

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

June 25, 2007

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.

Under the Farm Security and Rural Investment Act of 2002, PL 107-71, subtitle E, Animal Health Protection, Section 10401-10418, the Secretary of Agriculture, in order to protect the agriculture, environment, economy, and health and welfare of the people of the United States by preventing, detecting, controlling, and eradicating diseases and pests of animals, is authorized to cooperate with foreign countries, States, and other jurisdictions, or other persons, to prevent and eliminate burdens on interstate commerce and foreign commerce, and to regulate effectively interstate commerce and foreign commerce. This authority permits the Secretary to prevent, control, and eliminate domestic diseases such as Scrapie and brucellosis, as well as to take actions to prevent and to manage exotic diseases such as classical swine fever, African swine fever, and foot-and-mouth disease.

More specifically, the act authorizes the Secretary of Agriculture to take such measures as he/she may deem proper to prevent the introduction or dissemination of any contagious or communicable disease of animals or live poultry from a foreign country into the United States or from one State to another. Disease prevention is the most effective method for maintaining a healthy animal population and enhancing the ability of the United States to compete in the world market of animal and animal product trade. Veterinary Services (VS) of U.S. Department of Agriculture's (USDA) Animal and Plant Health Inspection Service (APHIS) is responsible for carrying out this disease prevention mission.

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 without clinical signs of disease and because there is no test that can detect the disease early in the incubation period and no known 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 regulations are found in part 54.

APHIS interstate movement requirements are designed to minimize any contact between high-risk animals and healthy animals, while the animal identification requirements help with traceback investigations conducted as a result of a Scrapie outbreak. APHIS indemnity program is designed to encourage more flock owners to report any signs of Scrapie in their flocks.

These regulations necessitate the use of a number of information collection activities, including the completion of applications to participate in the Scrapie Flock Certification Program (SFCP)

and to advance to certified status within the program; the creation of Post Exposure Management and Monitoring Plans (PEMMP); the completion of Scrapie test records and applications for indemnity payments; the completion of certificates, permits, and owner statements that allow for the interstate movement of certain sheep and goats; the completion of applications for premises identification numbers; and the application of APHIS-approved ear tags, back tags, or tattoos bearing either official USDA serial numbers or the identification number of the premises from which the animals originate.

To facilitate information gathering related to inspection and epidemiology, APHIS will replace an existing form with four new forms. The four new forms will allow APHIS to differentiate inspection and epidemiology information specific to different flock statuses. These forms will allow more space for collecting information and more clearly differentiate the information being collected for each type of inspection.

APHIS is asking the Office of Management and Budget (OMB) to (1) approve its use of these information collection activities for an additional 3 years; and (2) amend the information collection OMB No. 0579-0101 to include the use of 4 new forms in connection with APHIS' efforts to contain and eventually eradicate Scrapie in the United States.

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.

Cooperative Agreement Forms Family – SF-424, SF-424A, SF 424B, SF LLL

The Cooperative Agreement is a written commitment between APHIS and the animal health agency of a State to cooperatively administer the Scrapie Eradication Program and or the SFCP. These agreements describe the respective roles of APHIS and State personnel in implementing the Scrapie Eradication Program and or the SFCP. 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 and APHIS; assign specific activities related to the control of Scrapie within a State to APHIS or State personnel; establish schedules for APHIS or State representatives to visit flocks; establish procedures for maintaining and sharing program records; and specify other responsibilities of State and APHIS representatives in support of the Scrapie Eradication Program and the SFCP. Cooperative agreements include the transfer of funds or materials to the cooperator. The cooperative agreements specify the activities but do not identify the forms associated with the activities. Cooperative agreements for the Scrapie program are shown in table 1 below.

NOTE: The Workplan and Financial Plan are discussed at the end of Q. 2.

Memorandums of Understanding Forms Family

The Memorandum of Understanding is a written commitment between APHIS and the animal health agency of a State to cooperatively administer the Scrapie Eradication Program and or the SFCP. Memorandums of Understanding do not involve the transfer of funds. For more details for this activity, see the explanation provided above for cooperative agreements. Memorandums of Understanding for the Scrapie program are shown in table 1 below.

Table 1. Cooperative Agreements and Memorandums of Understanding for the Scrapie Program.

Region	State	Type		Expires	Number
		MOU	CA		
HQ	N/A		ASI	12/31/07	07-9100-0914-CA
WR	CO		Col Dept of Ag	12/31/07	07-9708-1794-CA
ER	CT		CT Dept of Ag	12/31/07	07-9609-0177CA
ER	GA		GA Dept of Ag	12/31/07	07-9613-0180CA
WR	IA		IA Dept of Ag and Land Stewardship	12/31/07	07-9719-1502-CA (Continuation)
WR	ID		ID State Dept of Ag	12/31/07	07-9716-1728-CA
ER	IL		IL Dept of Ag	12/31/07	07-9617-0248CA
ER	IN		IN Bd of An Hlth	12/31/07	07-9618-0039-CA
ER	MA		MA Dept of Ag	12/31/07	07-9625-0694-CA
ER	ME		ME Dept of Ag	12/31/07	07-9623-0656-CA
WR	MO		Missouri Dept of Agr.	12/31/07	07-9729-1803-CA (Continuation)
ER	MN		MN Bd of An Hlth	12/31/07	07-9627-0034-CA
ER	MS		MS Bd of An Hlth	12/31/07	07-9626-0244-CA
WR	MT		Mt. Dept of Livestock	12/31/07	07-9730-1810-CA (Continuation)
WR	ND		ND Sate Board of Animal Health	12/31/07	07-9738-1490-CA
WR	NE		NE Dept. of Agriculture	12/31/07	07-9731-1458-CA
WR	NM		New Mexico Livestock Board	12/31/07	07-9735-1796-CA
ER	NH		NH Dpt of Ag	12/31/07	07-9633-0670-CA
ER	OH		OH Dpt of Ag	12/31/07	07-9639-0266-CA
WR	SD		SD Animal Industry Board	12/31/07	07-9746-1807-CA (Continuation)
ER	TN		TN Dpt of Ag	12/31/07	07-9647-0691-CA
WR	TX		TX Animal Health Commision	12/31/07	07-9748-1759-CA
HQ	N/A		U of MN	12/15/07	05-9117-0911-CA
HQ	N/A		U of PA - MRI	12/20/07	05-9142-1001-CA
ER	VA		VA Dpt of Ag	?	07-9651-0191-CA
ER	VT		VT Ag of Ag	12/31/07	07-9650-0142-CA
ER	WV		WV Dpt of Ag	12/31/00	07-9654-0272-CA
WR	AK	CS		2/6/11	06-9702-0021-MU
WR	AR	CS		8/21/11	07-9705-0033-MU

Region	State	Type	Expires	Number
		MOU CA		
WR	AZ	CS	12/13/11	07-9704-0035-MU
ER	CT	CS	11/3/11	07-9609-0873MU
ER	FL	CS	7/5/11	06-9612-0316-MU
ER	GA	CS	7/1/10	05-9613-0288MU
ER	GA	PP	8/30/07	02-9113-0726-MU
WR	HI	CS	2/13/11	06-9715-0022-MU
WR	IA	CS	12/13/11	07-9719-0032-MU
WR	ID	CS	1/4/12	07-9716-0038-MU
ER	IL	CS	1/10/12	07-9617-0727-MU
ER	IN	CS	7/5/10	Unknown
WR	KS	CS	2/27/12	07-9120-0041-MU
ER	KY	CS	11/3/11	07-9621-0874-MU
ER	MA	CS	2/14/12	07-9625-0890-MU
ER	ME	CS	11/3/11	07-9623-0894-MU
ER	MN	CS	9/14/11	06-9627-0796-MU
ER	MS	CS	9/14/11	06-9628-0795-MU
WR	MT	CS	3/27/12	07-9730-0045-MU
ER	NC	CS	10/4/11	07-9637-0750-MU
WR	ND	CS	7/27/10	05-9738-0013-MU
WR	NE	CS	2/12/12	07-4731-0040-MU
ER	NH	CS	6/12/12	07-9633-0692-MU
ER	NJ	CS	10/4/11	07-9634-0026-MU
WR	NM	CS	3/27/12	07-9735-0044-MU
ER	OH	CS	5/24/11	06-9639-0028-MU
WR	OR	CS	11/15/11	07-9741-0031-MU
WR	SD	CS	11/15/11	07-9746-0030-MU
ER	TN	CS	3/30/12	07-9647-0766-MU
WR	TX	CS	4/3/12	07-9748-0046-MU
WR	TX	PP	7/7/07	02-9148-0719-MU
WR	UT	CS	3/27/11	06-9749-0025-MU
ER	VA	CS	2/2/11	06-9651-0781-MU
ER	VT	CS	6/14/12	07-9650-0776-MU
WR	WA	CS	3/13/11	06-9753-0023-MU
ER	WI	CS	2/8/12	07-9655-0763-MU
ER	WV	CS	2/1/11	06-9654-0782-MU
WR	WY	CS	9/13/07	02-9756-0331-MU

(CA = Cooperative Agreement; CS = Consistent State; ER = Eastern Region; HQ = Headquarters; MOU = Memorandum of Understanding; PP = Pilot Project; WR = Western Region)

Request for Information; Record of Animals Moved (VS Form 5-18)
Record of Animals Acquired (VS Form 5-18A) NEW
Flock Inspection and Epidemiology Report (VS 5-19)
Scrapie Epidemiology Report (VS 5-19D) NEW
Individual Animal Report (VS 5-20) NEW

When a flock owner applies for indemnity payments, APHIS may ask the owner to supply it with certain 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. There are times State representatives will complete these forms on behalf of USDA for businesses or farms. This data could prove extremely critical to APHIS during any traceback investigation APHIS may need to conduct in response to an adverse disease event.

With regard to VS 5-19, which records critical information on flock inspection and epidemiology, APHIS has created four different forms to target information based on the status of the flock and the activity being conducted. The VS 5-19, Flock Inspection and Epidemiology Report, collected data from all flocks regardless of status. However, not all information contained on the VS 5-19 applies to each status. Therefore, APHIS developed 4 forms to focus the requested information on the status of the flock and the activity being conducted.

Three of the new forms (5-19A, B, and C) are discussed separately from the 5-19D as the information collected on these forms is not required under 9 CFR 54.3(b) as a prerequisite for receiving indemnity.

This subdivision of the requested information will enable APHIS to better evaluate the data and provide respondents more space in which to record the requested relevant information. After the current inventory of VS 5-19 is depleted, APHIS will discontinue use of this form.

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

An APHIS or State representative will fill out the application for indemnification for the owner. The owner will then confirm the information that is in 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 contain certain information that in the case of known infected flocks has already been collected by APHIS as part of the request for 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. Providing all flock owners with an opportunity to receive indemnity payments will encourage these individuals to report incidents of Scrapie in their animals. This will ultimately hasten the eradication of Scrapie from the United States.

Written Agreement/Certification (signature only)

Before APHIS makes an indemnification payment to a flock owner, the owner must sign a written agreement certifying that he/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 that the owner 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.

This agreement/certification serves as 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) NEW

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

Flock Plan (signature only) NEW

A written flock management agreement is signed by the owner of a flock; the accredited veterinarian, if employed by the owner; and a State or APHIS representative. Each participant agrees to undertake actions specified in the flock plan to control the spread of Scrapie. These actions include identifying animals, collection of tissues, availability of records, monitoring for Scrapie, and alerting an APHIS or State representative of any signs of possible Scrapie infection.

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

This is an agreement between the flock owner, an accredited veterinarian, and an APHIS and or State 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 begin exhibiting signs of possible Scrapie infection.

Creating these agreements with flock owners who are coping with a Scrapie situation in their flock ensures that these flocks will continue to be closely monitored and controlled until 5 years after all signs of Scrapie have disappeared.

Report Suspect Animals

Accredited veterinarians or flock owners must immediately report via a telephone call, fax, or email any animals that appear to be infected. State representatives may also receive this report from businesses or farms and transmit it to APHIS. These reports alert State or APHIS veterinary medical officers concerning the presence of any animals with Scrapie-like signs. At an appropriate time, the infected animal is sacrificed to collect tissue specimens for confirmation of the Scrapie diagnosis.

Scrapie PEMMP Inspection Report (VS 5-19C) NEW

During or after an inspection, a veterinary medical officer completes the VS 5-19C, a new form, to record data on flocks inspected for the PEMMP. The data is obtained by asking the flock owners questions and through examination of the records. The flock owners are asked about signs of disease, compliance with identification requirements, and records. State representatives may also complete this report for businesses or farms.

Recordkeeping for Plans

For flock plans and PEMMP modifications, records for acquired animals and animals leaving the premises must be maintained by the flock owner for 5 years. These records would be invaluable if the flock becomes infected and a trace investigation becomes necessary.

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

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;

the identification number, age, breed, and sex of each animal tested; and the test type being conducted. This form is completed by an APHIS, State, or accredited veterinarian, with assistance from the flock owner.

Specimen Submission (VS Form 10-4) NEW

This form is used to record information on specimens from dead animals submitted for Scrapie testing to an approved laboratory. This form is completed by a State or APHIS representative or an accredited veterinarian and is critical for identifying affected and source flocks or for releasing exposed flock status. Information is usually provided by farms or businesses to allow completion of the form.

Request for Laboratory Approval NEW

State or other diagnostic laboratory directors may voluntarily 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 email 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 Laboratory (NVSL).

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) (Signature Only)

After the State or university diagnostic laboratory director requests approval of the laboratory (as discussed above under Request for Laboratory Approval), the AVIC will have the laboratory inspected to determine that it has the proper physical facilities and equipment. The AVIC will review the laboratory's responsibilities (both regulatory and technical) with laboratory officials. The laboratory director will then sign VS 5-21. Once the laboratory has one or more of its pathologists trained at NVSL, the laboratory will be approved as an official laboratory by NVSL.

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 abide by the provisions of the program. This pre-printed form requires that the flock owner fill in his/her name and address, the location of the owner's flocks, and the number of animals in each flock.

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

Flock owners assist the State or Federal employee in completing VS 5-19A. This new form records data previously requested on the VS 5-19 on the initial flock inspection for complete monitored status in the SFCP. Flock owners must keep these records for 7 years.

Flock Inspection and Epidemiology Report Flock Inspection for Complete Monitored Status in the SFCP (VS Form 5-19B) NEW and Recordkeeping.

Flock owners assist the State or Federal employee in completing the VS 5-19B. This new form records data previously requested on the VS 5-19 for subsequent SFCP inspections. 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 APHIS, if necessary, to trace any or all of these animals back to their flock of origin. The owner statement is simply a written statement by the flock owner that includes 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 that will prove invaluable during a traceback investigation.

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. These individuals 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 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 traceback investigation.

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 assigned by a State or Federal animal health official to the premises on which the sheep or goats originated. In most cases, obtaining and applying these premises identification numbers, which could be used in lieu of official USDA serial numbers, is the responsibility of flock owners.

These premises identification numbers provide APHIS with a means of more effectively monitoring sheep and goats moving in interstate commerce and would provide APHIS personnel with critical information if a traceback investigation is necessary.

Recordkeeping, Identification

Individuals 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 traceback investigation.

Recordkeeping, Animals Moved in Interstate Commerce

Flock owners must maintain certain records on each animal for at least 5 years after the animal is moved and make these records available for inspection by an authorized USDA or State employee. These records would be invaluable if an exposed or infected animal needs to be located. 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.)

Request for Approval To Produce Official Identification Devices NEW

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 to a State or APHIS representative, to a flock owner that APHIS or a State representative assigned a premises number or tag sequence, 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 in the process of replacing the monthly report with an automated report.) (Note: Most of the data entry is paid for under contract by USDA.)

Data Entry of Official Identification Devices Produced NEW

Tag manufacturers enter the sequences of tags shipped into the National Scrapie Database through a Web page interface or other means.

Request for Approval of New Device Type NEW

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 of approved means of sheep and goat identification.

Herd Owner Notification (No response required)

When an APHIS or State representative determines that a Scrapie issue exists in a flock, the 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 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.

Permit For Movement of Restricted Animals (VS Form 1-27; cleared under 0579-0051)

Permits are issued by APHIS or State personnel or accredited veterinarians authorized to issue such 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 points of an animal's origin and destination, 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 17-140 or Equivalent)

A flock owner wishing to move breeding animals interstate other than for slaughter must be issued a certificate. Since these animals are not deemed to be exposed or infected, the certificate can be issued by any accredited veterinarian. The flock owner assists the accredited veterinarian in completing the certificate by making 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 this certificate requires examination of the animals for clinical signs of Scrapie and provides APHIS with important information if a traceback investigation must be conducted.

Consistent State Application (VS Form 5-24)

States wishing to be classified as having effective Scrapie management programs (and are therefore subject to less stringent Federal interstate movement restrictions) must submit to APHIS an application describing the Scrapie management practices they are implementing. A critical component of any Scrapie management plan is that the State require its flock owners to permanently identify (with an official, permanent identification device or marking) all Scrapie-positive, -exposed, or -suspect animals, with the exception of those animals under 6 months of age moving within slaughter channels.

Workplan Associated with Cooperative Agreement

The Workplan accompanies the Cooperative Agreements used in the 37 States and not-for-profit institutions.

Financial Plan Associated with Cooperative Agreement

The Financial Plan accompanies the Cooperative Agreements used in the 37 States and not-for-profit institutions.

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.

The Cooperative Agreement and Memorandum of Understanding are hard copy documents requiring original signatures of State and Federal personnel to be valid.

The request for information (VS Forms 5-18, 5-19, 5-19D, and 5-20) contains 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 1-23) is completed for and signed by flock owners whose sheep are being destroyed because of exposure to Scrapie. The VS 1-23 is also used as a Report to Identify Animals and Their Disposition. This report is prepared by a State or APHIS representative with assistance from the flock owner. This report, containing original signatures of the flock owner and the supervising veterinarians, serves as the official written record that a specific number of animals in the owner's flock have been destroyed because of Scrapie. This form is not a candidate for electronic submission because it requires original signatures to be valid.

The Written Agreement/Certification by Owners are hard copy agreements requiring an original signature by the flock owner to be valid. They are therefore not candidates for electronic submission.

The Proceeds from Animals Sold for Slaughter, VS 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. They are therefore not candidates 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 therefore 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 5-19C) requires an original signature by the flock owner and is therefore not a candidate for electronic submission.

The Scrapie Test Record (VS 5-29) and its Continuation Sheet (VS 5-29A) are completed onsite by Federal or State veterinary authorities, with assistance from the flock owner. This form has been adapted for electronic use. However, the form is completed on the flock owner's property or other outdoor locations where computer access may not be readily available, requiring the use of some hard copies of the VS Forms 29 and 29A.

The Specimen Submission (VS 10-4) is completed onsite by Federal or State veterinary authorities. This form has been adapted for electronic use for slaughter surveillance samples and conversion for other sample types is planned. However, the form is completed at slaughter facilities, on the flock owner's property or other outdoor locations where computer access may not be readily available, requiring the use of some hard copies of the VS 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 hard copy.) The Agreement to Conduct Official Histopathology Examinations for the Diagnosis of Scrapie (VS 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 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 Monitored Status in the SFCP (VS 5-19A) requires an original signature from the flock owner and is therefore not a candidate for electronic submission.

The Flock Inspection and Epidemiology Report Flock Inspection for Complete Monitored Status in the SFCP (VS 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 a shipment's flock of origin and must physically accompany the shipment of sheep or goats across State lines. This document is not a candidate for electronic submission.

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 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, email or hardcopy. APHIS is in the process of automating the report to be run of an APHIS database.

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

The Identification Requirement allows the use of several devices and 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.

The Herd Owner Notification (provided by State or Federal personnel to the flock owner as a means of notifying the owner that a Scrapie issue exists in the owner's flock) is a hard copy document requiring an original signature by the veterinary medical officer providing the

notification. While this notification can occur less formally (via fax, telephone, or e-mail), a signed hard copy must be received by the flock owner for the notification to be official.

The Permit For Movement of Restricted Animals (VS 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 therefore physically accompany the shipment.

The Certificate issued by a State or Federal representative to authorize the movement of breeding animals is currently a hard copy document. However, VS is currently working on converting this certificate to an electronic format. APHIS anticipates this will be accomplished before the end of 2007.

Information contained in the Consistent State Application (VS 5-24) is currently submitted to APHIS in hard copy by the States. This form is a candidate for electronic submission, but is not yet available in electronic format.

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.

It should be noted that some of the information APHIS is requesting is already being recorded by flock owners as part of their routine business practices. This program, however, requires flock owners to engage in a number of additional information generating activities prior to moving their animals interstate and requires that certain information be maintained for 5 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.

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 owner when necessary. APHIS has no small entities involved with this information collection.

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.

There are no special circumstances requiring that the collection of information be conducted in a manner inconsistent with the guidelines established in 5 CFR 1320.5, except that certain records must be maintained for a minimum of 5 years following the death of an animal or the sale of an animal from the flock. This is because of the extremely long incubation period of Scrapie (typically 2 to 5 years).

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 2007, APHIS engaged in productive consultations with the following individuals concerning the information collection activities with this program:

Leo Tammi
American Polypay Sheep Association
Route 1, Box 274-A
Mt. Sidney, VA 24467
(540) 234-8526

Dr. John Glenn
American Association of Small Ruminant Practitioners
University of California, Veterinary Medicine Extension
1383 Surge 3
Davis, CA 95616
(530) 752-6892

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

On November 21, 2007, APHIS published in the *Federal Register*, a 60-day notice seeking public comments on its plans to request a 3 year renewal of this collection of information. APHIS received 1 comment, but it did not pertain to paperwork.

9. Explain any decision to provide any payment or gift to respondents, other than reenumeration 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. However, the confidentiality of information is protected under 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 operators, State and Federal animal health officials, and accredited veterinarians.

•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, market operators, dealers, tag manufacturers, accredited veterinarians, and State animal health authorities. APHIS estimates the total annual cost to these respondents to be \$11,518,952.06. APHIS arrived at this figure by multiplying the hours of estimated response time (670,485) by the estimated average hourly wage of the above respondents (\$17.18).

The hourly rate of \$17.18 is from the U.S. Department of Labor, Bureau of Labor Statistics June 2003 Report - National Compensation Survey: Occupational Wages in the United States, July 2002. See <http://www.bls.gov/ncs/ocs/sp/ncl0539.pdf>.

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.

There is zero annual cost burden associated with capital and start-up, operation and maintenance, and 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 \$958,303.63. (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.

There was a program change of +22,086 and an adjustment of +565,396. This increase occurred because APHIS adjusted the burden hours in several activities to more accurately reflect the estimated time required to complete the activity. Further, APHIS amended the collection to more accurately show the activities of the program. The reason for the increase is due to the inclusion of the recordkeeping required for the program's activities. These changes in activities include the addition of 4 new forms covering identification and indemnity and the removal of 1 form (Application for Advancement to Certified Status, VS Form 5-23).

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. 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.

If forms were to be discarded because of an outdated OMB expiration date, but otherwise usable, higher printing costs would be incurred by the Federal Government. Therefore, APHIS is seeking approval to not display the OMB expiration date on its 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.