

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 Layers 2013

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-XXXX
NAHMS Layers 2013**

September 3, 2012

A. Justification

1. Explain why the collection of this information is necessary

This submission is a request for approval to initiate the National Animal Health Monitoring System's (NAHMS') Layers 2013 Study, an information collection by the Animal and Plant Health Inspection Service (APHIS). This study will consist of a single in-person interview. Selected operations in 19 States² will be contacted to schedule an in-person interview. APHIS data collectors will administer the questionnaire.

In 1999, NAHMS conducted a national study of the table egg industry (Layers '99) to provide baseline information regarding health and management of table egg operations, and to estimate the prevalence of *Salmonella enterica* Enteritidis (*Salmonella* Enteritidis). No national, cross-company study on the table egg layer industry has been conducted since NAHMS' Layers '99 Study. Information collected through the Layers 2013 Study will be analyzed and used to:

- Update previously collected information on layer farm management practices relevant to *Salmonella* Enteritidis
- Estimate the prevalence of *Salmonella* Enteritidis on layer farms
- Investigate risk factors for *Salmonella* Enteritidis

The information collected through the Layers 2013 study will be analyzed and organized into descriptive reports. Several information sheets will be derived from these descriptive reports and will be disseminated by NAHMS to the producers, stakeholders, academia, veterinarians, and any other interested parties. The benefits to the layer industry from the Layers 2013 study include scientifically valid national estimates of health and management practices of the nation's layer industry. The data collected will also be used to measure change over time from the previous NAHMS' Layer study. Participation in this survey is voluntary. It is up to the individual producer to decide whether or not it is desirable to participate.

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

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

² AL,AR,CA,FL,GA,IA, IL,IN,MI,MN,MO,NC,NE,OH,PA,TX,WA,WI, and New England (considered as 1 state for purpose of sampling).

Protection Act, “Detection, Control, and Eradication of Diseases and Pests,” May 13, 2002. This collection of layer data is consistent with the APHIS mission of protecting and improving American agriculture’s productivity and competitiveness. Information about health and management practices on U.S. poultry operations is useful to the poultry industry as well as many Federal and State partners.

NAHMS will initiate the second national data collection of table egg layers through Layers 2013. A *Salmonella* Enteritidis working group was formed to identify areas where APHIS:VS should have a role in the prevention and control of *Salmonella* Enteritidis on table egg farms. This working group identified a need to update the information from the NAHMS Layers ’99 study as well as a need for a current estimate of the prevalence of *Salmonella* Enteritidis on table egg farms.

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.

Statistically summarized information and interpretation are disseminated to a wide variety of constituents. Producers will use the information to compare their operation’s animal health and productivity with other operations 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 Layers 2013 study to:

- Establish national production measures for producer, veterinary, and industry reference
- 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

Provide parameters for animal disease spread models.

National Surveys Providing Baseline Information

The Layers 2013 study is part of an ongoing series of NAHMS studies on the U.S. poultry population. The first NAHMS poultry study was NAHMS Layers 1999. The objectives of that study were to describe biosecurity and management practices used in the U.S. layer industry, and to identify risk factors associated with *Salmonella* Enteritidis in layer flocks.

Poultry 2004 was the second national monitoring activity focusing on the U.S. poultry population. Data were collected on the health and management of three distinct components of the nontraditional poultry industry: backyard poultry flocks, gamefowl flocks and live-bird markets.

The Small Enterprise Chicken study (2007) was the third NAHMS poultry study. The objectives of that study were to describe biosecurity and management practices on commercial chicken operations with fewer than 20,000 chickens.

The Poultry 2010 study was the fourth NAHMS poultry study. The objectives of that study were to describe biosecurity and management practices on chicken breeder operations, describe health and management practices of urban chicken operations, and estimate the prevalence and identify risk factors for Clostridial dermatitis on turkey grower operations.

Layers 2013 Data Collection Forms

NAHMS-298, Producer Agreement, will be presented to participants in the Layers 2013 study. This form is intended to increase the participant's understanding of the study focus, highlight confidentiality safeguards, and explain participation requirements. The form will be signed by the participant and an APHIS representative. One copy of this agreement will be retained by the participant and one copy will be retained by APHIS.

NAHMS 299, Layer 2013 Questionnaire, will be administered by APHIS personnel to collect data on management practices relevant to *Salmonella* Enteritidis. The questionnaire (without producer contact information such as name or address) will be returned to NAHMS in Fort Collins, CO, for data entry and validation.

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.

No automated, electronic, or mechanical techniques will be used to collect information for the Layers 2013 Study. Approximately 3-5 calls will be made to selected operations to schedule a time for in-person data collection. The data collection instrument will be a hard copy questionnaire.

4. Describe efforts to identify duplication.

Literature searches for existing data relevant to of the Layers 2013 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, 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. layer industry.

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

The Layers 2013 study is designed to collect the minimum amount of data required from a minimum number of table egg producers to ensure statistically and scientifically valid data. Operations eligible to participate in the study must have a minimum of 3,000 table egg layers. 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 producer to decide whether or not it is desirable for them to participate. Fifty-five percent of the sample will be small-scale operations.

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 status of the U.S. layer industry was last examined in 1999 and must continue with the collection of data relevant to *Salmonella* Enteritidis on layer operations in 2013. The type, quality, and frequency of data collected by the NAHMS 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 *Salmonella* due to management changes based on NAHMS data and the ability to inform FDA standards would also be nonexistent. Disease spread models would not have the necessary parameters to predict more accurately the spread of an outbreak.

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.*

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.**

Consultants used for planning the Layers 2013 Study:

Krista N. Eberle, Director of Food Safety Programs, United Egg Producers, (770) 360-9220

Eric Gingerich, DVM, President, Association of Veterinarians in Egg Production,
P.O. Box 74570, Cedar Rapids, Iowa 52407-4570 (319) 366-0745

David A. Halvorson, DVM, ACPV, Extension Veterinarian - Avian Health, College Of
Veterinary Medicine, University of Minnesota, 1971 Commonwealth Avenue, Saint Paul,
Minnesota 55108, 612-625-5292

The Agency's notice of information collection activity was announced in the Federal Register on Wednesday, July 18, 2012, page 42255. APHIS received two comments. One appreciated the work that APHIS does and the other related his/her perception of the maltreatment of animals. Neither comment related to paperwork burden.

- 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.**

On March 20, 2012, NAHMS was recognized by OMB as a statistical unit under Title V of the E-Government Act of 2002, Public Law 107-347, Section 513 (the Confidential Information Protection and Statistical Efficiency Act of 2002 (CIPSEA)). All information acquired under the Layers 2013 Study will be used for statistical purposes only and will be treated as confidential in accordance with CIPSEA guidelines. Only NAHMS staff and designated agents will be permitted access to individual-level data.

Only summary estimates based upon the inference population will be reported. Only the NAHMS designated data collector collecting 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 NAHMS. This link between participant and numeric code will be destroyed once data collection, entry, validation and report dissemination are complete. All completed survey forms will be stored securely in a limited access records room.

NAHMS has statutory protection that allows for the protection of respondent data 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 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.

Several additional U.S. Codes apply to data collected by 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

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

Questions regarding testing for *Salmonella* Enteritidis may be sensitive. These questions are essential to estimate prevalence and assess risk factors for *Salmonella* Enteritidis on layer farms. The questionnaire will address testing that producers are already doing in compliance with the FDA egg rule, which will be more efficient and cost effective than to duplicate their efforts by collecting biologic samples.

12. Provide estimates of the hour burden of the collection of information.

A. A total of 894 burden hours are needed to complete Layers 2013 over the collection period for this information collection. A detailed burden estimate has been included on the enclosed APHIS 71 Form.

B. Respondent costs: Estimated respondent costs for the information collection proposed are calculated based on a data collection estimate of \$10.91 per hour. The total respondent cost for Layers 2013 is \$9,753.54. (894 hours * \$10.91).

Salary was derived from the NASS Farm Labor published report for 2006, released November 20, 2009, available upon request.

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 \$45,079.76. 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 new collection.

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

Any published summary data will be available at <http://nahms.aphis.usda.gov>.

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 an exemption to display the expiration date for OMB approval.

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

APHIS is able to certify compliance with all provisions in the Paperwork Reduction Act.

