SUPPORTING STATEMENT FOR INFORMATION COLLECTION

UNITED STATES DEPARTMENT OF AGRICULTURE (USDA)

ANIMAL AND PLANT HEALTH INSPECTION SERVICE (APHIS)

VETERINARY SERVICES (VS)

CENTERS FOR EPIDEMIOLOGY AND ANIMAL HEALTH (CEAH),

NATIONAL ANIMAL HEALTH MONITORING SYSTEM (NAHMS)

NAHMS SHEEP 2011

Part A

SUPPORTING STATEMENT FOR INFORMATION COLLECTION BY THE CENTERS FOR EPIDEMIOLOGY AND ANIMAL HEALTH (CEAH), NATIONAL ANIMAL HEALTH MONITORING SYSTEM (NAHMS)[1]
OMB NUMBER 0579-0188
NAHMS SHEEP 2011 STUDY

October 2010

A. JUSTIFICATION

This submission is a request for approval to initiate the National Animal Health Monitoring System's (NAHMS')[1] Sheep 2011 study, a reinstatement of an information collection by the Animal and Plant Health Inspection Service (APHIS). The study will consist of two parts using two separate samples in 22 of the top sheep States[2] in the United States. The first sample will include producers with less than 20 ewes. A questionnaire (NAHMS-246 General Sheep Management Report, CATI) will be mailed to these producers, with a follow up telephone interview for non-respondents. The second sample will include producers with 20 or more ewes. The typical two phase NAHMS study will be conducted. In phase I, a National Agricultural Statistics Service (NASS) enumerator will contact and conduct interviews with producers (NAHMS-247 General Sheep Management Report, Enumerator). Upon completion of the questionnaire, respondents reporting 20 or more ewes will be asked to sign a consent form allowing NASS to present their names to APHIS- designated data collectors for further consideration in the study. Phase II (APHIS phase) will consist of completing the producer agreement (NAHMS-248) and one on-farm questionnaire. In addition, biologic sampling will be available to selected participants that complete the Veterinary Services (VS) Initial Visit questionnaire (NAHMS-249).

The collection will support the following objectives:

1) Describe trends in sheep health and management practices from 1996 to 2011.

2) Describe management and biosecurity practices used to control common infectious diseases, including scrapie, ovine progressive pneumonia, Johne's disease, and caseous lymphadenitis.

2) Estimate the prevalence of:
   - Gastrointestinal parasites and anthelmintic resistance,
   - Mycoplasma ovipneumonia in domestic sheep flocks. Relate presence of the organism in blood and nasal secretions to clinical signs and demographic and management factors.

[1] The National Animal Health Monitoring System is responsible for collecting national data on animal health and productivity from voluntary participants

[2] California, Colorado, Idaho, Iowa, Kansas, Kentucky, Michigan, Minnesota, Missouri, Montana, New Mexico, New York, Ohio, Oregon, Pennsylvania, South Dakota, Texas, Utah, Virginia, Washington, Wisconsin, and Wyoming. State selection document can be found in Background Information section.

3) Facilitate the collection of information and samples regarding causes of abortion storms in sheep.

4) Determine producer awareness of the zoonotic potential of contagious ecthyma (soremouth) and the management practices used to prevent transmission of the disease.

5) Provide serum to include in the serological bank for future research.

The information collected through the Sheep 2011 study will be analyzed and organized into descriptive reports. Several information sheets will be derived from this report and disseminated by APHIS to producers, stakeholders, academia, veterinarians, and other interested parties. Participation in this study is voluntary; it is up to the individual producer to decide whether or not it is desirable to participate.

1. Explain why the collection of this information is necessary.

Collection and dissemination of animal health data and information is mandated by 7 U.S.C. § 8301, the Animal Health Protection Act of 2002[3], which established the precursor of the APHIS, Veterinary Services, and 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[3].

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 animal health related issues and examine general health and management practices used on farms. These studies are driven by industry and stakeholder interest, and information collected is not available from any other source on a national basis. Information about health and management practices on U.S. sheep operations is useful to various parts of the sheep industry as well as many Federal and State partners.

NAHMS staff has completed a needs assessment which was a collaborative effort with producers, researchers, extension veterinarians, Federal and State personnel, and clinicians. Opinions were provided by stakeholders who responded to the needs assessment. Information gathered was used to determine the study objectives.

National Surveys Providing Baseline Information

The Sheep 2011 study is the second in depth study for the sheep industry, the first was conducted 10 years ago in 2001. Baseline information about animal health issues, health and management practices and biosecurity practices on U.S. sheep operations are useful to many stakeholders,

[3] 7 United States Code § 8301, and 7 U.S.C. § 8308, are available upon request.

including producers, researchers, extension veterinarians, Federal and State personnel, and clinicians.

The 22 states in the Sheep 2011 study will represent 85 percent of U.S. January 1, 2010 ewe inventory and 70 percent of U.S. farms with one or more ewes according to the 2007 Census of Agriculture.

2. ***Indicate how, by whom, and for what purpose the information is to be used. Indicate the actual use the Agency has made of the information received from the current collection.***

Data collected, analyzed, and interpreted will be disseminated to a wide variety of constituents[4]. 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 veterinarians 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 research priorities. State and Federal officials will use the data to make scientifically based decisions. Public health officials will use the information to estimate the magnitude of health conditions which affect public health. Research scientists will use the information to define current and future animal health issues and direct research programming. Veterinary and agricultural students will use these data to determine the occurrence, potential risk factors, and cost of animal disease as a foundation for training in health management, animal welfare, nutrition, and environmental impacts. The benefit to the industry from Sheep 2011 study is scientifically valid national estimates of health and management practices of the nation's sheep industry.

APHIS will use the data collected to:

- Establish national and regional production measures for producer, veterinary, and industry reference
- Predict or detect national and regional trends in disease emergence and movement
- Address emerging issues
- Examine the economic impact of health management practices
- Provide estimates of both outcome (disease or other parameters) and exposure (risks and components) variables that can be used in analytic studies in the future by APHIS
- Provide input into the design of surveillance systems for specific diseases

[4] A complete list of publications using NAHMS Sheep data is available on the web at: http://www.aphis.usda.gov/animal_health/nahms/index.shtml

- Provide parameters for animal disease spread models.

Sheep 2011 Study Data Collection Forms

NAHMS-246, General Sheep Management Report (CATI) – will be mailed to the sample of producers in the 22 States with less than 20 ewes, with a follow up telephone interview by a NASS enumerator for non-respondents, to collect data on the producer's sheep inventory, sheep management practices, and sheep disease knowledge. The questions are a small sub-set of those contained in NAHMS-247 for the larger size sheep operations, thus providing some base line information on sheep operations with one or more ewes. A unique NAHMS identification number is assigned to each operation. NASS will enter and validate data collected and provide the data file to the APHIS NAHMS in Fort Collins, Colorado.

NAHMS-247, General Sheep Management Report (Enumerator) – will be administered to the sample of producers with 20 or more ewes by a NASS enumerator, to collect data on the producer's sheep inventory, sheep management practices, and level of familiarity with specific sheep diseases. A unique NAHMS identification number is assigned to each operation. NASS will enter and validate data collected. Names of eligible consenting producers who are interested in the next phase of the study will be provided to the APHIS NAHMS coordinator in each of the 22 States. The complete dataset will be sent to NAHMS in Fort Collins, Colorado.

NAHMS-248, Producer Agreement – will be presented to the participant by the APHIS-designated data collector upon entry into the NAHMS study. This form 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, it will be signed by the participant and the data collector. One copy of this agreement will be left with the participant and one copy will be retained by the data collector.

NAHMS-249, VS Initial Visit Questionnaire - will be administered to consenting producers by an APHIS-designated data collector to collect data on management practices relating to animal health. Upon completion, the form (without producer contact information such as name or address) will be returned to NAHMS in Fort Collins, Colorado for data entry and validation. A copy will be retained by the data collector to facilitate validation.

NAHMS-250, Fecal Parasite Sample Collection Record –will be used by an APHIS-designated data collector or by the producer to collect fecal samples from individual ewes, and to record herd deworming history. The fecal samples will be sent to the University of Georgia Department of Infectious Diseases research laboratory for DrenchRite analysis. This test determines parasite resistance to various deworming drugs. Parasite resistance is a major concern for the sheep industry. Test results will be returned to NAHMS in Fort Collins, Colorado and will be added to the farm record database. The form will be returned to NAHMS for data entry and validation and a copy will be retained by the data collector to facilitate validation. Test results will be returned to the producers.

NAHMS-251, Nasal Swab and Blood Sample Collection Record – will be used by an APHIS-designated data collector to collect nasal swabs and blood samples from individual sheep, and to specify the breed and age of each sheep. The blood samples will be sent to the USDA Agriculture Research Service (ARS) Animal Disease Research Unit laboratory for caprine arthritis encephalitis testing. The blood samples will also be tested for Johne's disease at USDA NVSL in Ames, Iowa. Test results will be returned to NAHMS and will be added to the farm record database. The form will be returned to NAHMS for data entry and validation and a copy will be retained by the data collector to facilitate validation. Results of the testing will be returned to the producers.

NAHMS-252, Scab Sample Collection Record – will be used by an APHIS-designated data collector or by the producer to collect scab samples from ewes suspected of having sore mouth infection. The scab samples will be sent to the Centers for Disease Control (CDC) for analysis for sore mouth virus. Test results will be returned to NAHMS and will be added to the farm record database. The form will be returned to NAHMS for data entry and validation and a copy will be retained by the data collector to facilitate validation. Results of the testing will be returned to the producers.

NAHMS-253, Fecal Pathogen Collection Record – will be used by an APHIS-designated data collector or by the producer to collect fecal samples from areas where ewes spend most of the day. The fecal samples will be sent to the University of Georgia Department of Infectious Diseases research laboratory. Test results will be returned to NAHMS in Fort Collins, Colorado and will be added to the farm record database.

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.***

The second data collection attempt for the sample of producers with less than 20 ewes will be conducted via Computer Assisted Telephone Interviews (CATI) via NASS.

4. ***Describe efforts to identify duplication.***

Literature searches for existing data relevant to the Sheep 2011 study have been performed. Available data were 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 American Association of Small Ruminant Practitioners (AASRP), and universities. Personnel 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. sheep industry.

5. ***If the collection of information impacts small business or other small entities, describe the methods used to minimize burden.***

This survey is designed to collect the minimum amount of data required from a minimum number of producers with sheep to ensure statistically and scientifically valid data. Industry and producer input is solicited to ensure that information collected is relevant and timely. This is a voluntary study; it is at the discretion of the individual producer to decide whether or not it is desirable for them to participate. Producers (approximately 2,000 or 36%) with less than 20 ewes will receive a small sub-set of those questions on the General Sheep Management Report (Enumerator) to minimize burden.

6. ***Describe the consequences to Federal program or policy activities if the collection is not conducted or conducted less frequently, as well as any technical or legal obstacles to reducing burden.***

The type and quality 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.

Without this type of national data, the U.S.' ability to detect trends in management, production, and health status, either directly or indirectly, would be reduced or nonexistent. The possibility of assessing the reduction of risk to human health from food borne pathogens and zoonotic diseases 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 and production practices of the U.S. sheep population would be severely reduced, potentially impacting the global marketability of animals, meat and byproducts. Disease spread models would not have the necessary parameters to more accurately predict spread of an outbreak without this study.

7. ***Explain any special circumstances that would cause an information 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 often 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 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.**

This information collection is consistent with guidelines established 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.***

   In 2010, APHIS engaged in productive consultations with the following individuals concerning the information collection activities associated with this program:

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   E-mail: prodgers2@earthlink.net
   American Sheep Industry Association
   9785 Maroon Circle, Suite 360
   Centennial, CO 80112

   Paul Plummer
   Iowa State University
   Phone: (515) 294-9265
   Veterinary Diagnostic and Production Animal Medicine
   College of Veterinary Medicine
   1600 S. 16th St.
   Ames, IA 50011-1250

   Jim Logan - Chair Animal Health Committee, American Sheep Industry Association
   (307) 857-4140
   2020 Carey Ave., 2nd floor
   Cheyenne, WY 82002
   Telephone: (307) 777-7515
   Fax: (307) 777-6561

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 Questionnaire Repository 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. Item codes are then assigned and NASS performs the pretests, at least one in conjunction with the NAHMS staff. Pretests are conducted in at least two states which reflect different production and management practices. Pretest results are discussed via conference call and NASS makes the final updates for the enumerator version. For the VMO data collection, NAHMS is responsible for the materials. Field data collectors, university and lab specialists provide input to the data collection materials. Pretests are conducted in 5-7 States.

The Agency's notice of information collection activity was announced in the Federal Register on Friday, August 27, 2010, pages 52711-52712. No comments were received.

9. *Explain any decision to provide any payment or gifts 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.

APHIS will only release study results based on summary estimates from the inference population. Only the NASS designated APHIS agents collecting on-farm data will have knowledge of the participant's identity. All forms, data, and questionnaires will refer to the respondent by a numeric code assigned by NASS. This link between participant and numeric code will be destroyed once data collection, entry, validation and report dissemination are complete. All completed survey forms, without names and other identifying personal information, will be stored securely in a limited access records vault. In follow-on phases agreed to by respondents, no names, addresses, or other personal information is recorded on the questionnaire, therefore eliminating any connection between completed questionnaires or laboratory results and the respondent's information.

NASS has statutory protection, under Title 7, Section 2276 of the U.S. Code, Confidentiality of Information and additionally through the Confidentiality Information Protection and Statistical Efficiency Act (CIPSEA) of 2002 that guarantees NASS's ability to keep individual farm data and associated producer names and addresses confidential. Acting under the capacity granted to government statistical agencies, NASS designates APHIS personnel as confidential agents which allow access to record level data critical to project scope.

Every NASS employee and designated APHIS personnel that may handle a questionnaire, or data coming from a questionnaire, are required to sign a form certifying they understand the restrictions on the use of unpublished data. These documents reference protections provided by the aforementioned statutory and regulatory protections. Access to record-level data files is always restricted and these files are only accessible by NASS employees or designated APHIS personnel. APHIS designated personnel are never provided access to NASS respondents' name and address without producer consent. APHIS data collection is carried out in the field by veterinary medical officers or animal health technicians under the terminology of APHIS designated data collector.

11. Provide additional justification for any questions of a sensitive nature.

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.

A. A total of 9,356 burden hours are needed to complete the Sheep 2011 study information collection activity. A detailed burden estimate has been included on the enclosed APHIS 71 Form.

B. Respondent costs: Estimated respondent costs for the information collection proposed is calculated based on an on-farm data collection estimate of $10.83 per hour[5]. The total respondent cost for the Sheep 2011 Study is $101,325. (9,356 hours * $10.83).

13. Provide an estimate of the total annual cost burden to respondents or record keepers resulting from the collection of information (do not include any hour burden shown in items 12 and 14).

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

14. ***Provide an estimate of annualized cost to the federal government.***

The estimated cost to the Federal Government is $768,485. 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-I.

This is a reinstatement of collection 0579-0188. There is a program change of -1,302 annual responses and +266 burden hours since the original study was conducted in 2001. Due to the new statistical methodology (see Part B), fewer producers must be contacted. However, this is offset by the increased burden of new forms NAHMS 248 and 249.

[5] NASS Farm Labor, published report for 2010, released May 20, 2010, available upon request.

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 collection, editing, and cleaning of the data. 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, prevalence and point estimates. Variance measures and confidence intervals for the point estimates will be calculated in order to describe the precision of the descriptive statistics generated. SUDAAN software from RTI will be used to correctly calculate the standard error to account for the complex study design. Standard errors will be published along with the point estimates.

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 producers, universities, researchers, practitioners, animal health related industries, Federal agencies, legislators, and any other interested party. Copies of current and past information 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 is not seeking approval to not display the expiration date for OMB approval on the forms used in this collection.

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

APHIS is able to certify compliance with all provisions of the Act.