

Animal and Plant Health Inspection Service

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Voluntary Scrapie Flock Certification Program Standards

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Introduction

The Voluntary Scrapie Flock Certification Program is designed to monitor flocks and certify the scrapie status of the animals enrolled in the Program. Any sheep or goat owner or manager may apply to participate in the Voluntary Scrapie Flock Certification Program.

This document outlines the Voluntary Scrapie Flock Certification Program Standards and was approved by the Deputy Administrator of the U.S. Department of Agriculture (USDA), Animal and Plant Health Inspection Service, (APHIS) Veterinary Services (VS) on April 27, 1999.

Part I—Definitions

The following definitions cover the Voluntary Scrapie Flock Certification Program Standards but are superseded by any definitions pertaining to scrapie that are published in Title 9, Code of Federal Regulations (CFR), Parts 54 and 79.

Accredited veterinarian A veterinarian approved by the Administrator of APHIS, USDA, in accordance with

Title 9, CFR, Part 161, to perform functions required by cooperative State-Federal

animal disease-control and -eradication programs

Administrator The Administrator of APHIS, USDA, or any other official to whom the Administrator

has delegated authority to act in his or her stead

Animal Any sheep or goat

APHIS The Animal and Plant Health Inspection Service, U.S. Department of Agriculture

APHIS representative An individual employed by APHIS in animal health activities and authorized by the

Administrator to perform Voluntary Scrapie Flock Certification Program duties

Area Veterinarian-in-Charge (AVIC)

The veterinary official of VS, APHIS, USDA, assigned by the Administrator to super-

vise and perform official animal health work in a State(s)

Board The State Scrapie Certification Board

Breed associations and

registries

Organizations which maintain the permanent records of ancestry or pedigrees of animals (including the animal's sire and dam) and individual identification and owner-

ship of animals

Certified flock A Complete Monitored category flock that has been participating in the Program and

has met the provisions of part III for 5 years or more

Commingling Animals grouped together having physical contact. Commingling does not include

limited contacts (see this item later in these definitions). An example of commingling includes concurrently sharing the same section in a transportation unit where there is

uninhibited physical contact.

Deputy Administrator The Deputy Administrator for VS, APHIS, USDA, or any other official to whom the

Deputy Administrator has delegated authority to act in his or her stead

Enrolled flock A Complete Monitored category flock that has been participating in the Program but

has not yet met the criteria for certified status

Enrollment date The date on which the State Scrapie Certification Board gave final approval for initial

Program participation

Exposed animalAny animal that has been in the same flock at the same time within the previous 60

months as a scrapie-positive animal, excluding limited contacts

Exposed flock

A flock that had contained, within the previous 60 months, an animal that was later confirmed as scrapie positive in another flock. The flock in which the scrapie-positive animal resided will be classified as exposed until the diagnostic sampling requirements of part III.A.4 for Complete Monitored flocks and III.B.6 for Selective Monitored flocks have been met.

Flock category

Classification of a flock with regard to scrapie or the Voluntary Scrapie Flock Certification Program. The possible categories include

- Complete Monitored (Enrolled, Certified),
- Selective Monitored (Select),
- Exposed,
- Infected,
- · Source, and
- Trace.

Flock or Herd

All animals maintained on a single premises that are commingled and all animals under common ownership or supervision on two or more premises with animal interchange between the premises. Two flocks may be maintained on a single premises if they

- Are kept at least 30 feet apart by a double fence at all times while on the premises:
- Have flock records and identification that are separate;
- Have separate lambing or kidding facilities, including buildings and pastures (e.g., if lambing or kidding occurs on a pasture-type situation, the pasture used for lambing or kidding by one flock may not be used by the other flock at any time);
- Do not share equipment between the flocks without prior cleaning and disinfection (see appendix 2).

This document will use the term "flock" in reference to groups of animals.

High-risk animal

An animal which is (1) the progeny of a scrapie-positive dam; (2) born in the same flock during the same lambing or kidding season as progeny of a scrapie-positive dam, unless the progeny of the scrapie-positive dam are from separate contemporary lambing or kidding groups (groups that are managed as separate units and are not commingled during lambing or kidding and for 60 days following the date the last lamb was born, and that do not use the same lambing or kidding facility unless it is cleaned and disinfected between lambing or kidding in accordance with the guidelines in appendix 2; or (3) born during the same lambing or kidding season as a scrapie-positive animal in a source or trace flock

Infected flock

Any flock in which an APHIS representative or State animal health official has determined an animal to be positive for scrapie, as defined in Title 9, CFR, Part 79. A flock will no longer be considered an infected flock after it has completed the requirements of that CFR section.

Limited contact

Incidental contacts between animals off the flock's premises such as at fairs, shows, exhibitions and sales; between female animals being inseminated, flushed, or implanted; or between male animals at test or collection stations. Embryo transfer and artificial insemination equipment and surgical tools must be sterilized between animals for such contact to be considered limited. Limited contact does not include any contact with an animal during, or up to 60 days after, lambing or kidding. Limited contact does not include any activity where uninhibited contact occurs, such as sharing an enclosure, sharing a section of a transport vehicle, or residing on the premises of another flock for breeding except as allowed by the Scrapie Flock Certification Program Standards.

National Scrapie Oversight Committee

A national committee composed of industry, State, and Federal representatives that gives guidance to APHIS on the policies and practices of the Voluntary Scrapie Flock Certification Program

Nonparticipating flock

A flock that is not enrolled in the Voluntary Scrapie Flock Certification Program

Official identification

A unique individual identification that meets the following criteria:

- · Permanent,
- Secure.
- Capable of carrying unique numbers from a central repository, and
- Traceable

The following types of identification are approved for the Voluntary Scrapie Flock Certification Program:

- Tamper-resistant ear tag approved by APHIS for use in the Voluntary Scrapie Flock Certification Program,
- Flank or ear tattoo, and
- Electronic identification.

In the case of goats registered with the American Dairy Goat Association, the tattoo may be applied at the tail web.

Official laboratory

A laboratory designated by a State and approved by the Administrator to perform the Program-required scrapie diagnostic procedures. The National Veterinary Services Laboratories, APHIS, USDA, Ames, IA, is the reference laboratory for diagnostic procedures.

Owner

An individual, partnership, company, corporation, or other legal entity that has legal or rightful title to a flock of animals, regardless of any liens held on the animals or flock

Premises

The ground, area, buildings, and equipment occupied by one or more flocks of animals

Program

The Voluntary Scrapie Flock Certification Program

Scrapie

A nonfebrile, transmissible, insidious degenerative disease affecting the central nervous system of sheep and goats. Scrapie, a transmissible spongiform encephalopathy, may cause, but is not limited to causing, the following signs in affected animals:

- · Weight loss despite retention of appetite
- · Behavioral abnormalities
- Pruritus (itching)
- Wool pulling
- · Biting at legs or side
- · Lip smacking
- Motor abnormalities, such as incoordination
- High-stepping gait of forelimbs
- · Bunny-hop movement of rear legs
- Blindness
- Swaying of back end
- · Increased sensitivity to noise and sudden movement
- Tremor
- "Star gazing"
- Head pressing
- Recumbency.

It is important to note that not all scrapie-affected animals show all clinical signs.

Scrapie-positive animal

An animal that has had a diagnosis of scrapie confirmed through tests by an official laboratory

Scrapie suspect

An animal that displays clinical signs suggestive of scrapie

Source flock

A flock in which an APHIS representative has determined that at least two animals diagnosed as scrapie positive at an age of 54 months or less were born. In order to be a source flock, the second scrapie-positive diagnosis must be made within 60 months of the first scrapie-positive diagnosis. A flock will no longer be considered a source flock after it has completed the requirements of Title 9, CFR, Part 79.

State animal health official An individual who is employed in animal health activities by a State or a political subdivision of a State and who is authorized by the State or political subdivision to perform Voluntary Scrapie Flock Certification Program duties

Status

The classification of a flock participating in the Complete Monitored category. Enrolled status is given to flocks that are approved to participate in the Complete Monitored category. After the flock has successfully met all Program requirements for 5 continuous years, the flock will be eligible for Certified status.

Status date

Initially, the status date is equivalent to the enrollment date and is issued as the month and year of initial program participation (e.g., April 1998). If the flock continues to meet all Program standards, the status date will not change.

For flocks that acquire animals or commingle with animals that do not meet Program standards under part III, the status date will change to the date (month and year) the nonenrolled animals are acquired or commingled **or** to the status date of the flock with the most recent status date for animals commingled or acquired from an Enrolled flock.

Trace flock

A flock in which an APHIS representative or a State representative has determined that at least one animal was born that was diagnosed as scrapie positive at an age of 54 months or less

Voluntary Scrapie Flock Certification Program

A voluntary State-Federal-Industry cooperative effort established and maintained to:

- Reduce scrapie's occurrence and spread;
- Identify flocks that have been free of evidence of scrapie over specified time periods; and
- · Contribute to the eventual eradication of scrapie

Part II—Administrative Procedures

A. Oversight of the Voluntary Scrapie Flock Certification Program

The National Scrapie Oversight Committee will be appointed by APHIS from recommendations made by the following groups:

Animal producers,

Allied industry,

APHIS,

State animal health officials,

Accredited veterinarians, and

Animal breed registries and associations.

Priority for committee membership will be given to producers enrolled in the Program. The committee reviews the Voluntary Scrapie Flock Certification Program and makes individual recommendations to the Deputy Administrator regarding policy and technical improvements in the Certification Program.

The committee will meet at least once a year, consult with scientific and technical experts, consider Program improvement suggestions, and support the Program at national, State, and local sheep or goats events and in the sheep- and goat-producing community.

B. State Scrapie Certification Board

A State Scrapie Certification Board will be formed within each State to

- Administer the Voluntary Scrapie Flock Certification Program,
- Review Program enrollment applications and status advancement,
- Review situations that may result in a reduction of certification status or dismissal from the Program, and
- · Educate producers regarding scrapie.

The State Scrapie Certification Board will consist of APHIS' Area Veterinarian-in-Charge, animal producers, accredited veterinarians, and State animal health officials in cooperating States.

State Certification Boards should

- Be chaired by an enrolled producer,
- Encourage Board members who own sheep or goats to be enrolled in the Program,
- Support the Program at State and local sheep or goat events and in the sheepand goat-producing community, and
- Meet at least annually.

The AVIC, in cooperation with the State animal health official and flock owners, will appoint members to the State Scrapie Certification Board. Boards may delegate their authority to subcommittees and may enact more stringent requirements to fit their State's scrapie situation.

C. Duties of Program Participants

1. APHIS will

- Perform inspections, provide guidance and education, and collect and submit diagnostic samples in accordance with appendix 1, all in cooperation with State animal health agencies and accredited veterinarians; and
- · Maintain a records data base for use in the Program.

2. Producers will

- · Establish and maintain records:
- Make animals and records available for inspection by APHIS representatives or State animal health officials and State Scrapie Certification Board representatives, given reasonable prior notice;
- Authorize access to records maintained by breed associations, registries, livestock markets, and packers;
- Identify animals with official identification as specified by these Program standards;
- Allow State, Federal, or State Scrapie Certification Board representatives to enter premises to carry out Program procedures;
- Have the necessary facilities and personnel available to assist in the inspection of animals and animal records:
- Report scrapie-suspect animals to a State animal health official, APHIS representative, or an accredited veterinarian;
- Ensure that tissue samples are collected and submitted for diagnostic purposes as specified by Program standards; and
- Report acquisitions of lower status or nonparticipating animals in accordance with part III.

3. Breed registries and associations, livestock markets, and packers will

- · Maintain liaison with flock owners;
- Assist in providing flock owners with information on the Voluntary Scrapie Flock Certification Program;
- Facilitate the information exchange regarding transfer of animals; and
- Encourage information reporting between flock owners, State animal health agencies, and APHIS.

D. Application for Program Status

1. Entry into the Program

The State Scrapie Certification Board will review enrollment applications within 60 days of receiving the application package. The status date, for initial flock enrollment, is the date the State Board approves the application for entry into the Program. The application package includes

- · A completed Program application;
- A list of animals in the flock including at least official identification numbers, breed, and sex information as specified by the certification category applied for;
- A statement by an accredited veterinarian (if available) or a State or APHIS
 representative declaring that the flock is free of scrapie to the best of his or her
 knowledge; and

 An inspection report by an authorized State or APHIS regulatory official, including verification of the information provided on the application by the flock owner and verification of the official identification of each animal listed in the application.

State or Federal animal health officials will provide each enrolling Program participant and his or her accredited veterinarian with an educational scrapie review.

Once approved to enter the Program, a flock will be issued an enrollment date. This date will serve as the status date until the flock fails to meet any of the Program standards under part III. For flocks that acquire animals or commingle with animals that do not meet Program standards under part III, the status date will change to the date the nonenrolled animals are acquired or commingled or to the status date of the flock with the most recent status date for animals from Enrolled flocks. The enrollment date will not change.

2. Advancement to Certified status

When a flock has obtained a status date that is over 5 years old (that is, it has met all of the Program standards and has not acquired animals or commingled with unapproved animals), it may apply to advance to Certified status. The State Scrapie Certification Board will review advancement applications for movement from Enrolled status to Certified status within 60 days of the receipt of the application package. The application package includes

- A completed Program advancement application:
- A list of animals in the flock, including official identification numbers, breed, and sex information and additional information required on acquired and natural additions, as specified in part III, section A2d;
- A statement by an accredited veterinarian declaring that to the best of his or her knowledge there has been no evidence of scrapie in the flock since the status date; and
- An inspection report by a State or APHIS regulatory official, including verification of the information provided on the application by the flock owner and verification of the official identification of each animal listed in the application.

3. Maintenance of status

a. Flocks meeting all requirements during a year at current status

During the annual inspection, a flock's status date will be maintained if

- Scrapie has not been diagnosed in the flock and it has not been deemed a source flock since its enrollment;
- The minimal requirements for the status currently held by a flock have been fulfilled; and
- The flock has only had acquisitions or commingling of animals approved for the current status.

b. Flocks not meeting all requirements at current status

If, during the year at the current status, a flock (1) has not met the minimum requirements for the Status currently held or (2) has acquired or commingled animals in the flock that did not meet the requirements of the current status, or both, then the flock's status date will convert to the date when the flock was brought back into Program compliance or to the status date of the acquired or commingled animals.

E. Downgrading of Certification Status

1. Scrapie is found.

If an Enrolled or Certified flock has a confirmed diagnosis of scrapie or is revealed through epidemiologic investigation to be a source flock, the flock will be removed from the Program. The owner of the removed flock may reapply for enrollment in the Program after the flock has completed the requirements set forth in Title 9, CFR, Part 79 for infected or source flocks.

2. Female animals are added.

If a Certified flock acquires or commingles with female animals that are not from a Certified flock, the status of the Certified flock will be lowered to Enrolled, and its status date will change. If an Enrolled flock acquires or commingles with female animals from a nonparticipating flock or from a flock with a more recent status date, the receiving flock will continue with Enrolled status, but the status date will change. After acquiring or commingling with female animals from nonparticipating flocks, the receiving flock's status date will become the date that the female animals were acquired or commingled. After acquiring or commingling with female animals from Enrolled flocks with a more recent status date, the receiving flock will have its status date changed to the most recent status date of the flocks involved.

3. Male animals are added.

For Certified flocks, if male animals are acquired from nonparticipating flocks, the status of a Certified flock will be lowered to Enrolled with a status date 4 years before the date of acquisition. Therefore, this flock would have Enrolled status with 1 year left until an application for Certified status would be considered. For Certified flocks, if male animals are acquired from Enrolled flocks and do not meet the requirements in part III, section A5a, the flock status will be lowered to Enrolled, and its status date will change. For Certified and Enrolled flocks, if male animals are acquired from Enrolled flocks and do not meet the requirements in part III, section A5a, the status date of the receiving flock will be changed to the most recent status date of the flocks involved. For Enrolled flocks, if male animals are acquired from nonparticipating flocks and do not meet the requirements in part III, section A5a, the receiving flock's status date will change to the date of acquisition or commingling. See part III, section A7 for germ plasm acquisitions.

4. Compliance irregularities

The State Scrapie Certification Board shall recommend downgrading a participating flock's status or removing it from the Program if its owner or manager has not complied with the standards, unless a compelling argument based upon sound scientific principles can be presented. A flock may reenter the Program after fulfilling Board-determined requirements.

F. Appeal

Owner-reported reductions in flock status or status date due to animal acquisitions or commingling will be made as soon as possible following notification of the State Scrapie Board or AVIC without review by the Board unless the owner requests that the board do a formal review at the time the acquisition or commingling is reported. Except for owner-reported reductions, APHIS will notify a flock owner that his or her flock is being considered for reduction in status or removal from the Program by the State Scrapie Board. The State Board will give the owner of the affected flock an opportunity to present his or her views to the board before it makes its final recommendation about reduction or removal. APHIS will decide the status of the flock on the basis of the Board's recommendation and will notify the flock owner of the decision. The flock owner may appeal to the Administrator within 30 days after notification of the Board's recommendation.

Part III—Program Requirements

A. Complete Monitored Category

1. Program status

A Complete Monitored category flock gains Program status based on the flock's status date. Once a flock is approved to participate in the Program, that flock will be considered an Enrolled flock with a status date based on the date the application is approved by the Board. Advancement to Certified status is based on an Enrolled flock's compliance with the standards in this part and maintenance of a status date that is longer than 5 years.

An Enrolled flock is one that has been approved to participate in the Program under part II, section D1.

A Certified flock is an Enrolled flock that has participated in the Program for more than 5 years and has met the necessary requirements to progress beyond Enrolled status.

2. General provisions

The flock owner or manager who participates in the Complete Monitored category will agree to

- a. Immediately report scrapie-suspect animals and animals suspected of other neurologic and chronic debilitating (prolonged wasting) illnesses to a State or Federal animal health official or an accredited veterinarian.
- b. Ensure that proper tissue samples are collected and submitted for diagnostic purposes. Such animals shall not be used for breeding or be disposed of without the prior approval of a State or APHIS representative.
- c. Officially identify all animals 1 year of age or older within a flock. Officially identify all acquired animals prior to commingling with the flock. All animals less than 1 year of age will be officially identified when a change of ownership occurs, with the exception of those moving within slaughter channels. Official identification for the specified animals will be
 - · Permanent,
 - Secure,
 - Unique (assigned from a central repository), and
 - Traceable.

The following are types of Program-approved identification:

- Tamper-resistant ear tag,
- Flank or ear tattoo, and
- Electronic identification.

In the case of goats registered with the American Dairy Goat Association, the tattoo may be applied at the tail web.

A secondary form of identification may be maintained at the owner's discretion.

d. Maintain records in accordance with the following:

Records must be kept for a minimum of 5 years after an animal dies or has otherwise been removed from the flock.

The following records must be kept on animals present in the flock at the time of initial participation:

- 1. Official and any secondary identification number;
- 2. Sex:
- 3. Breed;
- 4. Disposition—date and cause of death, if known, or movement date and to whom:
- 5. Progeny's official and any secondary identification numbers and sex; and
- 6. If available, date of birth or date of acquisition, flock of origin and date of entry, and sire and dam's official and any secondary identification.

The following records are to be kept on acquired or natural additions to the flock subsequent to enrollment:

- 1. Official and any secondary identification number;
- 2. Sex:
- 3. Breed:
- 4. Date of birth or date of acquisition;
- 5. The flock of origin and date of entry;
- 6. Disposition—date and cause of death, if known, or movement date and to whom:
- 7. Sire and dam's official and any secondary identification numbers; and
- 8. Progeny's official and any secondary identification numbers and sex.
- e. Allow breed associations and registries, livestock markets, and packers to disclose records to APHIS representatives or State animal health officials. These records will be used to trace a source of exposure and other exposed animals.
- f. Notify the State Scrapie Certification Board about acquisitions that would lower the status, status date, or both, of a flock, as per part III, section A5c, within 30 days after the animal enters the flock.
- g. Make animals and records available for inspection by APHIS representatives, State animal health officials, and State Scrapie Certification Board representatives, given reasonable prior notice. The owner shall agree to have the necessary facilities and personnel available to assist in inspecting the identification of each animal and the records.
- h. Ensure that tissues from scrapie-suspect animals, and animals suspected of other neurologic and chronic debilitating (prolonged wasting) illnesses will be submitted to an official laboratory in accordance with part IV and appendix 1. Other tissues will be submitted at the request of the State Scrapie Certification Board or State or Federal animal health official.

3. Inspections

An authorized Federal or State animal health official representative must inspect Complete Monitored flocks every 11–13 months, on the basis of enrollment date. Inspectors will check each animal for official identification and scrapie signs and will examine records for:

- · Completeness,
- Accuracy, and
- All acquisitions, departures, births, and deaths.

4. Evidence of scrapie

Enrolled flocks identified as infected or source will be removed from the Program and handled according to Title 9, CFR, Part 79. If an Enrolled flock is deemed to be a trace or exposed flock, all of the animals 18 months of age or older that die on the farm will have tissues (brain and retropharyngeal and submandibular lymph nodes) submitted for diagnostic purposes. The probable cause of death must be maintained in the records. The rate of submission will continue for 3 years after the date of notification that the flock was identified as a trace or exposed flock. This rate may be modified with an exemption granted by the Deputy Administrator of VS. As part of the epidemiologic investigation, some animals in a trace or exposed flock may be deemed to be "high risk" as per Title 9, CFR, Part 79. It is recommended that these animals be removed from the flock and not sold for breeding purposes. If current regulations mandate more restrictive actions, the regulations will take precedence over the recommendations of this Program. If a preclinical diagnostic technique for screening a flock for scrapie becomes available, this method may be used to assess the risk of scrapie infection in trace and exposed flocks.

5. Acquisitions

The State Scrapie Certification Board must be notified about all acquisitions during the annual inspection process and all acquisitions that do not meet Program standards within 30 days of acquisition.

a. Male animal acquisitions

Enrolled flocks may acquire breeding male animals from any flock if the male animals are

- Officially identified;
- · Shown on the flock inventory; and
- Not scrapie suspects, scrapie-positive, affected, exposed or high-risk animals or animals that have resided in a source, infected, trace, or exposed flock in which an epidemiological investigation was not conducted or in which the records are either unavailable or inadequate to determine whether an animal is an exposed or high-risk animal. (For the purposes of this part, a flock will be considered to have been a source, infected, trace, or exposed flock from the date of entry, or birth, of a

scrapie-positive animal into the flock until the date the flock is no longer designated a source, infected, trace or exposed flock.)

Not currently part of an infected or source flock

(See II.E.3 for male animals not meeting these requirements.)

Certified flocks can only acquire male animals from other Certified flocks or Enrolled flocks and only if the acquired male animals meet the preceding requirements. To be considered as originating from an Enrolled flock, the male animal must either have been born in the Enrolled flock or have resided in an Enrolled flock for at least 1 year immediately prior to acquisition. Male animals cannot be commingled with other animals except as permitted by part III, section A6. (See II.E.3 for male animals not meeting these requirements.)

At present, there is no scientific evidence that implicates male animals as a risk for the spread of scrapie. Male animals are considered a lower risk for the spread of scrapie than female animals, but male animals cannot be totally ruled out as a risk of scrapie exposure. Producers should consider risk when selecting male animals from nonparticipating flocks.

b. Female animal acquisitions

Enrolled flocks may acquire female animals from flocks with the same status date or higher. If an Enrolled flock acquires female animals from an Enrolled flock with a more recent status date, the status date of the receiving flock will become the most recent status date of the flocks involved. Owners or managers of certified flocks may purchase female animals from Certified flocks, regardless of status date, without a change in enrollment status. The flock owner must notify the Board of acquisitions, which may change the flock's status or status date within 30 days of acquisition.

c. Program status transfer with purchased animals

A purchasing flock may retain the status date of acquired animals only if the animals have not been commingled with

- Nonparticipating animals or
- Animals from a flock with a more recent status date.

When establishing a new flock entirely from an Enrolled or Certified flock, the flock of origin's status date will transfer to the new flock if the owner of the new flock notifies the State Scrapie Board and submits an application for participation in the Program within 30 days of the animals' arrival on the farm. Applications received beyond 30 days will be treated as new applicants to the Program. Animals from a flock of higher status or an Enrolled flock with a status date older than the flock of destination will convert to the lower flock status (i.e., from Certified to Enrolled) with the status date of the flock of destination.

6. Commingling

An Enrolled flock's status and status date will be in jeopardy if

- Female animals are commingled with or housed in the lambing or kidding facilities of animals from a nonparticipating flock or an Enrolled flock with a more recent status date, other than limited contacts, and then returned to the original flock; or
- Male animals do not meet Program standards or if a male animal is used in a
 nonparticipating flock that is an infected, source, trace, or exposed flock and
 then returned to the Enrolled flock. (Enrolled flocks are encouraged to use
 the risk-reduction strategies required for Certified Flocks, which are listed in
 the following paragraph);

A Certified flock's status and status date will be in jeopardy if

- Female animals are commingled with or housed in the lambing or kidding facilities of animals from a nonparticipating flock or an Enrolled flock, other than limited contacts, and then returned to the original flock; or
- Male animals are commingled with animals from nonparticipating flocks and their use in nonparticipating flocks does not meet the following requirements:
 - —No commingling with female animals in the nonparticipating flock for 30 days prior to and 60 days following lambing or kidding.
 - —No housing or maintenance of the male animal in the lambing or kidding facilities of the nonparticipating flock.
 - —The male animal must reside in the certified flock except when being used for breeding purposes in another flock.
 - —The male animal shall not be used in a nonparticipating flock that is an infected, source, trace or exposed flock.

7. Use of semen and embryos

Enrolled and Certified flocks may not use germ plasm from any donor found to be a scrapie-positive animal.

Enrolled or Certified flocks may use semen from lower status or nonparticipating flocks with no effect on Program status or status date. Semen may not originate from a scrapie suspect; from a scrapie-positive, an affected, or a high-risk animal; or from any animal that resided in a source, infected, trace or exposed flock (prior to collection of the semen) in which the records are unavailable or inadequate to determine whether the animal is a high risk animal. (For the purposes of this part, a flock will be considered to have been a source, infected, trace or exposed flock from the date of entry or birth of a scrapie-positive animal into the flock until the date the flock is no longer designated a source, infected, trace or exposed flock.) The status of the semen will be determined on the date of insemination. If the status of the donor or the donor's flock changes after the insemination occurs, there will be no retroactive effect on the status of the recipient flock or any resulting offspring. However, in any case where the standards for semen are more restrictive than those for embryos, the requirements for embryos shall be used.

Enrolled or Certified flocks may receive embryos with no effect on Program status or status date if the embryos originated from

- Flocks with the same or higher Program status or status date,
- · A foreign country free of scrapie as designated by APHIS, or
- A flock in a foreign country that has Program standards that APHIS has recognized as equivalent to the ones in this publication if, and only if, that flock has the same or higher Program status or status date as the receiving flock.

To have status in the Voluntary Scrapie Flock Certification Program, an embryo must be stored and a record kept such that the identity, status, and status date of the embryo can be determined. Therefore, the record must include the identity, status, and status date of the embryo donor and the identity and status of the embryo sire and whether the embryo was produced by artificial insemination.

Embryo recipients must meet the Program's requirements for female animal acquisitions.

An embryo will have the highest status and the greatest number of months of status achieved by the donor at or following collection unless the donor's status is downgraded as a result of the donor or the donor's flock having been exposed to scrapie within 60 months prior to collection, in which case the embryo will have the highest status and the greatest number of months of status achieved by the donor following the downgrade. Changes in donor status following implantation of the embryo into the recipient will have no retroactive effect on the recipient flock's status or status date. The sire of the embryo or the semen used to produce the embryo must have met Program requirements for use in Enrolled flocks at the time of embryo collection, and the sire must not have been determined to be scrapie positive prior to implantation.

An embryo may be given Certified status irrespective of the donor's status if (1) the donor survives for at least 60 months after collection; (2) the donor is necropsied and tissues are submitted in accordance with appendix 1 and found negative for scrapie; (3) the resulting offspring is determined by DNA testing to have been the offspring of the donor; (4) the sire of the embryo or the semen used to produce the embryo met the Program requirements for use in Enrolled flocks at the time of embryo collection and the sire was not later determined to be scrapie positive, or the sire met the same requirements as the donor; and (5) the recipient resides in a Certified flock. (All testing will be done at owner expense.)

The status and status date of the embryo will be converted to the status and status date of the recipient on the date of implantation unless the status date of the embryo is more recent.

A flock owner may request that the State Scrapie Board review the status and status date of an embryo prior to implantation.

8. Imported animals

Imported animals from foreign countries may enter the Program at the appropriate level if they have an equivalent certification program recognized by APHIS or the country of origin is recognized free of scrapie by APHIS standards. These animals cannot at any time have commingled with animals of a lower Program status.

B. Selective Monitored Category

The Selective Monitored class is open to any flock and is mainly intended to help slaughter-lamb producers who wish to have an additional method of scrapie surveillance in large production flocks. Selective Monitored category flocks may apply for Enrolled status in the Complete Monitored category by making application to the State Scrapie Certification board under part II, section D1, and by meeting the requirements of the Program.

1. Entry into the Selective Monitored category of the Program

The State Scrapie Certification Board will review enrollment applications within 60 days of receiving the application package. The enrollment date is the date the State Board approves the application for entry into the Selective Monitored category of the Program. The application package includes

- A completed Program application;
- A list of male animals over 1 year of age in the flock including at least official identification numbers, breed, and sex information as specified by the certification category applied for;
- A statement by an accredited veterinarian (if available) or a State or APHIS
 representative declaring that the flock is free of scrapie to the best of his or
 her knowledge; and
- An inspection report by an authorized State or APHIS regulatory official, including verification of the information provided on the application by the flock owner and verification of the official identification of each animal listed in the application.

State or Federal animal health officials will provide each enrolling Program participant and his or her accredited veterinarian with an educational scrapie review.

Once approved to enter the Selective Monitored category of the Program, a flock will be issued an enrollment date.

2. Identification

Participants must officially identify all male animals 1 year old or older.

3. Animal records

Participants must keep the following records for all male animals 1 year and older:

- · Official and secondary identification,
- Breed.
- Acquisition date and flock of origin, and
- Disposition—date and cause of death if known, or date of movement and to whom.

4. Inspections

An Authorized APHIS representative or State animal health official must inspect participating flocks every 11–13 months (enrollment date \pm 1 month). Inspectors will check

- Each male animal 1 year old or older for official identification,
- · Records of slaughter inspections for all cull animals,
- The flock for signs of scrapie, and
- The records for completeness and accuracy.

5. Routine monitoring for evidence of scrapie

These flocks will be monitored for evidence of scrapie by one of the following methods:

- Flocks with 1,000 female animals or fewer must submit 1 animal for scrapie diagnosis as specified in part IV and appendix 1 each year. For flocks with more than 1,000 female animals, a submission rate of 1 animal per 1,000 must be made. The animal(s) should be an animal that was culled or died at more than 2 years old.
- If any animal 4 years old or older is necropsied by an accredited veterinarian, tissues will be submitted for scrapie diagnosis as specified in part IV and appendix 1.

The scrapie diagnostic requirement would be waived if a flock had no death or cull losses in animals more than 2 years old during the reporting period. All submissions of tissues for scrapie diagnosis must be made by an accredited veterinarian or an APHIS representative or a State animal health official.

6. Slaughter inspection

An accredited veterinarian will inspect all cull female animals in Selective Monitored flocks for clinical signs suggestive of scrapie

- · Before slaughter, and
- While the animals are still identifiable to the flock of origin.

7. Evidence of scrapie

Any animal(s) showing clinical scrapie signs (e.g., neurologic signs) in a Selective Monitored flock must be reported to the AVIC or to a State animal health official. Upon death, the animal must be necropsied by an accredited veterinarian or an APHIS or State regulatory veterinarian, and its tissues must be submitted in accordance with part IV and appendix 1.

These animals shall not be used for breeding or be disposed of without the prior approval of a State or APHIS representative.

Selective Monitored flocks identified as infected or source flocks will be handled according to Title 9, CFR, Part 79. Upon confirmation of scrapie, the flock's status will change to infected or source flock. If a flock is deemed to be a trace or exposed flock, all of the animals 18 months of age or older that die with clinical signs suggestive of scrapie (see definition of scrapie) will have tissues (brain and retropharyngeal and submandibular lymph nodes) submitted for diagnostic purposes. The probable cause of death must be maintained in the records. The rate of submission will continue for 3 years after the date of notification that the flock was identified as a trace or exposed flock. This may be modified with an exemption granted by the Deputy Administrator of VS. As part of the epidemiologic investigation, some animals in a trace or exposed flock may be deemed to be "high risk" as per Title 9, CFR, Part 79. These animals should be sold for slaughter. If current regulations mandate more restrictive actions, the regulations will take precedence over the recommendations of this Program. If a preclinical diagnostic technique for screening a flock for scrapie becomes available, this method may be used to assess the risk of scrapie in the flock.

8. Acquisitions and movements

Selective Monitored flocks must not receive animals from flocks listed as infected or source flocks.

Owners or managers of Selective Monitored flocks

- · Are encouraged to acquire animals from Complete Monitored flocks, and
- Must officially identify all male animals 1 year old or older and all male animals when ownership changes, except for those animals moving in slaughter channels.

9. Maintaining status in the Selective Monitored category

A Selective Monitored flock will maintain its status indefinitely, provided that the flock continues to meet the Selective Monitored requirements, or until it enters the Complete Monitored category.

Part IV—Laboratory Procedures and Test Interpretation

A. General considerations

Official laboratories will examine all Voluntary Scrapie Flock Certification Program tissues as submitted per appendix 1. The official laboratory will report diagnostic findings to the submitter and to APHIS.

B. Laboratories

APHIS' National Veterinary Services Laboratories (NVSL) will assist official laboratories in ensuring quality control for the diagnosis of scrapie.

C. Diagnostic tests

Official laboratories must use currently recognized procedures for

- · Examining tissues, and
- Establishing a presumptive scrapie diagnosis.

Official laboratories shall use histopathological examination such as described by Miller et al. (1985) and Race et al. (1992) as the primary diagnostic criteria. Official laboratories shall submit appropriate specimens to the reference laboratory, NVSL, Ames, IA, to confirm the presumptive diagnosis. All diagnostic laboratories, including official laboratories, where a diagnosis of scrapie cannot be made in animals exhibiting clinical signs suggestive of scrapie and in which no other disease condition can be diagnosed should send samples to NVSL for supplemental diagnostic tests.

The reference laboratory routinely

- · Examines brain tissue histopathologically and
- Conducts immunohistochemical surveys for prion protein (PrPsc) (Miller et al. 1994) for a final and official diagnosis.

Western blot techniques or other subsequently evolving methodologies acceptable to the veterinary community may augment histopathology and immunohistochemistry in diagnosing scrapie.

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Part V—Flock Information

The Centers for Epidemiology and Animal Health (CEAH) maintain a national information data base about:

- Enrolled and Certified flocks in the Voluntary Scrapie Flock Certification Program,
- · Infected flocks, and
- Source flocks.

Interested parties may access this information 24 hours a day, 365 days a year, by dialing 1–800–545–USDA (8732) on a Touch- Tone[™] phone. Select option 4 to connect with the Voluntary Scrapie Flock Certification phone query system. Producers may obtain more detailed information on the phone query system from an APHIS representative.

The National Animal Health Programs staff of VS prepares periodic reports from the national data base on Enrolled, infected, and source flocks. The following information will be made available to the public on flocks participating in the Program: name, address, enrollment date, and status date. These reports or lists are publicly available through the:

- · Phone query system,
- State animal health representative,
- AVIC,
- National Animal Health Programs staff at (301) 734-7709, and
- APHIS' Website: http://www.aphis.usda.gov/vs

Appendix 1—Specimen Collection and Submission

When scrapie is suspected in a live animal, the owner shall contact an APHIS representative, a State animal health official, or an accredited veterinarian. Those individuals will include the following with each diagnostic submission:

- All identification devices for use in traceback;
- Age of animal based on dental examination;
- · Record, breed, and sex of animal;
- Heparinized blood sample for potential DNA testing at the producer's expense;
- · Brain collected and packaged as described below; and
- Any additional samples as requested by the AVIC or State Veterinarian, including samples requested for research.

Brain Removal

The following protocol should enable the veterinarian to submit a proper brain specimen:

- 1. Wear rubber gloves.
- 2. Cut through the atlanto-occipital joint to separate the head from the carcass.
- 3. Incise the skin on the midline over the poll, forehead, and nose. Reflect the skin laterally to expose the skull, orbits, and caudal part of the nose.
- 4. Using a postmortem saw, transversely cut 1–2 cm deep across the caudal part of each orbit.
- 5. Cut on each side of the skull from the foramen magnum to a point 2–3 cm medial to the orbital rim, transecting the transorbital cut. Angle each cut inward at about 45° from the vertical axis.
- 6. Insert a heavy knife or bone chisel into the transverse cut and slowly pry the skull cap up and back. Take care to prevent the attached meninges from compressing or tearing the brain parenchyma. Cut the meninges as the skull cap is removed. Scissors are more suitable than a knife for cutting these membranous attachments.
- 7. Cut the meninges between the cerebral hemispheres and over the cerebellum. Reflect the meninges laterally to remove them.
- 8. Hold the head with the nose or jaw pointing upward to allow gravity to assist in removing the brain from the cranial cavity. Cut through the brain attachments starting with the
 - · Olfactory tracts,
 - · Optic nerves, and
 - Pituitary stalk

and work caudally through the other cranial nerve roots. Gently tease the brain out of the cranial cavity while cutting through the attachments. Allow the brain to drop gently onto a clean, dry surface.

Specimen Submission

Separately bag each tissue and label each bag with owner, animal, and tissue identification.

Complete a VS Form 10–4 for each sample submitted to NVSL. Place the separately bagged tissues in another bag with identification information on the owner and tissues to facilitate shipment, and ship the samples to NVSL. Remove and ship the brain with as little contamination, distortion, and laceration as possible.

Collect and send all manmade identification, a copy of the VS Form 10–4, and the heparinized blood sample to the AVIC to facilitate any epidemiologic investigation that may be related to this submission.

- Collect the brain with a portion of attached anterior spinal cord.
- Divide the brain and anterior spinal cord in half longitudinally. Start the cut rostrally between the cerebral hemispheres and proceed caudally.
- If possible, perfuse one-half of the brain with fixative after flushing the vascular bed with saline or water.
- Place the fixed half of the brain in at least 1 L of 10-percent, neutral, buffered formalin solution. The optimum fixative penetration is achieved with 20 to 40 times the tissue volume of fixative. Changes of fixative are desirable.
- Because the fixed tissue will be used for histopathology, keep this tissue separate from the dry ice, other ice packs, or frozen tissues.
- Place the other half of the brain in a separate sealed bag labeled with animal identification, owner's name, and tissue type. Keep this half refrigerated with ice packs during transit to an official laboratory.
- Properly prepare and separate the formalin-fixed tissue from the refrigerated tissue for shipment. Do not allow the formalin-fixed tissues to freeze. Place the owner's name and animal identification on the container.
- Deliver refrigerated fresh tissue to a laboratory within 36 hours of collection. Otherwise, freeze this tissue for shipment.

Appendix 2—Scrapie Disinfection Guidelines

None of the following suggested disinfection and inactivation procedures may guarantee total and complete elimination and inactivation of the infectious agent; however, on the basis of current information on the efficiency of the methods listed below, they are suggested for use outside the laboratory. Until more specific information becomes available, good sanitary practices will have to suffice.

Pastures

- Effective inactivation of the agent will destroy the forage.
- Do not graze animals on pasture where scrapie-infected animals have lambed.

Drylot

- When practical, remove the top 1–2 inches of soil or manure to reduce contamination.
- Bury, till under, or compost the removed material in areas not accessed by domestic animals or wildlife.

Nonearth Surfaces

(These include cement, wood, metal, tools, equipment, instruments, feed, hay, bedding, and other materials.)

- · Remove all organic material and compost or incinerate.
- Clean and wash surfaces and other items using hot water and detergent.
- Allow all surfaces, tools, and equipment to dry completely before disinfecting and sanitizing using the following suggested methods:
- 1. Incinerate items by high-temperature incineration methods when possible.
- 2. Autoclave instruments, small tools, and other items at 136 °C (277 °F) for 1 h when possible.
- 3. To clean dry surfaces, apply a 2-percent available chlorine solution (equivalent to about 20,000 p/m; available chlorine: 50 oz [6-1/4 cups] bleach in 1 gal water) at room temperature (at least 18.3 °C [65 °F]) for 1 h.
- 4. For environmental purposes, use this disinfection method when the preceding methods are not available: Expose dry surfaces by applying 1-molar solution of sodium hydroxide (approximately 4-percent solution [5 oz sodium hydroxide dissolved in I gal water]) at room temperature (at least 18.3 °C [65 %F) for at least 1 h. Synonyms for sodium hydroxide are caustic soda, soda lye, and sodium hydrate.

Appendix 3—Exhibition and Transportation Guidelines

Incomplete knowledge of scrapie transmission causes participants concern. Sheep and goat exhibitions and transportation pose a risk for scrapie transmission. The following guidelines may lower these risks:

- Separate enrolled from nonenrolled sheep or goats by a vacant pen, a barn alley, or a solid physical barrier sufficient to prevent any physical contact between enrolled and nonenrolled sheep or goats.
- Limit contacts in the show or sales ring to minimize risk of scrapie transmission.
 These contacts take place between animals off the flock's premises and not
 during or immediately after lambing or kidding. Limited contacts do not include
 commingling, which means the grouping of animals together with free physical
 contact.
- Lambing or kidding increases the exposure potential. Prevent contact with lambing or kidding animals at exhibits or sales.

Appendix 4—Identification Guidelines

Official identification for certain animals in the Voluntary Scrapie Flock Certification Program meets the following criteria:

- Permanence,
- Security,
- Assignment of a unique number from a central repository, and
- Traceability, for which the user is responsible.

The following are Program-approved means of identification:

- Tamper-resistant ear tag approved by APHIS,
- Flank or ear tattoos (or in the case of goats registered with the American Dairy Goat Association tail web tattoos),
- Electronic identification (radio frequency identification [RFID])

Participants are responsible for applying official identification. Users of tamperresistant ear tags should obtain tags that are approved by APHIS and have been permanently imprinted with the flock's premises code and individual animal number.

For premises identification, a two-letter abbreviation of the State followed by three numbers ranging from 001 to 999 should be initiated and maintained at the USDA, APHIS, VS, area office in a State. For example, a participating premises in the State of Alabama will be identified as AL001, AL002, etc., to AL999. If additional codes are needed, States can use an alphabetical identification system (e.g., AAA, AAB, A01, A02, etc).

Users of electronic identification should

- Place the implant above or dorsal to the auricular or ear cartilage.
- Provide an identification certificate when selling electronically identified animals, except to slaughter. This certificate must state
 - 1. Animal's date of birth, sex, breed, registration name and number;
 - 2. Electronic identification number and any secondary identification; and
 - 3. Breeder's name and address.

The buyer of an animal with electronic identification should keep the certificate with the animals records to document receiving electronic identification.

Users of ear or flank tattoos should

- Use two separate tattoos:
 - 1. A four-character alphanumeric premises code assigned by APHIS as explained above.
 - 2. A legible, unique, individual animal number.
- Apply the premises code in the right ear and individual animal number in the left ear, or place both numbers in each ear or on the right flank in the wool-free area.
- Animals with breed or registry tattoos require only a premises code tattoo in the
 right ear or right flank. American Dairy Goat Association registration tattoos that
 have a unique premises ID and a unique individual animal ID number may use the
 registered premises ID in place of a State code. In the case of goats registered
 with the American Dairy Goat Association, the tail web may be used.

Appendix 5—Genetics and Scrapie

Theories on the cause of scrapie have been debated for many years, and the debates still go on today. Initially, arguments over cause centered around a genetic versus infectious origin. Current information indicates that both genetics and an agent play a role in the occurrence of scrapie.

H. B. Parry felt that scrapie is an autosomal recessive genetic disease that is not naturally infectious and arises spontaneously in certain genotypes. He did concede that affected animals harbor a transmissible agent infectious by artificial routes. Data accumulated from 1,400 cases appeared to support his theory (Parry 1964). However, recent work (Hunter et al. 1997b) shows that genotypes considered the most likely to give rise to spontaneous scrapie also exist in New Zealand and Australia. Both countries are considered by most to be free of scrapie.

There is information to suggest that scrapie is a naturally occurring contagious disease caused by an infectious agent (Brotherson et al. 1968, Dickinson 1974, Hourrigan et al. 1979). However, the precise mechanism of natural transmission is not well understood.

Current information indicates that both genetics and an agent play a role in the occurrence of scrapie. It is evident there may be a wide variation in the clinical manifestations as well as the pattern and intensity of histopathological lesions associated with scrapie and related transmissible spongiform encephalopathies. Now it is well established that the expression of disease is a direct result of host–agent interaction. Some aspects of pathogenesis can differ, depending on the interaction of agent strain, host genotype, route of injection, and dose of agent. If any one of these parameters is altered, the phenotypic expression of the disease may also be altered. These distinct phenotypes must result from an interaction at the molecular level between host and scrapie strain. Characteristic of this disease is the control of the incubation period through host gene loci such as Sip (scrapie incubation period) in sheep and Sinc (scrapie incubation) in mice. It is likely that the PrP gene and the genes controlling scrapie incubation periods (Sip and Sinc) are the same (Carlson et al. 1986, Hunter et al. 1987 and 1989, Westaway et al. 1987).

In sheep, two phenotypes of the Sip gene, which correspond to the PrP gene, were identified in an experimental flock of Cheviot sheep. The phenotypes sA (short incubation allele) and pA (prolonged incubation allele) are associated with amino acid changes at codon 136 (Hunter et al. 1989). Sheep carrying either the 136 valine/valine (sA/sA) or 136 valine/alanine (sA/pA) genotypes develop clinical disease with strain A group scrapie isolate. Since this initial finding, other polymorphisms found at codons 154 and 171 have been associated with clinical scrapie.

Other genes or loci may yet prove to be important; however, as more genotyping is done, the picture may become more complex and the following substitution may occur:

- At codon 136, the nucleotide sequence codes for either valine or alanine.
- At codon 154, the nucleotide sequence codes for either histidine or arginine.
- At codon 171, the nucleotide sequence codes for glutamine, arginine, or histidine.

Experimental transmission studies using Cheviot sheep at the Neuropathogensis Unit (NPU) in Edinborough, Scotland, suggested that scrapie strains may be divided into either "A" or "C" groups. The "A" group strains interact with Sip genotypes in the standard way (i.e., the incubation period length in the sAsA genotype is short and the pApA genotype prolongs clinical disease to such an extent that the sheep are culled or die of other causes) and targets Valine at codon 136 (N. Hunter, pers. commun., 1998). In contrast, the only "C" strain identified thus far (CH1641) interacts with the host in the reverse direction (Goldmann et al. 1994 a and b) and appears to target homozygous glutamine at codon 171 (N. Hunter, pers. commun., 1998). Since the work has been limited to NPU Cheviots, one must be cautious and not assume that the categorization applies to other breeds.

It is important to note that more than one scrapie strain can be isolated from single cases of natural scrapie, and some natural cases of scrapie fail to transmit to mice (Fraser 1983).

Suffolk sheep rarely carry the 136 valine allele. In this breed, natural and experimental scrapie are associated with 171 glutamine/glutamine (Westaway et al. 1994, O'Rourke et al. 1996). With very few exceptions, naturally infected sheep of several breeds in the United States, the United Kingdom, Europe, and Japan carry either 136 valine (136 valine/valine or 136 valine/alanine) or 171 glutamine/glutamine (QQ) (Belt et al. 1995, Clouscard et al. 1995, Hunter et al. 1993 and 1994, Ikeda et al. 1995, Laplanche et al. 1993, Westaway et al. 1994, O'Rourke et al. 1996). There has been only one report of a scrapie-affected Suffolk carrying 171 arginine/arginine (RR) (Ikeda et al. 1995). There have been four reports of Suffolks carrying 171 arginine/glutamine (QR) that have developed clinical scrapie (Ikeda et al. 1995, Hunter et al. 1997a, Junghans et al. 1998).

In sheep, other PrP gene polymorphisms have been identified; however, it appears that the ones identified at codons 136, 154, and 171 play the largest role in scrapie (Hunter et al. 1996). The clinical and pathological heterogeneity observed following infection appears to be controlled by both the particular scrapie strain and the host PrP genotype.

Many questions must still be answered before the role of genetics in relationship to scrapie susceptibility can be fully understood:

- 1. Do certain genotypes fully prevent scrapie infection or merely protect against the clinical manifestation of the disease?
- 2. Is there a carrier state wherein clinically normal animals are shedding the agent and are a risk to other susceptible sheep?
- 3. If a flock were bred to be "resistant" to a certain strain of scrapie and another strain were introduced, would a vast majority of the animals succumb to the disease?

The PrP gene may be responsible for directing the infectious agent to specific target sites within and outside of the central nervous system (Bruce et al. 1991, Scott et al. 1992).

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