unpublished Data. Furthermore, once data is published, individuals are generally limited to the use of aggregate data files. Access to individual data files is restricted to maintain respondent confidentiality.

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 83-1.

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

A total of 11,728 burden hours are needed to complete this information collection activity. A detailed burden estimate has been included on the enclosed APHIS 71 Form.

Respondent costs: Estimated respondent costs for the information collection proposed is calculated based on an on-farm data collection estimate of $10.90 per hour[4]. The total respondent cost for the Swine 2012 Study is $ 127,952.

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

[4] NASS Farm Labor, published report for February 17, 2011 (http://usda.mannlib.cornell.edu/usda/current/FarmLabo/FarmLabo-08-18-2011.pdf).

burden shown 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/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.

The estimated cost to the Federal Government for the Swine 2012 study is $599,004. 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.

This is a reinstatement of Collection 0579-0315 resulting in 11,728 burden hours that will investigate current issues and examine general health and management practices of swine used on farms. The information collected through this study will be used by APHIS to identify the prevalence of risk factors for reintroduction of diseases in the population at risk and provide starting estimates and distributions for simulation modeling of program diseases.

The survey methodology is essentially unchanged since the last approval of this but the questions being asked have been changed to reflect the current needs of the program. This survey will support the following objectives:

1) Describe current U.S. swine production practices including general management practices, housing practices, productivity, disease prevention and mortality for five phases of production: gestation, farrowing, nursery, grow/finish and wean-to-finish;

2) Describe trends in swine health and management practices.

3) Determine the prevalence and associated risk factors for select respiratory, neurologic, gastrointestinal, systemic and food-borne pathogens found in weaned market hogs;

4) Describe antibiotic usage patterns in weaned market hogs to control and treat disease and promote growth;

5) Evaluate presence of or exposure to select pathogens and characterize isolated organisms from the collection of biological specimens (feces, sera, saliva);

6) Estimate the economic cost of a selected respiratory, neurologic, gastrointestinal, systemic, or food-borne pathogen found in commercial swine herds.

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

Information from this survey will be summarized immediately following the data collection and validation phase. Data will be entered into a database management system utilizing microcomputers or workstations, and statistical calculations will be performed; e.g., descriptive statistics including frequency distribution, and prevalence and point estimates of producer opinions. Variance measures and confidence intervals for the point estimates will be calculated in order to describe the precision of the descriptive statistics generated. Findings will be utilized as inputs for computer modeling, so that prediction of future events can be estimated.

Considerable effort has been placed on reducing the time between the end of data collection and release of a final publication. Hardcopy information from the study will be made available to swine producers, universities, researchers, practitioners, animal health related industries, Federal agencies, legislators, and any other interested parties. Copies of current and past information sheets from the NAHMS are available at: http://www.aphis.usda.gov/animal_health/nahms/index.shtml.

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 will display the expiration date for OMB approval on the forms used in this collection.

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 under the Act.