

SUPPORTING STATEMENT – OMB NO. 0579-0101
SCRAPIE IN SHEEP AND GOATS; INTERSTATE MOVEMENT RESTRICTIONS AND
INDEMNITY PROGRAM

March 2011

A. Justification

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.

The Animal Health Protection Act (AHPA) of 2002 is the primary Federal law governing the protection of animal health. The law gives the Secretary of Agriculture broad authority to detect, control, or eradicate pests or diseases of livestock or poultry. The Secretary may also prohibit or restrict import or export of any such animal or related material if necessary to prevent spread of any livestock or poultry pest or disease. The AHPA is contained in Title X, Subtitle E, Sections 10401-18 of P.L. 107-171, May 13, 2002, the Farm Security and Rural Investment Act of 2002.

Scrapie is a progressive, degenerative, and eventually fatal disease affecting the central nervous system of sheep and goats. Its control is complicated because the disease has an extremely long incubation period. There is no test that can detect the disease early in the incubation period and no treatment. APHIS restricts the interstate movement of certain sheep and goats to control the spread of scrapie within the United States. APHIS also operates an indemnity program to compensate owners of sheep and goats destroyed because of scrapie. APHIS interstate movement and animal identification regulations are contained in title 9 of the *Code of Federal Regulations*, part 79, while its scrapie indemnification, flock cleanup, testing and Scrapie Flock Certification Program (SFCP) regulations are found in part 54.

APHIS interstate movement requirements minimize any contact between high-risk animals and healthy animals, while the animal identification requirements help trace scrapie- exposed animals. The APHIS indemnity program encourages more flock owners to report scrapie signs and to eliminate scrapie from their flocks.

These regulations necessitate the use of a number of information collection activities, including completing applications for participation and advancement in the SFCP; Flock Clean-up Plans and Post Exposure Management and Monitoring Plans (PEMMPs) for infected and source flocks; scrapie test records; applications for indemnity payments; certificates, permits, and owner statements that allow for the interstate movement of certain sheep and goats; and applications for premises identification numbers. They also include recording the application of APHIS-approved eartags, backtags, or tattoos.

APHIS is asking the Office of Management and Budget (OMB) to approve these information collection activities for an additional 3 years and to amend the information collection OMB 0579-0101 to include the use of two new forms, data entry screens, and worksheets used to facilitate capture and storage of the data collected in connection with APHIS' efforts to contain and eventually eradicate scrapie in the United States. Data entry screens are used by USDA employees, contractors and State cooperators. They are not available to the general public.

2. Indicate how, by whom, how frequently, 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.

APHIS uses the following information activities to minimize any contact between high-risk animals and healthy animals, while the animal identification requirements help trace scrapie- exposed animals and encourages more flock owners to report scrapie signs and to eliminate scrapie from their flocks through the indemnity program.

Cooperative Agreement and Grants Forms Family – SF-424, SF-424A, SF 424B, SF LLL, SF 425
The cooperative agreement is a written commitment between APHIS and the animal health agency of a State or Tribal government to administer the National Scrapie Eradication Program (NSEP) and the SFCP. These agreements describe the roles of APHIS and State or Tribal personnel in implementing the scrapie program. Agreements may also be made with universities and other organizations to further scrapie eradication.

Each agreement may specify the financial, material, and personnel resources to be committed to these programs and other scrapie control measures by the State, Tribe, and APHIS; assign specific activities related to the control of scrapie within a State or Tribe; establish schedules for flock visits; establish procedures for maintaining and sharing program records; and specify other responsibilities. Cooperative agreements include the transfer of funds or materials to the cooperator. They specify the activities but do not identify the forms associated with the activities. Cooperative agreements for the scrapie program are shown in Table 1. (Refer to Appendix A-1 for reporting guidelines used for cooperative agreements. Appendix A-2 includes an example of a cooperative agreement. In addition to cooperative agreements, APHIS may also award grants to not-for-profit entities and States. (See Appendix A-3.)

The workplan and financial plan for cooperative agreements and grants are discussed at the end of question 2.

Record of Animals Moved (VS Form 5-18 or equivalent records) and continuation (VS Form 5-18A)/Individual Animal Report (VS Form 5-20 or equivalent records)

When a flock owner applies for indemnity payments, APHIS may ask the owner for specific information as a condition for receiving the indemnity payments. The owner must submit this information (such as animal registration certificates or sale and movement records) to APHIS within 30 days of the request for the information. State representatives may complete VS Form 5-18, 5-18A, and VS Form 5-20 on behalf of APHIS for businesses. This information is extremely critical in order for APHIS to conduct trace investigations in response to an adverse disease event.

Flock Inspection and Epidemiology Report (VS Form 5-19)/Scrapie Epidemiology Report (VS Form 5-19D)

An APHIS or State veterinarian records all epidemiological findings of an investigation on these forms. Information is obtained from examining records and animals and through questioning the flock owner regarding flock health, management practices, and animal movements (animals sold for slaughter or breeding, purchased additions, etc). Information collected on VS Form 5-19D is required under 9 CFR 54.3(b) as a prerequisite for receiving indemnity. VS Form 5-19D is an updated form and will eventually replace VS Form 5-19.

Application for Payment (VS Form 1-23) and Continuation Sheet (VS Form 1-23A)

An APHIS or State representative completes the application for indemnification for the owner. The owner then confirms the information on the application. If a flock is not currently determined to be scrapie affected, the owner may apply directly to APHIS for indemnification. The written application must provide specific information including the name, address, and social security number of the flock owner; the number and breeds of animals within the flock; the location of the flock; and reasons the owner believes the flock may be eligible for indemnification. In the case of known infected flocks, this information has already been collected by APHIS as part of the investigation and request for information. Giving flock owners an opportunity to receive indemnity payments encourages producers to report incidents of scrapie in their animals, which hastens the eradication of scrapie from the United States. This report, containing original signatures of the flock owner and the supervising veterinarians, also serves as the official written record that a specific number of animals in the owner's flock have been destroyed because of scrapie.

Written Agreement/Certification (signature only)

Before APHIS makes an indemnification payment to a flock owner, the owner must sign a written agreement certifying the following: (1) he or she will make available to APHIS any bills of sale, pedigree registration certificates, and other records regarding movement of animals into and from the flock; and (2) he or she will maintain any current flocks (or any new flocks acquired within 5 years after the last scrapie-positive, -exposed, or -suspect animal has been removed from the premises) in accordance with a PEMMP. When a flock plan is also required, this statement is included as part of the flock plan to minimize the number of signatures required. This agreement/certification is a valuable tool in APHIS' efforts to closely monitor sheep and goat operations that have been impacted by scrapie.

Proceeds from Animals Sold for Slaughter (VS Form 1-24)

This form documents salvage value of animals destroyed by slaughter and is required for the calculation of indemnity. The buyer or seller of the animals completes the form.

Flock Plan (signature only) and Recordkeeping

A written flock management agreement is signed by the owner of a flock designated as infected or source, a State representative, and an APHIS representative. Each participant agrees to undertake actions specified in the flock plan to control the spread of scrapie. These actions include official identification of animals, collection of tissues, availability of records, monitoring for scrapie, and notification of an APHIS or State representative if any animals exhibit signs of possible scrapie infection. The flock owner must maintain records for acquired animals and animals leaving the premises for 5 years. These records are invaluable if the flock becomes infected and a trace investigation is necessary.

Post Exposure Management and Monitoring Plan (PEMMP, signature only) and Recordkeeping

This is an agreement between the flock owner, a State representative, and an APHIS representative describing a plan to carefully monitor a flock for at least 5 years following removal of the last scrapie-positive, -exposed, or -suspect animal from the flock. In this plan, the owner agrees to maintain records for 5 years for each animal in the flock, including each animal's sex, breed, date of acquisition, and the source of acquisition (previous flock). The owner also agrees to alert an APHIS or State representative if any animals in the flock show signs of possible scrapie infection. Entering into these agreements with owners of infected flocks or flocks with exposed animals ensures that these flocks will be closely monitored and controlled until 5 years after all scrapie-positive and/or high-risk animals have been removed or died. The records are invaluable if the flock becomes infected and a trace investigation is necessary.

Report Suspect Animals

Accredited veterinarians or flock owners must immediately report to an APHIS or State Animal Health Official via a telephone call, fax, or e-mail any suspect animals. A suspect animal may be euthanized and tissue specimens submitted for scrapie testing.

Scrapie PEMMP Inspection Report (VS 5-19C) and Recordkeeping

This form is used by APHIS or State personnel to record data on flocks that are inspected as part of a PEMMP. Information is obtained through examining animals and records and by asking questions of flock owners. Flock owners are asked about signs of disease, compliance with identification requirements, and records. They are required to maintain these records for 5 years.

Scrapie Test Record (VS Form 5-29) and Continuation Sheet (VS Form 5-29A)

Testing of affected and exposed flocks is a key component of the eradication program. The scrapie test record form is used to record the herd being tested; the owner's name and address; official identification number(s), age, breed, and sex of each animal tested; and the type of test required. VS Form 5-29 and 5-29A are used for submission of samples for genotype testing and/or tissues for antemortem scrapie testing. An APHIS or State representative or accredited veterinarian completes these forms with assistance from the flock owner.

APHIS developed worksheets based upon the VS Forms 5-29 and 5-29A to provide additional space to apply barcodes used to identify specimens and to serve as a draft copy when collection of samples and specimens occurs under adverse conditions. (See Appendix B-1.)

Specimen Submission (VS Form 10-4)

An APHIS or State representative or accredited veterinarian completes this form to submit specimens from dead animals to an approved laboratory for scrapie testing. These individuals usually obtain information to complete this form from the flock owners or other business owners, such as slaughter plant owners. This form is critical for identifying infected and source flocks or for releasing exposed flock status.

To facilitate the collection of information at sheep or goat slaughter plants and when producers submit whole heads from individual animals for scrapie testing, APHIS developed a simplified worksheet. Use of the worksheet decreases the time that would be needed to complete VS Form 10-4 and also serves as a draft copy when collection of samples occurs under adverse conditions. (See Appendix B-2, 3.)

Request for Laboratory Approval

State or other diagnostic laboratory directors may request approval for their laboratory to conduct an official test for the diagnosis of scrapie or for scrapie susceptibility genotyping. The request can be made by letter or e-mail through the Area Veterinarian in Charge (AVIC) in the State in which the laboratory is located or to the Director of the National Veterinary Services Laboratories (NVSL). (A university laboratory not affiliated with a State may also request approval, but to date, none have done so.)

Agreement to Conduct the Official Histopathology Examination for the Diagnosis of Scrapie in Sheep and Goats and Bovine Spongiform Encephalopathy in Cattle (VS Form 5-21)

After the State diagnostic laboratory director requests approval of the laboratory (as discussed above under Request for Laboratory Approval), APHIS inspects the laboratory to determine that it has the proper physical facilities and equipment, the inspector reviews the laboratory's responsibilities (both regulatory and technical) with laboratory officials. The laboratory director then signs VS Form 5-21. Once the laboratory has one or more of its pathologists trained at NVSL, the laboratory is approved as an official laboratory by NVSL. (A university laboratory not affiliated with a State may also request approval, but to date, none have done so.)

Application for the Scrapie Flock Certification Program (VS Form 5-22)

Any flock owner desiring to participate in the SFCP must sign an application form, agreeing to follow the provisions of the program. This pre-printed form requires the flock owner to provide his/her name and address, the location of the flock(s), and the number of animals in each flock.

Flock Inspection and Epidemiology Report Initial Flock Inspection for Complete or Export Monitored Status in the SFCP (VS Form 5-19A) and Recordkeeping

APHIS or State personnel use this form to collect information from flock owners as part of their application to enroll in SFCP. Flock owners assist the State or Federal employee in completing VS Form 5-19A and must keep these records for 7 years. The information describes their inventory.

Flock Inspection Report Annual Inspection Report for Scrapie Flock Certification Program Enrolled or Certified Flocks (VS Form 5-19B) and Recordkeeping

Flock owners assist the State or Federal employee in completing the VS Form 5-19B. This form records data regarding subsequent SFCP inspections. The information describes their inventory and management practices, including additions and disposition of animals. Flock owners must keep these records for 7 years.

Owner Statement

An owner statement may be used as an additional or alternative means of identifying regulated sheep and goats to their flock of origin. When these animals are moved across State lines, it is vital that APHIS has documentation that will enable it to trace animals back to their flock of origin. The flock owner completes this form with the owner's name, signature, address, telephone number, the date the animals left the flock of origin, the number of animals involved in the movement, the premises identification number assigned to the premises, and other identifying information.

Agreement to Use Blue Tags

Owners, operators, or managers of livestock markets, slaughter plants, or other concentration points may only accept animals for interstate movement if the animals are or can be identified as required. To ensure that these representatives understand the requirements for handling animals that are not identified as required, APHIS asks them to enter an agreement with APHIS and the States. By signing the agreement, they agree to, among other things, report to APHIS or the State a list of occurrences when animals are not identified. They further agree to identify any unidentified animals with blue meat (slaughter-only) tags. The representatives must document the process for ensuring that animals are sold for slaughter or feeding for slaughter only. They must also document that they advise the buyers of this process. These representatives then sign and date the agreement. State and APHIS representatives also sign and date the agreement.

Report for Consignments when Identification is Applied

As part of the agreement to use blue tags, dealers or owners, operators, or managers of livestock markets, slaughter plants, or other concentration points agree to report consignments of animals that arrive without identification and that are not eligible for certain forms of official identification because the flock-of-origin cannot be determined. The representatives report to APHIS or the State representative a list of official identification numbers applied; date or receipt, consignor name and address; number, species, and breed or class of animal; number of unidentified animals; and a statement (or photographs of the teeth and ears of the unidentified animals), noting whether the second permanent incisor of the unidentified animals had erupted. The agreement and report enable the facility to accept the animals that arrived without identification. These documents also avoid having to return the animals to the truck and reshipe them.

Recordkeeping, Animals Moved in Interstate Commerce

Flock owners must maintain specific records on each animal for at least 5 years after the animal is moved or sold, and make these records available for inspection by an authorized APHIS or State representative. These records include such information as the number of sheep and/or goats; the breed or cross if known; the name, street address, including city and State, or the township, county, and State, and the telephone number if the telephone number is available, of the owner of the flock of origin and, if different, the person from whom the sheep or goats were purchased or otherwise obtained or to whom they were sold or otherwise disposed; and a copy of any documents required to accompany the animal including any certificate, owner statement, letter, or permit; and in some cases, the identifying marks or tags on the animal. (Much of this recordkeeping is part of normal business records that people maintain for tax and other purposes.) These records would be invaluable if an exposed or infected animal needs to be located.

Request for Approval to Produce Official Identification Devices

Tag manufacturers request by mail or e-mail approval to produce official identification devices. Approval packages include data supporting the durability of the tag, durability and legibility of the identification numbers, and high retention rates of the tags in animals, preferably sheep or goats, and a signed agreement.

Agreement to Send Official Eartags to Specified Individuals

As part of the request for approval to produce official identification devices, tag manufacturers must provide a signed statement agreeing to send official eartags only to a State or APHIS representative, to a flock owner that has been assigned a premises number or tag sequence by APHIS or a State representative, or as directed by APHIS.

Monthly Report of Official Identification Devices Produced

Tag manufacturers provide a monthly report by State of all tags produced, including the tag sequences produced, the recipient's name, and shipping address. (APHIS is replacing the monthly report with an automated report. Most of the data entry is paid for under contract by USDA.)

Data Entry of Official Identification Devices Produced

Tag manufacturers enter the sequences of tags shipped into the Animal Identification Management System (AIMS) database through a Web-based interface. (See Appendix E-2.)

Request for Approval of New Device Type

An individual wishing to use or produce an identification device or marking not listed in 9 CFR 79.2(a) (2) must submit to APHIS a written request for approval of the device or marking. If APHIS determines that the device or marking will provide an adequate means of tracing sheep and goats in interstate

commerce, APHIS will publish a proposed rule in the *Federal Register* to add the device or marking to the list.

Herd Owner Notification

When an APHIS or State representative determines that a scrapie exposure has or may have occurred in a flock, the APHIS representative must notify the flock owner in writing of this determination and provide the owner with a description of APHIS interstate movement restrictions and identification requirements. APHIS or the State representative communicates this information to flock owners so they will be fully and promptly advised of their flock's new status with regard to interstate movement. The flock owner is not required to respond to this notification.

Permit For Movement of Restricted Animals (VS Form 1-27)

Authorized APHIS or State personnel or accredited veterinarians issue permits for the interstate movement of scrapie-exposed, scrapie-positive, or other high-risk animals. A permit lists the owner's name and address, the origination and destination of the animals, how many animals are involved in the movement, the purpose of the movement, the transportation vehicle's license number, and all official identification on each animal being moved.

Certificate of Veterinary Inspection (VS Form 17-140 or Equivalent) and Recordkeeping

A flock owner wishing to move sheep or goats in interstate commerce for reasons other than for slaughter or feeding for slaughter must be issued a certificate of veterinary inspection (CVI). Since these animals are not designated exposed or infected, any accredited veterinarian can issue the CVI. The flock owner assists the accredited veterinarian in completing the CVI by having the animals available for inspection and providing the purpose for which the animals are being moved, the points of origin and destination, the consignor, and the consignee. The issuance of the CVI requires examination of the animals for clinical signs of scrapie or other communicable diseases, listing of official identification, and provides APHIS with important information if a trace investigation must be conducted. The receiving and shipping States retain these records for at least 10 years.

Consistent State Application (VS Form 5-24)

States wishing to remain classified as having an effective scrapie management program must submit to APHIS an annual application for renewal describing the State's scrapie management actions during the preceding fiscal year. These include inspections done to monitor compliance with official identification and recordkeeping requirements, reports of disease events, actions taken in response to these events, and surveillance activities. In addition, the VS Form 5-24 requires signatures by the State Animal Health Official. The current version of this form simplifies the application and relies upon transmission of an electronic spreadsheet as part of the reporting process rather than summarizing the information on a hard copy form.

Application for Identification Numbers

Flock owners, dealers, accredited veterinarians, and market operators must apply to the appropriate State or Federal representative to be assigned USDA serial numbers that correspond to official animal identification devices. They must provide their name, address, phone number, number of animals, and type of operation so that the State or Federal representative can place their order and create a record. These applications are generally made by calling the State or Federal representative. If flock owners, dealers, accredited veterinarians, and market operators give this information to their State representatives, the State representatives would record the application data.

Application for Premises Identification Numbers

APHIS employs an additional (but optional) identification system that allows sheep and goats moving in interstate commerce to be identified with an approved eartag, backtag, or tattoo bearing a premises identification number (also referred to as a flock identification number) assigned by a State or Federal animal health official to the premises on which the sheep or goats originated. Obtaining and applying these premises identification numbers, which could be used in lieu of official USDA serial numbers, is the responsibility of flock owners. To apply for these numbers, the flock owners contact the State or Federal representative by telephone or other means and give their name, address, phone number, number of animals, and type of operation so that the State or Federal representative can create a record. If the flock owners give this information to the State representative, the State would record the information. These premises identification numbers help APHIS and States monitor sheep and goats moving in interstate commerce and provide APHIS and States with critical information if a trace investigation is necessary.

Recordkeeping, Identification

Flock owners, market operators, dealers, slaughter plant owners, tag manufacturers, and accredited veterinarians using official identification devices or methods must record all serial numbers and other identification numbers that are affixed to the sheep and goats, as well as the location where the identification was applied and the name, address, and when available, telephone number of the animal's owner and the owner of the flock of origin if different. This information must be maintained for at least 5 years, and could provide invaluable information to State or Federal personnel conducting a trace investigation. APHIS does not prescribe a form for recording this information.

Cooperative Agreements and Grants Workplan

The workplan accompanies the cooperative agreements used by States and Tribal governments and not-for-profit institutions. These entities complete the workplan.

Cooperative Agreements and Grants Financial Plan

The financial plan accompanies the cooperative agreements used by States and Tribal governments, and not-for-profit institutions. These entities complete the financial plan.

Cooperative Agreement or Grant Quarterly Report

States and Tribal governments and not-for-profit institutions complete quarterly reports on their cooperative agreements.

Memorandums of Understanding Forms Family

The memorandum of understanding (MOU) is a written commitment between APHIS and the animal health agency of a State to cooperatively administer the NSEP and the SFCP. MOUs do not involve the transfer of funds. For more details of this activity, see the explanation provided above for cooperative agreements. (See Appendix A-4 for the MOU template.)

Cooperative agreements, MOUs, and grants for the scrapie program are shown in Table 1 below.

Table 1. Cooperative Agreements, MOUs, and Grants for the Scrapie Program.

Region	State	Cooperator Name	Expires	Number
WR	ND	ND State Board of Animal Health	03/31/2011	09-9738-1490-CA
WR	NM	NM Livestock Board	09/30/2010	09-9735-1796-CA
WR	CA	CDFAs	03/31/2011	10-9706-1415-CA
WR	HI	HI Dept. of Ag.	03/31/2011	10-9715-1723-CA
WR	ID	ID State Dept. of Ag.	03/31/2011	10-9716-1728-CA
WR	LA	LA Dept. of Ag. & Forestry	03/31/2011	10-9722-2056-CA
WR	SD	SD Animal Industry Board	03/31/2011	10-9746-1807-CA
WR	WY	WY Livestock Board	03/31/2011	10-9756-1568-CA
WR	TX	TAHC	03/31/2011	10-9748-1759-CA
WR	NV	NV Dept. of Ag.	03/31/2011	10-9732-1541-CA
WR	IA	IA Dept. of Ag. and Land Stewardship	03/31/2011	10-9719-1502-CA
WR	OK	OK Dept. of Ag. Food & Forestry	03/31/2011	10-9740-1667-CA
WR	MO	MO Dept. of Ag.	03/31/2011	10-9729-1803-CA
WR	AZ	Navajo Nation	07/18/2014	10-9704-1983-CA
WR	CO	CO Dept. of Ag.	03/31/2011	10-9708-1794-CA
WR	AK	AK Dept. of Environmental Conservation	02/05/2011	06-9702-0021-MU
WR	AR	AR Livestock & Poultry	12/12/2011	07-9705-0033-MU
WR	AZ	AZ Dept. of Ag.	12/12/2011	07-9704-0035-MU
WR	CA	CDFAs	07/17/2012	07-9706-0052-MU
WR	CO	CO Dept. of Ag.	09/09/2012	07-9708-0054-MU
WR	HI	HI State Dept. of Ag.	02/16/2011	06-9715-0022-MU
WR	IA	IA Dept. of Ag. and Land Stewardship	12/12/2011	07-9719-0032-MU
WR	ID	ID State Dept. of Ag.	01/03/2012	07-9716-0038-MU
WR	KS	KS Animal Health Dept.	02/26/2012	07-9720-0041-MU
WR	LA	LA Dept. of Ag & Forestry	06/27/2012	07-9722-0051-MU
WR	MO	MO Dept. of Ag.	01/24/2015	10-9729-0064-MU
WR	MT	MT Dept. of Livestock	03/26/2012	07-9730-0045-MU
WR	ND	ND State Board of Animal Health	08/09/2015	10-9738-0065-MU
WR	NE	NE Dept. of Ag.	02/11/2012	07-9731-0040-MU
WR	NM	NM Livestock Board	03/26/2012	07-9735-0044-MU
WR	NV	NV Dept. of Ag.	09/30/2015	11-9732-0066-MU
WR	OK	OK Dept. of Ag. Food & Forestry	12/12/2011	07-9740-0034-MU
WR	OR	OR Dept. of Ag.	11/14/2011	07-9741-0031-MU
WR	SD	SD Animal Industry Board	11/14/2011	07-9746-0030-MU
WR	TX	TAHC	04/02/2012	07-9748-0046-MU
WR	UT	UT Dept. of Ag. & Food	04/05/2011	06-9749-0027-MU
WR	WA	WA State Dept. of Ag.	03/13/2011	06-9753-0023-MU
WR	WY	WY Livestock Board	09/19/2012	07-9756-0055-MU
ER	IL	IL Dept. of Ag.	3/31/2011	09 9617 0248 CA
ER	CT	CT Dept. of Ag.	3/31/2011	10 9609 0177 CA
ER	GA	GA Dept. of Ag.	3/31/2011	10 9613 0180 CA
ER	IN	IN State Board of Animal Health	3/31/2011	10 9618 0039 CA

Region	State	Cooperator Name	Expires	Number
ER	KY	KS Dept. of Ag.	3/31/2011	10 9621 0875 CA
ER	ME	ME Dept. of Ag., Food and Rural Resource	3/31/2011	10 9623 0656 CA
ER	MA	MA Dept. of Ag. Resource	3/31/2011	10 9625 0694 CA
ER	MI	MI Dept. of Ag.	3/31/2011	10 9626 0146 CA
ER	MN	MN Board of Animal Health	3/31/2011	10 9627 0034 CA
ER	MS	MS Board of Animal Health	3/31/2011	10 9628 0244 CA
ER	NH	NH Dept. of Ag., Markets and Food	3/31/2011	10 9633 0670 CA
ER	NC	NC Dept. of Ag. and Consumer Service	3/31/2011	10 9637 0761 CA
ER	OH	OH Dept. of Ag.	3/31/2011	10 9639 0266 CA
ER	PA	PA Dept. of Ag.	3/31/2011	10 9642 0929 CA
ER	TN	TN Dept. of Ag.	3/31/2011	10 9647 0691 CA
ER	VT	VT Agency of Ag., Food and Market	3/31/2011	10 9650 0142 CA
ER	VA	VA Dept. of Ag. and Consumer Service	3/31/2011	10 9651 0191 CA
ER	WV	WV Dept. of Ag.	3/31/2011	10 9654 0272 CA
ER	WI	WI Dept. of Ag. Trade and Consumer Pr otection	3/31/2011	10 9655 0995 CA
ER	PA	PA Dept. of Ag.	7/12/2011	10 9642 1083 CA
ER	KY	KY Dept. of Ag.	8/31/2011	10 9621 1084 CA
ER	WI	WI Dept. of Ag., Trade and Consumer P rotection	9/15/2011	10 9655 1081 CA
ER	OH	OH Dept. of Ag.	5/15/2011	06 9639 0028 MU
ER	MN	MN Board of Animal Health	9/13/2011	06 9627 0796 MU
ER	MS	MS Board of Animal Health	9/13/2011	06 9628 0795 MU
ER	NJ	NJ Dept. of Ag.	10/3/2011	07 9634 0026 MU
ER	CT	CT Dept. of Ag.	11/2/2011	07 9609 0873 MU
ER	KY	KY Dept. of Ag.	11/2/2011	07 9621 0874 MU
ER	IL	IL Dept. of Ag.	1/9/2012	07 9617 0727 MU
ER	NC	NC Dept. of Ag. and Consumer Service	1/18/2012	07 9637 0750 MU
ER	WI	WI Dept. of Ag., Trade and Consumer Protection	2/1/2012	07 9655 0763 MU
ER	NH	NH Dept. of Ag., Markets and Food	2/13/2012	07 9633 0764 MU
ER	TN	TN Dept. of Ag.	3/29/2012	07 9647 0766 MU
ER	MI	MI Dept. of Ag.	7/19/2012	07 9626 0779 MU
ER	PA	PA Dept. of Ag.	7/30/2012	07 9642 0797 MU
ER	DE	DE Dept. of Ag.	7/31/2012	07 9610 0807 MU
ER	MD	MD Dept. of Ag.	7/31/2012	07 9624 0806 MU
ER	RI	RI Dept. of Environmental Management Division of Ag.	9/27/2012	07 9644 0828 MU
ER	AL	AL Dept. of Ag. and Industries	1/18/2015	10 9601 1003 MU
ER	SC	Clemson University	1/25/2015	10 9645 0883 MU
ER	VA	VA Dept. of Ag. and Consumer Service	1/27/2015	10 9651 0781 MU
ER	IN	IN State Board of Animal Health	7/26/2015	10 9618 0696 MU

Region	State	Cooperator Name	Expires	Number
ER	GA	GA Dept. of Ag.	7/27/2015	10 9613 0228 MU
ER	NY	NY State Dept of Ag.	8/15/2015	10 9636 1018 MU
National	CO	American Sheep Industry	4/29/2011	10-9100-1231-CA
National	CO	National Institute for Animal Ag.	3/31/2011	10-9121-0100-GR

(CA = cooperative agreement; ER = Eastern Region; GR = Grant; HQ = Headquarters; MU = memorandum of understanding; WR = Western Region)

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.

Overview of Scrapie Program Databases

- **Scrapie National Generic Database (SNGD)**

APHIS or State personnel enter information provided by producers and nonproducer entities (livestock markets, slaughter plants, and dealers) into the SNGD. Information is from the various official forms and other listed activities, such as owner name, address, contact information, premises identification numbers, premises name, address, type of premises (production unit, market, slaughter plant, etc), and species. Specific forms from which information is collected and entered into the SNGD are the VS Forms 5-18, 5-18A, 5-19A-D, 5-20, and 5-22. In addition to this information, events (inspections or testing), test results, and flock status (SFCP or disease) are entered into the SNGD. (See Appendix C for screenshots of these electronic forms.)

- **Veterinary Services Laboratory Submissions (VSLS)**

VSLS is a Web-based interface for submission of various specimens for testing by APHIS and contract laboratories. Three VSLS modules are used by the scrapie program: (1) Regulatory Scrapie Slaughter Surveillance (RSSS); (2) Genotyping; and (3) On-farm surveillance. In addition to APHIS employees, State cooperators, contract laboratories, and contract sample submitters have access to one or more VSLS modules. Specific forms from which information is collected and entered into the VSLS modules are the VS Forms 5-29, 5-29A, and 10-4. (See Appendix D for screenshots of these electronic forms.)

- **Animal Identification Management System (AIMS)**

This is a Web-based system used to manage the distribution of official eartags. This database is used by APHIS and State employees and approved tag manufacturers. (See Appendix E for screenshots of forms.)

Justification for Continued Use of Hard Copy Forms

The cooperative agreements and grants are hard copy documents requiring original signatures of State and Federal personnel to be valid. They are not candidates for electronic submission.

The request for information (VS Forms 5-18, 5-18A, 5-19, 5-19D, and 5-20) contain information supplied by the flock owner to APHIS that is necessary for the flock owner to receive indemnity payments. The flock owner attests to the accuracy of this information by signing the forms. Since an

original signature is necessary for these forms to be valid, they are not candidates for electronic submission.

The Application for Payment of Indemnity (VS Forms 1-23 and 1-23A) is completed for and signed by flock owners whose sheep are being destroyed because of exposure to scrapie. This form is not a candidate for electronic submission because it requires original signatures to be valid.

The Written Agreement/Certification by Owners is a hard copy agreement requiring an original signature by the flock owner to be valid. Therefore, it is not candidates for electronic submission.

The Proceeds from Animals Sold for Slaughter, VS Form 1-24, requires an original signature of the buyer or seller to document salvage value of animals destroyed by slaughter, which is required for the calculation of indemnity. Therefore, this form is not a candidate for electronic submission.

The Flock Plan and PEMMP are hard copy agreements requiring an original signature by the flock owner to be valid. They are not candidates for electronic submission.

Reporting the presence of suspect animals is usually accomplished by the flock owner or accredited veterinarian with a telephone call to Federal or State authorities. This information can also be e-mailed or faxed.

The Scrapie PEMMP Inspection Report (VS Form 5-19C) requires an original signature by the flock owner and is, therefore, not a candidate for electronic submission.

The Scrapie Test Record (VS Form 5-29) and its Continuation Sheet (VS Form 5-29A) are used for submission for testing for genetic susceptibility to scrapie and tissue biopsies (third eyelid or rectal biopsy). This form has been adapted for electronic use through Mobile Information Management System (MIMS) tablet and is used by State and Federal personnel who have this equipment. In addition, all genotype tests are entered into the VSLS genotyping module, and the information is submitted electronically to APHIS and contract laboratories for resulting. Data for genotyping may be scanned into VSLS (RFID tags or specimen barcodes), or entered manually. Beginning in 2011, VSLS On-farm module will be available, and all submissions of tissue biopsies will be entered into VSLS. (Refer to Appendix D for screenshots of VSLS electronic forms). Hard copies of VS Form 5-29 and 5-29A or worksheets containing the same information (Appendix B-1) are still needed when the form is completed on the flock owner's property or in other outdoor locations where computer access may not be readily available. State personnel who do not have e-Authentication accounts and accredited veterinarians will continue to use hard copies of these forms since these individuals do not have access to VSLS.

The Specimen Submission (VS Form 10-4) is typically completed onsite by Federal or State veterinary authorities. This form has been adapted for electronic submission of slaughter and on-farm surveillance samples. (Refer to Appendix D for screenshots of VSLS electronic forms.) Electronic submission is required for APHIS personnel and State personnel with e-Authentication accounts. Hard copies of VS Form 10-4 or worksheets containing the same information (Appendices B-2, 3) are needed when the form is completed in slaughter facilities, on the flock owner's property, or in other outdoor locations where computer access is not available.

The identification requirement allows the use of several devices including electronic eartags. By using the electronic devices, APHIS employs an official animal identification that can be read electronically,

can be listed by a computer, and can be used to facilitate the completion of forms requiring animal identification to be listed, such as the VS Forms 5-29 and 10-4.

A laboratory's request to APHIS to conduct official scrapie tests can be accomplished with a telephone call. (The subsequent documentation supporting the laboratory's request can be submitted to APHIS electronically or in hardcopy.)

The Agreement to Conduct Official Histopathology Examinations for the Diagnosis of Scrapie (VS Form 5-21), a document that is developed only after the laboratory has received APHIS approval to conduct the tests, is a signature-only agreement.

The Application for the Scrapie Flock Certification Program (VS Form 5-22) is pre-printed requiring an original signature from the flock owner. These formal agreements are not candidates for electronic submission.

The Flock Inspection and Epidemiology Report: Initial Flock Inspection for Complete or Export Monitored Status in the SFCP (VS Form 5-19A) requires an original signature from the flock owner and is, therefore, not a candidate for electronic submission.

The Flock Inspection Report: Annual Inspection Report for Scrapie Flock Certification Program Enrolled or Certified Flocks (VS Form 5-19B) requires an original signature from the flock owner and is, therefore, not a candidate for electronic submission.

The owner statement is a hard copy document that identifies the flock of origin of sheep or goats in a shipment. The document must accompany the shipment across State lines and, therefore, is not a candidate for electronic submission.

The agreement to use blue tags is also not a candidate for electronic submission. The agreement requires original signatures.

The report for consignments does not use a standard form and may be submitted by e-mail, fax or regular mail. Submitting this information electronically is not practical based on stakeholder preferences.

Recordkeeping can be accomplished either by maintaining hard copies of records (such as bills of sale and copies of movement permits or certificates) or electronically storing certain information (such as the name and address of the individual from whom an animal was purchased, the animal's sex, year of birth, and breed; date the animal entered the flock, and the animal's final disposition). APHIS encourages recordkeepers to store as much of this information electronically as possible.

Request for identification approval is not a candidate for electronic submission because it requires original signatures to be valid.

The agreement to send official eartags to specified individuals is not a candidate for electronic submission because it requires original signatures to be valid.

The Monthly Report of Official Identification Devices Produced is currently submitted by CD, e-mail, or hard copy. APHIS is in the process of revising 9 CFR to remove this requirement since the information can now be obtained from an APHIS database.

Data entry of official identification devices produced is done through an APHIS Web site and stored in an APHIS database.

Request for approval of new device type requires an original signature and is, therefore, not a candidate for electronic submission.

The Herd Owner Notification (provided by State or Federal personnel to the flock owner as a means of notifying the owner that he/she has or may have had a scrapie-positive or scrapie-exposed animal in his/her flock) is a hard copy document requiring an original signature by the veterinary medical officer providing the notification. While this notification is frequently less formal (via fax, telephone, or e-mail), a signed hard copy is also sent to document that the flock owner received the notification.

The Permit for Movement of Restricted Animals (VS Form 1-27) to move scrapie exposed or other high risk animals across State lines must contain original signatures from various personnel involved in the movement at both the point of origin and the point of destination, and must accompany the shipment. This form is not a candidate for electronic submission.

The CVI (VS Form 17-140), which authorizes the movement of breeding animals in interstate commerce, may be completed and submitted electronically. This form can be submitted through the Veterinary Services Process Streamlining database, which has an electronic CVI.

Information contained in the Consistent State Application (VS Form 5-24) is currently submitted to APHIS in hard copy by the States. This form is not a candidate for electronic submission since it requires original signatures.

The application for identification numbers and application for premises identification can be made to APHIS via a telephone call, e-mail, mail or fax. These requests are then processed through an APHIS Web site and stored in an APHIS database.

Recordkeeping for identification can be accomplished either by maintaining a hard copy or an electronic record of official identification applied to sheep or goats. APHIS encourages recordkeepers to store as much of this information electronically as possible.

The workplan, the financial plan, and quarterly reports associated with cooperative agreements are also not candidates for electronic submission. They are submitted with other forms that require original signature.

The MOUs are hard copy documents requiring original signatures of State and Federal personnel to be valid. They are not candidates for electronic submission.

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

The information that APHIS will be collecting in connection with this program is not available from any other source. APHIS is the only Federal Agency responsible for controlling the interstate spread of domestic animal diseases. Some information APHIS is requesting is already being recorded by flock owners as part of routine business practices. This program, however, requires flock owners to engage in a number of additional activities before moving their animals interstate and that certain information be maintained for 5 to 7 years after an animal dies or is sold.

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

APHIS estimates that 99 percent of the respondents in this information collection are small businesses. Only the information needed to conduct a successful program is being collected. APHIS minimizes the burden on flock owners by having its own personnel complete as many of the required forms as possible, with occasional input from the owners when necessary.

6. Describe the consequence 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.

If the information was collected less frequently or not collected, APHIS efforts to more aggressively prevent the spread of scrapie would be severely hindered. APHIS would be unable to fulfill its mission of eradicating this economically damaging disease from the United States.

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 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;**

Certain records must be maintained for a minimum of 5 years after the death of an animal or the sale of an animal from the flock. In some cases, records need to be kept for more than 5 years. This is because of the 2- to 5-year incubation period of scrapie; the disease may not appear in a live animal until 5 years or longer after the death or departure of a transmitting animal, but would still have to be traced to that transmitting animal. Keeping records for long periods of time enable animal health officials to trace infected animals. Moreover, the international standard for SFCP is 7 year.

- **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.**

There are no other special circumstances associated with this information collection 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 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 2011, APHIS engaged in productive consultations with the following individuals concerning the information collection activities with this program:

Tom Johnson, DVM
 American Association of Small Ruminant Practitioners
 P.O. Box 3614
 Montgomery, AL 36109
 515-306-1129

Mr. Paul Rodgers
 American Sheep Industry Association
 Route 2, Box 94
 Ronceverte, WV 24970
 (304) 647-9981

Mr. Tom Boyer
 American Goat Federation
 2200 Chalk Creek

Coalville, UT 84017
(801) 376-4685

On Thursday, July 21, 2011, pages 43649 -43650, APHIS published in the Federal Register, a 60- day notice seeking public comments on APHIS' plans to request a 3-year extension of this collection of information. During that time APHIS received no comments.

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

This information collection activity involves no payments or gifts to respondents.

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

No additional assurance of confidentiality is provided with this information collection. Any and all information obtained in this collection shall not be disclosed except in accordance with 5 U.S.C.552a.

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.

This information collection activity will ask no questions of a personal or sensitive nature.

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-I.**

See APHIS Form 71. Burden estimates were developed from discussions with flock owners; livestock market owners, operators, or managers; dealers; slaughter plant owners, operators, or managers; feedlot owners, operators, or managers; managers of producer organizations; tag manufacturers; accredited veterinarians; and State and Federal animal health officials.

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

Respondents are flock owners; livestock market owners, operators, or managers; dealers; slaughter plant owners, operators, or managers; feedlot owners, operators, or managers; managers of producer

organizations; tag manufacturers; accredited veterinarians; and State and Federal animal health officials. APHIS estimates the total annual cost to these respondents to be \$30,131,237.70. APHIS arrived at this figure by multiplying the hours of estimated response time (897,030 hours) by the estimated average hourly wage of the above respondents (\$33.59).

Flock owners: \$20.53 [11-9012 Farmers and Ranchers]

Market owners, operators, or managers: \$31.13 [11-9011 Farm, Ranch, and Other Agricultural Managers]

Dealers: \$30.02 [13-1021 Purchasing Agents and Buyers, Farm Products]

Slaughter plant owners, operators, or managers: \$31.13 [11-9011 Farm, Ranch, and Other Agricultural Managers]

Feedlot owners, operators, or managers: \$31.13 [11-9011 Farm, Ranch, and Other Agricultural Managers]

Managers of producer organizations: \$49.47 [11-0000 Management Occupations]

Tag manufacturers: \$16.01 [51-0000 Production Occupations (Major Group)]

Accredited veterinarians: \$43.32 [29-1131 Veterinarians]

State animal health authorities: \$49.47 [11-0000 Management Occupations]

The average hourly rate is derived from the U.S. Department of Labor; Bureau of Labor Statistics May 2009 Report – National Occupational Employment and Wage Estimates United States. See [http://www.bls.gov/oes/#tables.](http://www.bls.gov/oes/#tables)]

13. Provide estimates of the total annual cost burden to respondents or recordkeepers resulting from the collection of information (do not include the cost of any hour 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.

No annual cost burden is associated with capital and startup costs, operation and maintenance expenditures, or purchase of services.

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.

Annual cost to the Federal Government is estimated at \$1,092,621.03. (See APHIS Form 79.)

15. Explain the reasons for any program changes or adjustments reported in Items 13 or 14 of the OMB Form 83-1.

ICR Summary of Burden:

	Requested	Program Change Due to New Statute	Program Change Due to Agency Discretion	Change Due to Adjustment in Agency Estimate	Change Due to Potential Violation of the PRA	Previously Approved
Responses	737,472	0	127,195	0	0	610,277
Annual Time Burden (Hr)	896,780	0	224,147	0	0	672,633
Annual Cost Burden (\$)	0	0	0	0	0	

The Agreement to Use Blue Tags, the Report for Consignments when Identification is Applied, Written Agreement Certification, Flock Plan, Post Exposure Management and Monitoring Plan, and Record Keeping associated with the Plans are new to this collection causing a **program change** of +2,083 additional respondents +127,195 responses resulting in +224,147 burden hours.

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

APHIS routinely publishes summary information in monthly and yearly reports at http://www.aphis.usda.gov/animal_health/animal_diseases/scrapie/. This information may also be published in newsletters or scientific journals. APHIS also presents summary information at various scientific and industry meetings that is occasionally published in a meeting compendium or posted by the meeting sponsor on the Web. Additionally, APHIS posts information at the above site listing the status in the program of participants in the SFCP and listing noncompliant flocks as described in 9 CFR 54.21.

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.

VS Form 1-23, VS 1-23A, 1-27, 10-4 and 17-140 are used in multiple collections; therefore, it is not practical to include an OMB expiration date because of the various expiration dates for each collection. APHIS is seeking approval to not display the OMB expiration date on these forms.

APHIS has no plans to seek approval for not displaying the OMB expiration date on the remaining forms.

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

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

B. Collections of Information Employing Statistical Methods

Statistical methods are not used in this information collection.