

## DEPARTMENT OF AGRICULTURE

## Animal and Plant Health Inspection Service

## 9 CFR Parts 54 and 79

[Docket No. 97-093-5]

RIN 0579-AA90

## Scrapie in Sheep and Goats; Interstate Movement Restrictions and Indemnity Program

**AGENCY:** Animal and Plant Health Inspection Service, USDA.

**ACTION:** Final rule.

**SUMMARY:** We are amending the regulations for the interstate movement of sheep and goats by requiring certain animal identification for sheep and goats moving interstate, by establishing a list of States that conduct an active State scrapie program that is consistent with Federal requirements, by establishing requirements for moving sheep and goats interstate from those States and from States that do not conduct such programs, by reinstituting an indemnity program for certain sheep and goats affected by scrapie, and by making other associated changes. These changes will help prevent the interstate spread of scrapie, an infectious disease of sheep and goats.

**DATES:** *Effective Date:* September 20, 2001. *Compliance Dates:* The compliance date for all requirements to identify animals that are not scrapie-positive animals, suspect animals, high-risk animals, exposed animals, or animals from an infected or source flock is November 19, 2001. The compliance date for all requirements for the identification of commercial whitefaced breeding sheep under 18 months of age and commercial breeding goats is February 18, 2002.

**FOR FURTHER INFORMATION CONTACT:** Dr. Diane Sutton, Senior Staff Veterinarian, National Animal Health Programs Staff, 4700 River Road Unit 43, Riverdale, MD 20737-1235, (301) 734-6954.

**SUPPLEMENTARY INFORMATION:****Background**

Scrapie is a degenerative and eventually fatal disease affecting the central nervous systems of sheep and goats. It is a member of a class of diseases called transmissible spongiform encephalopathies (TSE's). Its control is complicated because the disease has an extremely long incubation period without clinical signs of disease.

To control the spread of scrapie within the United States, the Animal

and Plant Health Inspection Service (APHIS), U.S. Department of Agriculture (USDA), administers regulations at 9 CFR part 79, which restrict the interstate movement of certain sheep and goats. APHIS also has regulations at 9 CFR part 54, which describe a voluntary scrapie free flock certification program.

On November 30, 1999, we published in the **Federal Register** (64 FR 66791-66812, Docket No. 97-093-2) a proposal (referred to below as the November 30 proposal) to amend 9 CFR parts 54 and 79. We proposed three significant areas of change:

- Further restrictions on the interstate movement of sheep and goats from States that do not consider scrapie a reportable disease or do not quarantine infected flocks or source flocks. We also proposed standards describing how a State must conduct a quarantine in order to avoid further restrictions on interstate movement of animals.

- Additional official identification requirements for sheep and goats moved interstate to allow for a more effective national program for surveillance for scrapie and traceback of scrapie-positive animals. The proposed identification requirements were similar to current requirements for cattle and swine.

Reinstatement of a scrapie indemnification program for sheep and goats that owners agree to destroy. As proposed, the owners of destroyed high-risk animals and animals diagnosed as scrapie positive by an approved live-animal test would be eligible for indemnity payments.

We solicited comments concerning our proposal for 30 days ending December 30, 1999. We reopened and extended the deadline for comments until January 14, 2000, in a document published in the **Federal Register** on January 7, 2000 (65 FR 1074, Docket No. 97-093-3). We received 171 comments by that date. They were from State agriculture agencies, sheep and goat industry associations, sheep and goat producers, livestock auction and slaughter companies, and universities and researchers.

After receiving comments on the November 30 proposal, we published another proposed rule in the **Federal Register** on August 15, 2000 (65 FR 49770-49775, Docket No. 97-093-4, referred to below as the August 15 proposal). We solicited comments concerning the August 15 proposal for 30 days ending September 14, 2000. The August 15 proposal to amend 9 CFR part 79 fulfilled a promise made in the November 30 proposal, which stated that before the November 30 proposal was finalized, APHIS would develop and publish for comment a list of States

that conduct an active scrapie program that is consistent with Federal requirements and, therefore, qualify as Consistent States. The August 15 proposal listed all 50 States as Consistent States and also proposed certain changes to the criteria by which States may qualify to be designated as Consistent States.

The comments received on both the November 30 proposal and the August 15 proposal, and the changes we are making in response to some of them, are discussed below by topic.

*Definition of Certificate*

We are making certain changes to the process for issuing certificates for sheep and goats. These changes are discussed later in this document in the discussion of § 79.5, "Issuance of certificates." Because we are moving certain requirements from the definition of *certificate* in §§ 54.1 and 79.1 to § 79.5, we are also changing the definition of *certificate* to read, "An official document issued in accordance with § 79.5 of this chapter by an APHIS representative, State representative, or accredited veterinarian at the point of origin of an interstate movement of animals."

*Definitions of Exposed Animal and Exposed Flock*

In the November 30 proposal, we tried to define the term *exposed animal* in a manner that would include all animals that were exposed to conditions that might result in the animal becoming infected with scrapie. We defined *exposed animal* in §§ 54.1 and 79.1 as "Any 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. Any animal born in a flock after a scrapie-positive animal was born into that flock, if born before that flock completes the requirements of a flock plan." Our proposed definition of *flock* included "All animals that are maintained on a single premises and all animals under common ownership or supervision on two or more premises with animal interchange between the premises."

Several commenters were concerned over the effect of these definitions on shows and sales and asked whether all animals that attended a show or sale where a scrapie-positive animal was in attendance would be considered exposed animals, regardless of their degree of contact with the scrapie-positive animal. That was not our intention, and we have modified the definition of *exposed animal* to include animals that have exposure to scrapie while at shows or sales without

classifying all animals at a show or sale as exposed animals. We have done this by adding to the definition of *exposed animal* specific means of exposure that could cause a sheep or goat to contract scrapie and by revising the definition of *flock* to specifically exclude animals at shows and sales. These changes were based on research into the means of scrapie transmission and our knowledge of the manner in which sheep and goats are marketed and shown. We added the following language to the definition of *exposed animal*: "Any animal that was commingled with a scrapie-positive female animal during or up to 30 days after she lambed, kidded, or aborted, or while a visible vaginal discharge was present, or that was commingled with any other scrapie-positive female animal for 24 hours or more, including during activities such as shows and sales or while in marketing channels."

Commenters also suggested that we review the scientific basis for the timeframe requirements in the proposal. We reviewed the assumption that there is a particular timeframe, during which an animal might transmit scrapie, between the time it becomes infected and the time it dies from the disease or shows obvious symptoms and is destroyed. One of the places the proposal used this assumption is the proposed definition of exposed animal, which counted exposure if it occurred "within the previous 60 months."

We have reviewed research on this matter. One of the sources relied on for the proposal was Mission Field Trial data. The study monitored 653 sheep and goats that were exposed to the scrapie agent at birth, and 145 sheep and goats that were exposed post-weaning. Results showed that 91 percent of the sheep exposed at birth that died of scrapie died before the age of 54 months and 98 percent died at 67 months or less. For sheep exposed post-weaning 100 percent of those that died of scrapie died at an age of 73 months or more. These data suggest that animals diagnosed with scrapie at an age of 72 months or less were probably exposed at birth, which suggests that their flock of birth should be designated a source flock. Upon reexamining these findings we believe that the assumption that an infected animal has an effective timeframe for developing signs of scrapie for only 60 months, as implied by the proposed definition of *exposed animal*, is too conservative, since infected sheep might survive longer than this, particularly if the animals are exposed post-weaning. The results of the Mission Field Trial suggest that this timeframe should be removed. Therefore, we have removed this

timeframe in the definition of *exposed animal*. As discussed below, we have changed a similar timeframe in the definition of *source flock* from 54 months to 72 months to be consistent with the data for animals exposed at birth.

Other commenters noted that the November 30 proposal discussed actions that were required for flocks exposed to scrapie, particularly with regard to post-exposure management and monitoring plans, but did not define *exposed flock*. We agree that such a definition would be useful and have added the following definition of *exposed flock* to §§ 54.1 and 79.1: "Any flock in which a scrapie-positive animal was born or lambed. Any flock that currently contains a female high-risk, exposed, or suspect animal, or that once contained a female high-risk, exposed, or suspect animal that lambed in the flock and from which tissues were not submitted for official testing and found negative. A flock that has completed a post-exposure management and monitoring plan following the exposure will no longer be classified as an exposed flock."

#### Definition of Flock

Comments on the definition of *flock* in §§ 54.1 and 79.1 noted that the proposed definition could be interpreted to consider separate groups of animals to be a single flock when they are temporarily placed on the same premises, even when this does not involve close contact or a significant risk of spreading scrapie. These commenters suggested the definition be revised to note that animals maintained temporarily on a premises for activities such as shows and sales or while in marketing channels are not a flock. We agree, and have made the requested change.

One commenter also indicated the definition of *flock* is overly restrictive in addressing when groups of animals on the same premises can be considered separate flocks. We agree that separate flocks can be kept in close proximity without risk of spreading scrapie if there is a physical barrier between the flocks. We are, therefore, adding the phrase "or are separated by a solid wall through, over, or under which fluids cannot pass and through which contact cannot occur" to this part of the definition.

#### Definition of Flock of Origin

Several commenters noted that the term *flock of origin* was used in the November 30 proposal without being defined. For scrapie control purposes, the important consideration for determining the flock of origin is to

identify the flock(s) that are likely to harbor or spread scrapie as a result of an infected animal "originating" in the flock. In this sense, an infected animal originated in any flock where the animal gave birth, was bred, or was born. For clarity, we are adding a definition of *flock of origin* to §§ 54.1 and 79.1, to read as follows: "The flock in which an animal most recently resided in which it either was born, gave birth, or was used for breeding purposes. The determination of an animal's flock of origin may be based either on the physical presence of the animal in the flock, the presence of official identification on the animal traceable to the flock, the presence of other identification on the animal that is listed on the bill of sale, or other evidence, such as registry records."

#### Definition of Infected Flock

Several commenters stated that, in addition to designating as infected flocks the flocks of origin of scrapie-positive female animals, we should consider as infected any flock in which a scrapie-positive ewe lambed. We agree, and have changed the definition of infected flock in §§ 54.1 and 79.1 accordingly. The definition of *infected flock* has been changed to read: "The flock of origin of a female animal that a State or APHIS representative has determined to be a scrapie-positive animal; or any flock in which a State or APHIS representative has determined that a scrapie-positive female animal has resided, unless an epidemiologic investigation conducted by a State or APHIS representative shows that the animal did not lamb in the flock. A flock will no longer be considered an infected flock after it has completed the requirements of a flock plan."

#### Definition of Limited Contacts

One commenter suggested that the proposed definition of *limited contacts* in §§ 54.1 and 79.1, intended to define contacts that do not present a significant risk of spreading scrapie, was overly strict and would unnecessarily restrict the way in which animals are shown and transported. The proposed definition stated that a contact was not limited if it occurred within 60 days after lambing or kidding. We have reduced this exclusion to 30 days, since tissues and fluids associated with lambing are unlikely to be prevalent beyond this 30-day period. However, we have also added that the contact is not limited if it is with an animal that has aborted within the past 30 days or that had a vaginal discharge at the time of the contact, since infectious materials from abortions or discharges may

contaminate nearby animals. We are changing the text to read "Limited contacts do not include any contact, incidental or otherwise, with a female animal during or up to 30 days after she lambed, kidded, or aborted or when there is any visible vaginal discharge at the time of the contact." Readers interested in this issue should also note that the changes in the definitions of *flock* and *exposed animal* reduce the effect of the *limited contacts* definition on the transport and showing of animals.

Some commenters stated that they were confused by the language in the definition of *limited contacts* that said contact was not limited if it involved "uninhibited contact while sharing a section of a transport vehicle, or transportation to other flocks for breeding." The first restriction on sharing a section of a transport vehicle appears to make the second restriction redundant. For clarity, we have changed the second restriction to "residing in other flocks for breeding or other purposes."

#### *Definition of Official Eartag*

Several comments indicated confusion regarding the relationship of the terms *official eartag* and *premises identification* and questioned whether the proposal was consistent with existing national identification standards. We agree that the discussion in the proposal was unclear, and we are clarifying that the National Uniform Eartagging system or a combination of premises and individual animal identification numbers may be used. We have added a definition of *official eartag* to § 79.1 that reads "An identification eartag approved by APHIS as being sufficiently tamper-resistant for the intended use and providing unique identification for each animal. An official eartag may conform to the alphanumeric National Uniform Eartagging system or another system approved by APHIS, or it may bear a premises identification number that either contains or is used in conjunction with the producer's livestock production numbering system to provide a unique identification number."

#### *Definition of Official Identification*

We used the term *official identification* in the proposed rule, but commenters noted that it was undefined. We are adding a definition of *official identification* to § 79.1 for clarity. The definition reads as follows: "Identification mark or device approved by APHIS for use in the Scrapie

Eradication Program. Examples are listed in § 79.2(a)(2)."

#### *Definition of Premises Identification*

One commenter requested that ear notches that are officially registered be allowed in addition to brands, and another suggested that temporary paint brands (where owners of animals that will be temporarily commingled each mark their own animals with a strip of a particular paint color, to facilitate later separation of the animals) were adequate premises identification for animals that move without changing ownership. We agree and are revising the proposed definition of *premises identification* in § 79.1 to allow for the use of ear notches. We are changing the definition to read, "An APHIS approved eartag, backtag, or legible tattoo bearing the premises identification number, consisting of the State postal abbreviation or code followed by a unique alphanumeric number or name, assigned by a State or Federal animal health official to the premises of the flock of origin for the sheep or goats that, in the judgment of the State animal health official or area veterinarian in charge, is epidemiologically distinct from other premises, or a permanent legible brand or ear notch pattern registered with an official brand registry. Premises identification may be used when official individual animal identification is required, if the premises identification method either includes a unique animal number or is used in conjunction with the producer's livestock production numbering system to provide a unique identification number and where, if brands or ear notches are used, the animals are accompanied by an official brand inspection certificate. Clearly visible and/or legible paint brands may be used on animals moving directly to slaughter and on animals moving for grazing or other management purposes without change in ownership."

#### *Definition of Separate Contemporary Lambing Groups*

Several commenters suggested that we review other APHIS animal disease eradication programs to improve implementation of the scrapie program. This review showed that cleaning and disinfection for other disease programs are carried out under supervision. We agree that supervision is necessary, and have changed the definition of *separate contemporary lambing groups* in §§ 54.1 and 79.1 accordingly, to require supervision of cleaning and disinfection by an APHIS or State representative or an accredited veterinarian, and to require records documenting animal

grouping and documenting cleaning and disinfection.

We have also clarified the proposed definition, which stated that guidelines for cleaning and disinfection could be found in the Scrapie Flock Certification Program standards. We have moved requirements for cleaning and disinfection from the Scrapie Flock Certification Program standards into § 54.7(e) of the regulations. Guidelines and examples regarding how to apply these requirements may now be found in both the Scrapie Flock Certification Program standards and the Scrapie Eradication Uniform Methods and Rules.

#### *Definition of Source Flock*

Several commenters suggested that the definition of *source flock* in §§ 54.1 and 79.1 should be qualified by stating how the determination that an animal was born in a flock should be made. We agree and have changed the definition to state that the determination that an animal was born in a flock will be based on such information as the presence of official identification on the animal traceable to the flock, the presence of other identification on the animal that is listed on the bill of sale, or other evidence, such as registry records, to show that a scrapie-positive animal originated from the flock, combined with the absence of any records indicating that the animal was purchased from outside and added to the flock.

One commenter recommended that only official identification be accepted for tracebacks. We disagree, because there are often cases where registry records or bills of sale are adequate for positive identification of an animal, and sometimes these documents are available when official identification is not. Commenters also suggested that DNA comparison be used for positive identification of traced animals. We agree that an owner should be allowed to request verification of a traced animal's identity through DNA comparison, at the owner's expense, when the conditions exist to make such verification possible and reliable. These conditions exist in those cases where DNA has been archived at an approved genotyping laboratory, or if DNA collection and storage are required for breed registration and the breed registration has appropriate safeguards in place to ensure the integrity of the banking process, and when adequate records and identification have been maintained by the owner and the repository. We have changed the definition of *source flock* accordingly.

As discussed above regarding the definition of *exposed animal*, commenters suggested we reexamine the scientific basis of the timeframes in the proposed rule. The proposal assumed that animals exposed at birth would die by the age of 54 months. We reexamined the data and concluded that it shows that while almost all animals that contract scrapie at birth die at an age of 72 months or less, animals that contract scrapie post-weaning do not die from it until at least the age of 73 months. Weaning normally occurs 80–90 days after birth. Therefore, if an animal is diagnosed with scrapie at an age of 73 months or more, it did not contract scrapie at birth, and its flock of birth should not be considered a source flock based on the diagnosis. Therefore, we have amended the definition of *source flock* to state that it includes flocks where at least one animal was born that was diagnosed as a scrapie-positive animal at an age of 72 months or less.

As amended according to the comments discussed above, the definition of source flock in this final rule now reads as follows: “A flock in which a State or APHIS representative has determined that at least one animal was born that was diagnosed as a scrapie-positive animal at an age of 72 months or less. The determination that an animal was born in a flock will be based on such information as the presence of official identification on the animal traceable to the flock, the presence of other identification on the animal that is listed on the bill of sale, or other evidence, such as registry records, to show that a scrapie-positive animal was born in the flock. If DNA from the animal was previously collected by an accredited veterinarian and stored at an approved genotyping laboratory, or if DNA collection and storage are required for breed registration and the breed registration has appropriate safeguards in place to ensure the integrity of the banking process, the owner may request verification of the animal’s identity based on DNA comparison if adequate records and identification have been maintained by the owner and the repository to show that the archived DNA is that of the animal that has been traced to the flock. The owner will be responsible for all costs for the DNA comparison. A flock will no longer be a source flock after it has completed the requirements of a flock plan.”

#### Definition of High-Risk Animal

Commenters suggested two specific changes to the definition of *high-risk animal*. The first suggestion was that

only sexually intact animals should be considered high-risk, since other animals are extremely unlikely to spread scrapie. The second suggestion was that an animal born into the same flock in which a scrapie-positive animal was born should not be considered high-risk if the animal was born after the flock completes the requirements of a flock plan, designed to remove the risk of spreading scrapie.

We agree, and have added language to the definition of high-risk animal in §§ 54.1 and 79.1 to accomplish these changes. We have also made changes to this definition in response to comments suggesting that the regulations incorporate the most recent scientific research on animal genetics and resistance to scrapie, discussed below. As revised, the definition of *high-risk animal* reads as follows: “A sexually intact animal, excluding male sheep that have tested RR at codon 171 and AA at codon 136 using an official genotype test, that is:

(1) The progeny of a scrapie-positive dam; or

(2) Born in the same flock during the same lambing season as progeny of a scrapie-positive dam, unless the progeny of the scrapie-positive dam are from separate contemporary lambing groups; or

(3) Born in the same flock during the same lambing season that a scrapie-positive animal was born, or during any subsequent lambing season, if born before that flock completes the requirements of a flock plan; or

(4) An exposed female sheep that has not tested QR, HR, or RR at codon 171 using an official genotype test.”

#### Definition of Suspect Animal

Some commenters indicated that the movement restrictions in proposed § 79.3 were overly complex. In response, we have combined the categories of *suspect animal* and *affected animal* into one category. We have done this by adding the following to the definition of *suspect animal* in §§ 54.1 and 79.1: “A sheep or goat that has tested positive for scrapie or for the proteinase resistant protein associated with scrapie on a live-animal screening test or any other test is a suspect animal, unless it is designated a scrapie-positive animal.” This removes the need to use the term *affected animal*, which essentially applied to animals that tested positive to a live-animal screening test. In the November 30 proposal, the same movement restrictions applied to suspect animals and affected animals, so this change will not alter movement restrictions. This change reduces the complexity of the rule and removes the

need for States to change their regulations to separately address affected animals. It also closes a loophole that would have allowed sheep and goat owners to use unofficial tests without any risk that positive results would result in restrictions on the movement of the animals. Under the new definition, animals that test positive to unofficial tests would be designated suspect animals. This designation may be removed in accordance with § 79.4.

#### New Definitions of Commercial Sheep or Goat, Low-Risk Goat, and Low-Risk Commercial Sheep

Several commenters suggested that lesser interstate movement restrictions were appropriate for animals that are raised primarily for production and that are of a breed type or cross that has a low prevalence of scrapie. These commenters suggested that whitefaced animals from commercial flocks in States where scrapie has not been reported in whitefaced animals do not represent a substantial scrapie risk.

We agree, and have added two new definitions to § 79.1 that are used in the chart of interstate movement restrictions in § 79.3, *commercial sheep or goat* and *blackfaced sheep*. A commercial sheep or goat is any animal from a flock from which animals are moved only either directly to slaughter or through slaughter channels to slaughter or any animal that is raised only for meat or fiber production and that is not registered with a sheep or goat registry or used for exhibition. A blackfaced sheep is any purebred suffolk, hampshire, shropshire or cross thereof, any non-purebred sheep known to have suffolk, hampshire, or shropshire ancestors, and any non-purebred sheep of unknown ancestry with a black face, except commercial hair sheep. We are defining blackfaced sheep in the regulations, rather than whitefaced sheep and whitefaced crossbreeds, because blackfaced sheep are the higher risk category and defining this term makes it easier to address risk in the requirements and exemptions contained in the regulations.

Several commenters suggested that we should simplify the chart of interstate movement restrictions in § 79.3 and provide lesser restrictions for certain low-risk goats and commercial sheep. We agree, and have done so by adding definitions of low-risk goat and low-risk commercial sheep and then referring to those defined terms in the chart. We are defining *low-risk goat* in § 79.1 as a goat that is not a scrapie-positive, suspect, high-risk, or exposed animal, that has not been commingled with sheep, and

that meets certain other requirements that indicate the goat has a low risk of spreading scrapie. These other requirements are that the goat must be from:

(1) A State in which scrapie has not been identified in a goat during the previous 10 years;

(2) A State in which scrapie has been identified in a goat during the previous 10 years, but the scrapie-positive goat was not born in the State and resided in the State for less than 72 months and did not kid while in the State; or,

(3) A State in which scrapie has been identified in a goat during the previous 10 years, and the scrapie-positive goat was commingled with sheep, but flock records allowed a complete epidemiologic investigation to be completed and all resulting infected, source, and exposed goat herds have completed flock plans and are in compliance with post-exposure monitoring plans.

Similarly, we are defining *low-risk commercial sheep* in § 79.1 in a manner that excludes blackfaced sheep, animals that are known to be at risk of having scrapie or having been exposed to scrapie, and animals that are not sufficiently identified to determine their flock of origin. We define *low-risk commercial sheep* as "Commercial whitefaced, whitefaced cross, or commercial hair sheep from a flock with no known risk factors for scrapie, including any exposure to female blackfaced sheep, that are identified with a permanent brand or ear notch pattern registered with an official brand registry and that are not scrapie-positive, suspect, high-risk, or exposed animals and are not animals from an infected, source, or exposed flock. The term brand includes official brand registry brands on ear tags in those States whose brand law or regulation recognizes brands placed on ear tags as official brands. Low-risk commercial sheep may only exist in a State where scrapie has not been diagnosed in the previous 10 years in commercial whitefaced, whitefaced cross, or commercial hair sheep that were not commingled with female blackfaced sheep."

#### *Additional New Definitions*

We are also adding new definitions for the following terms: *commercial hair sheep*, *ownership brand*, *official test*, *official genotype test*, *approved laboratory*, *unofficial test*, *direct movement to slaughter*, and *flock sire*.

In order to properly separate risk categories it is necessary to make distinctions between hair sheep and other types of sheep, making it

necessary to define commercial hair sheep. We are adding a definition of *commercial hair sheep* to § 79.1 to read "Any commercial sheep with hair rather than wool that is either a full-blooded hair sheep or that resulted from the cross of a hair sheep with a whitefaced wool sheep."

In the proposal ownership brands were not defined. We have added a definition of *ownership brand* to § 79.1, using the definition commonly accepted in livestock industries: "A unique permanent brand or ear notch pattern applied to an animal that indicates ownership by a particular person when the brand pattern is registered with a State's official brand recording agency."

Several commenters recommended that there be greater flexibility in the handling of infected and source flocks. We agree. In order to organize changes to provide greater flexibility it is necessary to define a term that includes all approved tests and that indicates where such tests must be conducted in order to be used for this purpose. We are adding the following definition of *official test* to §§ 54.1 and 79.1: "Any test for the diagnosis of scrapie in a live or dead animal that is approved by the Administrator for that use and conducted either at an approved laboratory or at the National Veterinary Services Laboratories." Commenters also stated that if the rule distinguishes the risk level of animals based on their genotype, it should define a means for approving acceptable methods of genotype testing. We agree, and are adding the following definition of *official genotype test* to §§ 54.1 and 79.1: "Any test to determine the genotype of a live or dead animal that is conducted at either an approved laboratory or at the National Veterinary Services Laboratories, when the animal is officially identified and the samples used for the test are collected and shipped to the laboratory by either an accredited veterinarian or a State or APHIS representative." We are also adding a complementary definition of *approved laboratory* to §§ 54.1 and 79.1: "A laboratory approved by the Administrator in accordance with § 54.11 to conduct one or more scrapie tests, or genotype tests, on one or more tissues."

To clearly distinguish official tests from other tests that owners may conduct for their own purposes, we are also adding the following definition of *unofficial test* to §§ 54.1 and 79.1: "Any test for the diagnosis of scrapie or for the detection of the proteinase resistant protein associated with scrapie in a live or dead animal that either has not been approved by the Administrator or that

was not conducted at an approved laboratory or at the National Veterinary Services Laboratories."

One commenter stated that, in some circumstances, the proposal would require that animals be moved directly to slaughter, but did not define what this means. We agree that clarification would be useful, and we have added to § 79.1 a definition of *direct movement to slaughter* that reads "Transported to a facility for slaughter, without stops or unloading except for feeding and watering during which the animals are not commingled with any other animals."

We are also adding to § 54.1 the following definition of *flock sire*, a type of animal that is eligible for a premium indemnity under the rule: "A sexually intact male animal that has ever been used for breeding in a flock."

#### *Destruction by Slaughter of High-Risk, Exposed, and Scrapie-Positive Animals*

Several commenters indicated that high-risk and exposed animals and animals that test positive to a live-animal screening test should be permitted to move to slaughter because there is no known human health risk from scrapie and Food and Drug Administration (FDA) regulations provide adequate protection against inclusion of the scrapie agent in ruminant feed. These commenters argued that sending these animals to slaughter is usually more economical and less difficult than arranging other means of disposal.

We agree that there is no evidence that scrapie is a human health risk and significant evidence that it is not a human health risk. The World Health Organization recommendation calls for the exclusion of small ruminants showing signs of a TSE from slaughter to address a theoretical risk. In keeping with this recommendation small ruminants with clinical evidence of central nervous system disease are condemned by the Food Safety Inspection Service (FSIS) on ante-mortem inspection. Excluding test-positive animals goes one step farther to exclude the scrapie agent from the food and feed chains. We believe that excluding from slaughter animals that test positive to a live-animal test is warranted to maintain consumer confidence and minimize the risk of the scrapie agent entering the human and animal food chains.

We agree with the commenters that most scrapie-exposed and high-risk animals do not, in fact, contain the scrapie agent. Under the proposed rule, high-risk animals would be indemnified but prohibited from going to slaughter

while scrapie-exposed animals would not be indemnified and could be slaughtered. Since both types of animals share the same, low risk of spreading scrapie, we have now decided that it is not consistent to keep one set of these animals from slaughter but allow the other set to go to slaughter. Also, owners of non-indemnified scrapie-exposed and high-risk animals can recoup much of the animals' economic value by sending the animals to slaughter, although such animals usually fetch a discounted price from slaughter plants. Keeping these animals from slaughter would also present additional environmental problems related to finding enough landfills and incinerator capacity to deal with the large number of exposed and high-risk animals. Therefore, we are changing the definition of *destroyed* in § 54.1 to allow indemnified high-risk animals to move to slaughter; however, we continue to prohibit movement to slaughter of animals that test positive to a live-animal test in order to minimize the amount of scrapie agent in the food chain, since these animals are known to contain PrP-sc, which has been linked to the presence of the scrapie agent. We are also making corresponding changes in § 54.7, "Procedures for destruction of animals," to allow indemnified animals (except for scrapie-positive or suspect animals) to move to slaughter, or to a quarantined research facility or another location for destruction, if the movement is approved by APHIS. Note that this change does not affect the FDA regulations that continue to prohibit the inclusion of animal protein derived from mammalian tissues in ruminant feed.

We are also amending the definition of *destroyed* to include movement to a quarantined research facility when such movement is authorized by the Administrator. The scrapie program has always authorized some animals that would otherwise have to be euthanized to be moved for research purposes, and this change to the definition acknowledges that such movements satisfy the regulatory requirement to destroy an animal.

#### *Cooperative Agreements and Memoranda of Understanding With States*

The November 30 proposal did not propose regulatory requirements for cooperative agreements and memoranda of understanding, but it did solicit comments on whether it would be desirable to require States to sign a compliance agreement with APHIS describing State scrapie program operations, cooperative activities with APHIS, and planning and financing

details for these activities. Several commenters suggested that the final rule should contain a section authorizing and describing such agreements. We agree, and have added a new § 54.2 describing cooperative agreements and memoranda of understanding for activities under both the Scrapie Eradication Program and the Scrapie Flock Certification Program. Based on suggestions from commenters, this section states that such agreements will describe the respective roles of APHIS and State personnel in implementing the Scrapie Eradication Program and the Scrapie Flock Certification Program. Each agreement may specify the financial, material, and personnel resources to be committed to these programs and other scrapie control measures by APHIS and the State and assign specific activities related to the control of scrapie within a State to APHIS or State personnel. The agreements may also establish schedules for APHIS representatives or State representatives to visit flocks, establish procedures for maintaining and sharing program records, and specify other responsibilities of State representatives and APHIS representatives in support of the Scrapie Eradication Program and the Scrapie Flock Certification Program.

#### *Indemnity Values and Application for Indemnity*

Numerous commenters indicated that the indemnity value set for sheep was too low and should be based on market value. The indemnity payments proposed were \$150 for registered animals and \$50 for other animals and were significantly lower than the average national sale price of sheep. After evaluating comments on this issue, we agree that an indemnity that approximates fair market value would increase compliance and assist scrapie control. We have considered several methods for establishing market value and have decided to rely, as other indemnity programs have done, on the average sale price information published by the U.S. Department of Agriculture's Agricultural Marketing Service (AMS). The indemnity value will be set weekly by APHIS based on the ewe and lamb market prices reported by AMS and will be posted on the APHIS scrapie web page. We are field testing this market based method by using it to purchase animals for diagnostic purposes.

Specifically, we are changing § 54.6, which sets the amounts of indemnity payments, to state that indemnity for sheep will be set based on the following AMS price reports: The weekly weighted average Choice/Prime

slaughter lamb prices at Greeley, CO; the weekly weighted average Utility slaughter ewe prices at San Angelo, TX; the monthly weighted average commercial western ewe lamb replacement price per head; the monthly weighted average commercial western yearling ewe replacement price per head; the monthly weighted average commercial western running age ewe price per head; and the monthly weighted average commercial western aged ewe price per head.. If pricing information is unavailable from these markets during a given week or month, or if the numbers sold are too low to give an accurate market value, the preceding week or month's value will be used. The AMS reports from the most recent week or month prior to the date APHIS first offers to pay an owner indemnity shall be used to calculate the indemnity for that owner's sheep.

In contrast to indemnities for sheep, indemnities for goats will be calculated based directly on the value of the goat as indicated by the producer's purchase records and sales records for the preceding 12 to 24 months, not to exceed the maximum indemnity allowed for sheep. We are not establishing a complicated, market price-based formula for calculating indemnities for goats because based on program experience there will be extremely few goats eligible for indemnity. Program experience also suggests that sales and purchase records of goats are a good guide to the fair market value of goats, and it will be cost-effective to calculate the indemnity individually in each case from these records.

The amount of indemnities for sheep will be calculated as follows: For sheep under 1 year of age, the indemnity will equal the weekly weighted average Choice/Prime slaughter lamb price per pound times 50 lbs, or times the actual weight, whichever is more. (The default weight of 50 lbs was selected to fairly compensate owners whose sheep were identified as eligible for indemnity while very young, before they achieved significant weight gain.) However, for ewe lambs under 1 year of age, the indemnity will equal the monthly weighted average commercial western ewe lamb replacement price per head, if this price is higher, since ewe lambs might have a greater potential value as breeding animals. For sexually intact sheep 8 years of age or older and castrated animals 1 year of age or older, the basic indemnity shall equal the weekly weighted average Utility slaughter ewe price per pound times 150, based on an average weight of 150 lbs. For mature sexually intact sheep at

least 1 year of age and under 2 years of age, the indemnity will equal the greater of the monthly weighted average commercial western yearling ewe replacement price per head, or the weekly weighted average Utility slaughter ewe price per pound times 150, based on an average weight of 150 lbs. For mature sexually intact sheep at least 2 years of age and under 6 years of age, the basic indemnity will equal the greater of the monthly weighted average commercial western running age ewe price per head, or the weekly weighted average Utility slaughter ewe price per pound times 150, based on an average weight of 150 lbs. For mature sexually intact sheep at least 6 years of age and under 8 years of age, the basic indemnity will equal the greater of the monthly weighted average commercial western aged ewe price per head, or the weekly weighted average weekly Utility slaughter ewe price per pound times 150, based on an average weight of 150 lbs. If records and identification are inadequate to determine the actual age of animals, an APHIS or State representative will count all sexually intact animals that are apparently under 1 year of age, and those that are apparently at least 1 and under 2 years of age, based on examination of their teeth, and the indemnity for these animals will be calculated. The total number of these animals will be subtracted from the total number of sexually intact animals in the group to be indemnified, and indemnity for the remainder will be calculated based on the assumption that the remainder of the flock is 80 percent aged 2 to 6 years and 20 percent aged 6 to 8 years. This assumed age distribution reflects the fact that animals tend to die or be culled as they get older. Most ewes in commercial flocks are eliminated between 6 to 8 years of age.

As many commenters requested, we will increase the indemnity amounts for registered animals to partially compensate owners for the greater value of these animals. We will add a premium to the basic indemnity for each registered animal equal to \$100 for each registered animal under 1 year of age, \$200 for each registered animal at least 1 year of age and under 4 years of age, and \$100 for each registered animal at least 4 years of age and under 8 years of age. In addition to this, we will add a premium of \$50 to the indemnity for each flock sire. Also, any animal that is not registered at the time indemnity is first offered, but is eligible to be registered, will receive the registered animal premium reduced by \$50. The

owner must provide adequate records to qualify for these premiums.

As a result of the change in the definition of *destroyed* to allow high-risk animals eligible for indemnity to be destroyed by slaughter, it was necessary to address the effect of moneys received from slaughter plants on the amount of indemnity received by owners of animals disposed of by being sent to slaughter. We are changing § 54.6 to provide that, for animals destroyed by slaughter, the owner will retain the salvage value (the amount paid by a slaughter plant for the animal) of animals. If the salvage value, less shipping costs, is less than the slaughter price used to calculate indemnity, APHIS will pay the owner the difference. APHIS will also indemnify the owner in the amount of any productivity, registered animal, or flock sire premiums for which the animal qualifies.

We anticipate that owners will wish to have recourse if they believe that the average weights used to calculate indemnities do not fairly represent the weights of animals in their flock. We have revised § 54.6 to allow an owner who disagrees with the average weight estimate to have the sheep weighed at a public scale at his own expense (the usual average weighing fee is less than \$1 per animal, though there will be additional expense if the owner must transport them to be weighed). In such a case, the owner will be paid based on the actual weight times the AMS weekly average price.

We have also clarified that indemnity will be paid to an owner only for animals actually in a flock at the time indemnity is first offered. Animals removed from the flock as part of a post-exposure management and monitoring plan will be paid indemnity based on the AMS average prices at the time an APHIS representative designates the animals for removal.

We received several comments concerning § 54.4, the section describing how to submit an application for indemnity. One comment noted that the proposal stated that normally a State or APHIS representative would initiate the application for a flock that is already under a State quarantine. This comment stated that some States do not actually call the movement restrictions they place on flocks a "quarantine," and the regulations should not use this term here to avoid confusion. We agree, and have changed "State quarantine" to "State movement restrictions." In such cases, the flock owner will confirm information about the flock's eligibility for indemnity that is contained in the application submitted by the APHIS or

State representative. Another comment noted that under the proposal, flock owners could choose to apply directly for indemnity, rather than having a State or APHIS representative make the application, in all cases, except for flocks that were under State quarantines (movement restrictions). The commenter did not see the purpose of excluding flocks under State movement restrictions from applying directly for indemnity. Neither do we, and we have removed this restriction.

Another commenter noted that proposed § 54.4(a)(5) required registration papers for any registered animals in a flock to accompany the application for indemnity. This commenter stated that the language did not make it clear that owners may apply for indemnity for unregistered animals without registration papers. To clarify this, we have added the phrase "registration papers are not required for the payment of indemnity for animals that are not registered" to this paragraph.

#### *Certification by Owners Receiving Indemnity*

Proposed § 54.5 required owners receiving indemnity to sign an agreement with APHIS certifying that the owner would cooperate with certain conditions. One of these conditions was to allow an APHIS representative, upon request, to review bills of sale and other records of the flock. One commenter suggested that this agreement should also allow State representatives to review these records. We agree, and have made that change.

The proposed agreement would also require flock owners that maintain a flock after receiving indemnity to maintain that flock under a post-exposure management and monitoring plan. One commenter suggested that the agreement should specify how long the flock would have to be subject to the post-exposure management and monitoring plan. We agree, and have added "for 5 years" to this requirement. Five years of monitoring is consistent with normal epidemiological practice and guidance in the Scrapie Flock Certification Program standards.

We have also added to the agreement, based on another comment, that the owner must allow any animal for which indemnity is paid to be removed to a U.S. Department of Agriculture facility or a quarantined research facility, slaughtered, or euthanized and necropsied and tissues removed for diagnostic or other purposes. This change will ensure that APHIS has access to animals when they are needed



for testing to further our knowledge of scrapie transmission patterns.

#### *Identification of Sheep and Goats in Interstate Commerce*

Several commenters suggested changes to proposed § 79.2(a)(1), which specified where and when identification should be attached to animals that must be identified under the regulations. The proposal stated that animals must be identified at whichever of the following occurs first: The point of first commingling of the sheep or goats in interstate commerce with sheep or goats from any other source; upon unloading of the sheep or goats in interstate commerce at any livestock market; upon transfer of ownership of the sheep or goats in interstate commerce; or upon arrival of the sheep or goats in interstate commerce at their final destination.

Some commenters stated that animals should always be identified before being moved from their flock of origin, rather than at any later stage of movement, because this would minimize chances for errors in identification and would eliminate the need for markets, slaughter plants, or other businesses to apply identification. We agree in part and have changed the wording in § 79.2(a)(1) to require the owner of the flock of origin or his agent to identify the animals. This does not preclude the owner of the flock of origin from contracting with a livestock market, slaughter plant, or other person to act as his agent for the purpose of applying official identification at the first point in movement where official identification is required. In response to comments suggesting that animals be identified to their flock of birth, not just their flock of origin, we are requiring identification to the flock of birth for animals born after January 1, 2002. The delay in this requirement's effective date will give owners an opportunity to prepare for the new requirement. To further mitigate the impact on owners and markets, we are allowing animals moving interstate *directly to slaughter* to move without flock-of-birth identification until June 1, 2003.

We have also amended § 79.2(a)(1) to note the fact that the regulations, in § 79.6(a)(10)(i), allow Consistent States to exempt certain low-risk animals in intrastate commerce from being identified to their flock of origin or birth. It would be impractical and unnecessary to require that these animals be identified to their flock of origin or birth in order to move interstate, so we have amended our identification requirements for animals in interstate commerce to state that animals that Consistent States have

exempted from flock of origin identification in intrastate commerce in accordance with § 79.6(a)(10)(i) may be moved interstate with only individual animal identification traceable to the State of origin and to the owner of the animals.

We have also clarified that if an owner fails to arrange required official identification for his animals, other persons engaged in moving those animals (shippers, markets, slaughter plants, etc.) may not move the animals unless the required identification is accomplished. It would have undesirable effects on compliance with the regulations if other persons engaging in interstate commerce were free to move animals that an owner failed to identify. In some cases, this requirement may result in shippers, markets, or other parties applying official identification to animals, using information from owners' statements or bills of sale, in order to legally move the animals in interstate commerce.

Commenters also suggested that identification requirements be kept to a minimum. In response to this we have identified one case where the proposed identification requirement appears to be unnecessary. The proposal required individual identification of animals whose final destination was a slaughter plant. The proposal also allowed those animals to be moved interstate without such identification if it was applied after the animals arrived at the slaughter plant. Since individual identification would be required at slaughter plants primarily to allow APHIS to conduct slaughter sampling and trace back positive animals, we believe that this identification would serve no purpose on those days when APHIS does not conduct slaughter sampling at a plant, and we have removed this individual identification requirement in such cases.

A commenter noted that the requirements for Consistent State status mean that States will require identification even when animals change ownership within a State. The commenter also noted that the State requirement would facilitate identifying animals moving interstate under the Federal regulations. We agree. No change is necessary in response to this comment since § 79.2(a)(1)(iv) requires identification "upon transfer of ownership of the sheep or goats in interstate commerce."

In accordance with the above comments, we have revised § 79.2(a)(1) to read as follows:

(1) The sheep or goat must be identified to its flock of origin and, for an animal born

after January 1, 2002, to its flock of birth, by the owner of the flock or his or her agent; at whichever of the following points in commerce comes first, Except that; animals born after January 1, 2002, may be moved interstate direct to slaughter without identification to flock of birth until June 1, 2003, and animals that cannot be identified to their flock of origin because Consistent States have exempted them from flock of origin identification in intrastate commerce in accordance with § 79.6(a)(10)(i) may be moved interstate with only individual animal identification traceable to the State of origin and to the owner of the animals at the time they were so identified:

(i) The point of first commingling of the sheep or goats in interstate commerce with sheep or goats from any other flock of origin;

(ii) Upon unloading of the sheep or goats in interstate commerce at any livestock market, except a market described in paragraph (a)(1)(iii) of this section;

(iii) Upon leaving a livestock market that has been approved in accordance with this chapter to handle sheep and goats in interstate commerce and that has agreed to act as an agent for the owner to apply official identification to the animals. In such cases the animals must be:

(A) Moved to the market and maintained until officially identified in distinguishable groups identifiable to their flocks of origin and when required their flock of birth by means of partitions or other such maintenance; and,

(B) Accompanied by an owner statement that contains the information needed to officially identify the animals to their flock of origin and, when required, their flock of birth;

(iv) Upon transfer of ownership of the sheep or goats in interstate commerce;

(v) In the case of animals shipped directly to slaughter at a slaughter plant that has agreed to act as an agent for the owner to apply official identification to the animals, upon arrival of the sheep or goats in interstate commerce at the slaughter plant. In such cases the animals must be:

(A) Moved to the slaughter plant and maintained until officially identified in distinguishable groups identifiable to their flocks of origin and when required their flock of birth by means of partitions or other such maintenance; and,

(B) Accompanied by an owner statement that contains the information needed to officially identify the animals to their flock of origin and, when required, their flock of birth. If the slaughter plant has agreed to allow APHIS to conduct slaughter sampling, animals need not be identified if they arrive at the plant on days that an APHIS designated sampler is not available at the plant to collect samples; or

(vi) Prior to moving a sheep or goat across a State line, unless the animals are moving to an approved livestock market in accordance with (a)(1)(iii) of this section or to an approved slaughter plant in accordance with (a)(1)(v) of this section.

Numerous commenters requested that we acknowledge that some forms of premises identification could satisfy the



proposed requirement for identification of animals moving interstate. It is in some cases less expensive and troublesome for owners and persons selling and buying animals to apply premises identifications to the animals, and to maintain records indicating which premises animals came from, than to maintain records of a unique identifying number for each animal when a group of animals is moved interstate.

We agree that we can make some changes to the individual animal identification requirements in proposed § 79.2 to make the process less burdensome. However, the identification must be sufficient to allow traceback of individual animals at any point in interstate commerce or else the disease control purpose of the identification suffers. To address the concerns of commenters to the extent possible, we are adding provisions to § 79.2 that will allow interstate movement of animals marked with a premises identification eartag or backtag that bears a unique number associated with the animal to which the tag is applied. Eartags approved for use in the Scrapie Flock Certification Program (SFCP) are already approved for this use, and other eartags and backtags may be approved by APHIS.

Specifically, we are changing § 79.2(a)(2), which identifies acceptable means of identification, by revising paragraphs (ii) and (iii), which refer to eartags and backtags, respectively.

Paragraph (ii) in the proposal read: "Official eartags, including tags approved for use in the SFCP, when used on any sheep or goat." We are changing paragraph (ii) to read: "Official eartags, including tags approved for use in the SFCP or APHIS-approved premises identification number eartags when combined with a unique animal identification number."

Paragraph (iii) in the proposal read: "United States Department of Agriculture backtags, when used on sheep or goats moving to slaughter." We are changing paragraph (iii) to read: "United States Department of Agriculture backtags or official premises identification backtags that include a unique animal identification number, when used on sheep or goats moving directly to slaughter and when applied within 3 inches of the poll on the dorsal surface of the head or neck." This change is based on comments that suggested that premises backtags that include a unique animal identification number are suitable for individual animal identification, and that suggested a standard location on the

head or neck to make it easy to collect the tag at slaughter.

Comments on proposed § 79.2(b), which dealt with how serial numbers and other codes for official identification would be issued, suggested that APHIS provide more detail on how these codes would be assigned by USDA to State officials and other intermediaries who could ultimately assign them for use by particular flocks. These comments suggested that it would be efficient to allow various animal health personnel, such as 4-H leaders, to be assigned blocks of codes that they could reassign to flocks. The comments stated that this means of assigning codes would be convenient for flock owners and would be reliable as long as USDA had initial control of the code assignments and subsequent assignments were identified to the premises on which the codes are used in a USDA database.

We agree, and have added the following language to § 79.2(b): "The official responsible for issuing eartags in a State may assign serial numbers of official eartags to other responsible persons, such as 4-H leaders, if the State animal health official and the area veterinarian in charge agree that such assignments will improve scrapie control and eradication within the State. Persons assigned serial numbers may either directly apply eartags to animals, or may reassign eartag numbers to producers. If these persons reassign eartag numbers, they must maintain appropriate records that permit traceback of animals to their flock of origin, or flock of birth when required. Premises identification eartag, backtag, and tattoo numbers (series of alphanumeric USDA tags and backtags may be assigned as premises identification if they are linked to the premises in the National Scrapie Database) will be assigned to animal owners by the State animal health official or the area veterinarian in charge, whoever is responsible for assigning premises codes in that State."

Proposed § 79.2(c) provided that, when animals move interstate, the buyers, sellers, and transporters would all have to keep records containing all serial numbers and other approved means of identification appearing on each sheep or goat. In this final rule, these requirements have been changed and moved to § 79.2(d). This paragraph now provides that, when the animals are identified to the premises of the flock of origin, the records will have to show the premises identification, which will be the same for all animals from a premises, rather than the unique identification number associated with

each animal. The eartag or backtag on each animal will have a unique identification number, which APHIS can use, if necessary, in combination with the flock owner's records to conduct an epidemiologic investigation. We have also amended § 79.5, "Issuance of Certificates," to note that for movements where premises identification instead of individual animal identification is allowed, the certificate will record the premises identification number rather than individual animal identification numbers.

#### *Chart of General Restrictions*

Comments have led us to substantially revise the chart in § 79.3, which contains restrictions and identification requirements for sheep and goats moved interstate. Many commenters suggested that the chart in this section should take more note of the fact that sexually intact female animals present an inherently higher risk of spreading scrapie than neutered animals, since lambing and kidding have been identified as chief opportunities for the spread of scrapie.

When consolidated, these comments suggested that the chart should be organized to provide different levels of identification and restriction for six different groups of animals. The six groups represent six different risk levels for spreading scrapie, ranging from high risk to low risk. The groups are as follows, beginning with the highest risk group:

- Scrapie-positive, suspect, or high-risk animals.
- Animals from an infected or source flock that are not scrapie-positive, suspect, or high-risk animals.
- Exposed female animals that are sexually intact and are not scrapie-positive, suspect, or high-risk animals or from an infected or source flock.
- Sexually intact female animals that are not scrapie-positive, suspect, high-risk, or exposed animals or animals from an infected or source flock.
- Commercial whitefaced sheep, commercial hair sheep, and commercial goats when they are in low-risk flocks.
- Castrated or spayed animals that are not scrapie-positive or suspect animals and are not from an infected or source flock.

We have reorganized the chart based on these major groups of animals, although the chart actually establishes more categories using risk-based subdivisions of these groups. The restrictions and identification requirements this final rule requires for the various categories of animals are similar to the requirements in the chart

in the proposal, and range from prohibition of movement for the first group through no requirements for some members of the last group.

Like the chart in the proposed rule, the chart in this final rule distinguishes the level of restriction and identification required based on whether an animal is being moved to slaughter, to be bred, to be displayed at a show, or for other reasons. As commenters pointed out, it is necessary to preserve these distinctions because each type of movement presents different opportunities for animals to spread or contract scrapie, and therefore different levels of risk.

Many commenters also suggested that the identification requirements for lambs moved to slaughter be relaxed. The proposal required that lambs moved to slaughter be individually identified if they were over 6 months of age. Some commenters presented economic arguments that it was simply too expensive and difficult for large production flocks to individually identify hundreds or thousands of lambs in order to move them to slaughter. Other commenters presented arguments based on the age at which scrapie can be first diagnosed. Both types of comments urged that individual animal identification for animals moving to slaughter should not be required until animals reach sexual maturity. The age at which commenters suggested lambs should be identified ranged from 9 to 18 months.

APHIS agrees that age and sexual maturity are important benchmarks that can be used to divide animals into different groups characterized by different risk levels for scrapie transmission or differing suitability for diagnosis of the disease. We have revised the chart to take this into account. The chart contains lesser restrictions for animals under 18 months of age and greater restrictions for animals over that age. The more severe restrictions will also apply to animals that have lambed or kidded, even if they did so at less than 18 months of age. Specifically, the dividing line in the chart will impose greater restrictions on an animal that has lambed or kidded, or that is over 18 months of age, as evidenced by eruption of the second incisor.

One commenter recommended that identification not be required for animals under 14 months of age, whether they are from Consistent or Inconsistent States, when the animals are in slaughter channels or have been castrated. We agree in part and have removed the identification requirement for castrated animals under 18 months

of age and for sexually intact animals that are under 18 months of age when they are moved directly to slaughter or to a terminal feedlot from an Inconsistent State. No identification is required for castrated or sexually intact animals under 18 months of age in slaughter channels when they are moved from a Consistent State.

Some commenters wanted the identification and permitting requirements for high-risk animals relaxed. APHIS believes that it is critical to maintain control of these animals through slaughter to ensure that they do not return to the farm. No changes were made based on these comments.

Based on comments that movement restrictions should use newly-developed genetic tests as a tool, we have added genetic testing as a requirement for the movement of sexually intact exposed animals that are moved for breeding, show, grazing, or other purposes. We have added a requirement to § 79.3(a)(3) and (d)(3) that for female sheep in these classes, the results of an official genotype test showing QR or RR at codon 171 must be included on or attached to the permit that is required to move these animals.

Several other changes to the chart in § 79.3 are discussed below, in context with the comments which brought them about. These comments addressed movement restrictions for goats, methods for issuing certificates and the statements certificates should contain, and other issues.

#### *Proposed List of Consistent States*

In the August 15 proposal we stated that the Administrator had evaluated the qualifications of States in accordance with the standards for Consistent States proposed in the November 30 proposal. The Administrator evaluated State statutes, regulations, and directives pertaining to animal health activities, reports, and publications of State animal health agencies, and a written statement from each State animal health agency describing State scrapie control activities. The August 15 proposal announced that all 50 States had submitted written statements indicating their willingness to comply with the proposed requirements and provided copies of their regulatory authority to carry out these actions. The August 15 proposal also proposed certain changes to the standards that a State would have to meet to qualify as a Consistent State and announced that, based on the Administrator's evaluation of all State submissions and other information and reports describing scrapie quarantine and control activities in the States, the

Administrator had determined that all 50 States meet the proposed standards for Consistent State status. One of the standards for Consistent State status, in § 79.6(a)(3) of this final rule is that each State must sign a memorandum of understanding (MOU) between APHIS and the State that delineates the respective roles of each in National Scrapie Program implementation. Prior to the August 15 proposal, all States signed letters of intent to draft and sign an MOU with APHIS. The designation of all 50 States as Consistent States is contingent on the State actually signing the MOU. To date, not all States have signed such an MOU. If any States have not signed the necessary MOU by the effective date of this final rule, APHIS will publish another final rule in the **Federal Register** changing the status of those States to Inconsistent.

We received eight comments on the proposal to list all 50 States as Consistent States under the revised standards contained in the August 15 proposal. All of these comments supported the revised qualification standards and supported designating all 50 States as Consistent States, although some suggested associated changes to the regulations. Therefore, this final rule designates all 50 States as Consistent States contingent upon the signing of the MOU and finalizes the standards for Consistent State status that were proposed in the August 15 proposal.

One commenter on the August 15 proposal stated that there should be procedures in the regulations for APHIS to work with individual producers to allow interstate movement of animals, so that producers "doing a good job" are not penalized due to problems in another part of the State.

We are not making any change in response to this comment because we believe the problem is addressed by the lighter restrictions on interstate movements from Consistent States in § 79.3, as well as by the provision in § 79.6(a)(10)(i)(A) that allows Consistent States to exempt from identification commercial whitefaced sheep under 18 months of age moving in intrastate commerce if the State has had no case of scrapie in commercial whitefaced sheep and no commercial whitefaced flocks in the State have been exposed by a female animal. We consider it impractical and overly expensive for both APHIS and States to apply this exemption on a basis smaller than Statewide, or to develop unique movement requirements for individual flocks. Also, flock owners would be subject to the most burdensome, Statewide restrictions only in Inconsistent States, but this rule

establishes all States as Consistent States, at least for now, if they sign the appropriate MOU.

Several commenters on the August 15 proposal said that APHIS should clearly state that entering data in the Generic Database is an acceptable alternative to entering data in the National Scrapie Database and would minimize the burden and costs to States.

We agree; in fact, the National Scrapie Database is in fact a subset of the Generic Database, and States already entering the required scrapie data in the Generic Database will not have to reenter it. APHIS will continue to work cooperatively with States to minimize the data entry burden for scrapie and other animal health databases. To clarify this point, we have also added to §§ 54.1 and 79.1 a definition of *National Scrapie Database* to read "A database designated by the Administrator in which APHIS and State animal health agencies cooperatively enter data concerning scrapie outbreaks, flocks and premises affected by scrapie, individual animal identification and premises identification data, and other data to support the Scrapie Eradication Program and the Scrapie Flock Certification Program."

One commenter on the August 15 proposal said that APHIS should define "commercial goats" to clarify which goats must comply with identification requirements and which are exempted. The same commenter suggested that we define "slaughter channels" to include private sales of kids to individuals for slaughter.

We agree, and as discussed above, we have added a definition of *commercial sheep or goat* to § 79.1. We are also adding to both §§ 54.1 and 79.1 a definition of *slaughter channels* to read as follows: "Animals in slaughter channels include any animal that is sold, transferred, or moved either (1) directly to a slaughter facility, (2) to an individual for custom slaughter, or (3) for feeding for the express purpose of improving the animals' condition for movement to slaughter. Any sexually intact animal that is commingled with breeding animals or that has been bred is not in slaughter channels. When selling animals for slaughter, owners should note on the bill of sale that the animals are sold only for slaughter."

One commenter on the August 15 proposal requested that APHIS exempt animals that are removed from feedlots for breeding purposes from the requirement that animals not in slaughter channels be traceable to premises of birth. The commenters stated that changing economic conditions often makes this necessary

and maintained that such animals need to be traced back only to the feedlot for program purposes.

We disagree. Tracing animals to a feedlot is of little epidemiologic value unless the feedlot maintains records that would allow the animals to be traced back to their flocks of origin. Currently this is not the case, and we do not believe imposing such a recordkeeping burden would be warranted at this time. The primary purpose of traceback is to locate infected breeding flocks, not to locate feedlots where animals have temporary residence.

Several commenters on the August 15 proposal suggested that APHIS should begin now to enhance the education and training of producers and accredited veterinarians.

We agree and are engaged in activities to support education and training regarding scrapie control. In addition to projects by APHIS public information offices, we are cooperating on projects with the American Sheep Institute and the National Institute of Animal Agriculture.

One commenter on the August 15 proposal stated that APHIS should develop the Uniform Methods and Rules (UM&R) with full coordination of all segments of industry and the pertinent advisory committees.

We agree, and the final rule states that APHIS will consult with Consistent States and provide an opportunity for industry and public review of the UM&R. We also intend to provide the United States Animal Health Association and the public with the opportunity to review the UM&R in draft form. In regard to this review, it should be noted that the legal requirements for the interstate movement of sheep and goats due to scrapie are contained in 9 CFR parts 54 and 79. The UM&R provides additional guidance to the States regarding the minimum standards necessary for States to participate in the National Scrapie Eradication Program. The UM&R also provides examples of how to comply with those requirements.

One commenter on the August 15 proposal stated that the language concerning the Paperwork Reduction Act in the proposed rule, stating that there were "no new impacts" associated with the rule, was inaccurate because livestock markets in particular will have to keep many new records.

The paperwork statement was accurate for the particular rule in which it appeared, i.e., the proposal to list 50 States as Consistent States. That proposal added no new records or forms not already addressed in the earlier November 30 proposed rule. Please refer

to the Paperwork Reduction Act section of this final rule to see final analysis of the paperwork issues raised in the November 30 proposed rule.

One commenter on the August 15 proposal stated that since the risk of a positive ram transmitting scrapie is effectively zero, the program should take no regulatory action against a flock based on the presence of an infected ram that was purchased from another flock.

We agree, and the revised definitions of *exposed animal* and *exposed flock* discussed above require the exposure to be to a scrapie-positive female animal, not a ram. On the same basis, to update classifications made under earlier versions of the regulations, § 79.4(b)(8) of the final rule allows an exposed animal to be reclassified if the exposure was only by an infected ram, outside of lambing and breeding situations. This final rule primarily regulates rams by requiring that they be individually identified in certain circumstances. This requirement does not reflect a belief that rams may directly spread scrapie, but rather it exists to allow scrapie-positive rams to be traced back to their flocks of origin or birth, as required, so that the necessary regulatory requirements may be imposed on those flocks.

#### Comments on Goats

Several commenters requested that goats be exempted from part or all of the regulations due to the low incidence of scrapie in goats. We have made the following changes in response to these comments.

- Since there is no immediate intent to collect diagnostic specimens from goats at slaughter, we have removed the requirement from § 79.3(b) to identify goats in slaughter channels, except for goats that have been exposed to scrapie.

- In § 79.3(a) we have exempted commercial goats that are not in contact with sheep from identification requirements if they originate in a State that has not had a case of scrapie in goats.

- We have allowed Consistent States that have had no cases of scrapie in goat flocks to exempt commercial goats from identification while in intrastate movement.

- We have partially removed the requirement that breeding goats moving interstate from Inconsistent States must originate from a SFCP flock. In this final rule, such goats must originate from a SFCP flock only if they have commingled with sheep, or are from a State that has had scrapie diagnosed in goats that were not commingled with sheep.

### *Comments on Genetics and Testing*

A few commenters recommended that animals that have an R at codon 171 should be exempted from the regulations because of their resistance to scrapie. APHIS disagrees with exempting all animals with an R at codon 171 from all regulation, for the following reasons. While Suffolk sheep with an R at codon 171 are documented in the literature to be more resistant to clinical scrapie than Suffolks that are QQ at codon 171, there have been several reports of sheep that are QR and one report of a sheep that is RR at codon 171 that were diagnosed with scrapie. Also, there has been inadequate work done with other breeds to know if or to what degree an R at codon 171 increases resistance in these sheep. It is also unknown whether a carrier state exists in sheep that are RR or QR at codon 171. However, we believe it is appropriate to classify highly exposed male sheep that are RR at codon 171 and AA at codon 136 as exposed, rather than high risk, since the lower risk from a male sheep combined with the lower genetic susceptibility associated with this genome lowers the risk of spread to a range similar to or less than that of other exposed animals. Likewise, exposed female sheep that are QQ at codon 171 are more susceptible and therefore of higher risk than other exposed animals and so have been included in the definition of high risk animals. APHIS is supporting further research with the U.S. Department of Agriculture's Agricultural Research Service to assess the utility of genotyping for regulatory purposes and will propose adjustments to the regulations as appropriate based on the results.

Several commenters urged the approval of the third eyelid test and also asked that we specify how tests would be approved by the Administrator. We are in the final steps of evaluating the third eyelid test. We have included new §§ 54.10 and 54.11 describing how APHIS will approve tests and laboratories in response to this comment. Essentially, the Administrator will approve new scrapie tests for live or dead animals after evaluating the test protocols and study data regarding each test's methodology, sensitivity, specificity, and reproducibility. The Administrator will approve laboratories after evaluating them using the same type of standards used to evaluate other laboratories authorized to conduct official tests under APHIS regulations. These are well-established standards for evaluating the methodology, personnel, and quality control procedures of diagnostic laboratories. For examples of

current APHIS regulations for approval of laboratories, see the equine infectious anemia regulations at § 75.4(c), pseudorabies regulations at § 85.1, and contagious equine metritis regulations at § 93.301(i).

Several commenters have objected to references to a live-animal test that has not been approved yet. We believe that the third eyelid test will be validated by the time this regulation is finalized and will be approved by the Administrator soon thereafter. The references to live-animal tests in this final rule will then aid the speedy and orderly introduction of the test.

### *Identifying an Animal's Premises of Birth*

Several commenters recommended that breeding animals be marked with flock of birth identification. We agree that this is an ideal method to allow complete traceback of animals and encourage its use; however, we are allowing other forms of identification on breeding sheep since birth premises identification is impractical in some circumstances, such as for sheep that no longer reside in their flock of birth or that lose tags after leaving the flock of birth. We have added a requirement to the general movement restrictions in § 79.3(a)(3) and (a)(4) and to the conditions for issuing certificates in § 79.5(a) that, for breeding sheep born after January 1, 2002, the flock of birth must be indicated on any health certificate issued for those sheep. This requirement will make it possible to trace these animals to their flock of birth. Also, as discussed in the August 15 proposal, we have added a requirement to the Consistent State qualification requirements at § 79.6(a)(10)(i), requiring official identification, upon change of ownership, of all animals of any age not in slaughter channels and any sheep over 18 months of age. This requirement will help us trace animals back to their flock of birth in Consistent States. Consistent States must meet this identification requirement within 2 years of their designation as Consistent. When Consistent States impose this identification requirement for intrastate movements, it will substantially increase our ability to trace animals back to their flock of birth.

### *Publication of Lists of Infected Flocks, Source Flocks, and Flocks Participating in the SFCP*

In the past, APHIS has published and has made available through the Internet lists of all known infected flocks, source flocks, and flocks participating in the Scrapie Flock Certification Program.

APHIS intends to continue publishing a list of participating flocks, which is available by writing to us or at URL <http://www.aphis.usda.gov/vs/scrapie>. We have amended § 54.21 to state that a list of noncompliant flocks (defined below) will also be developed and published at that address. However, we do not intend to continue publishing lists of infected and source flocks.

Several commenters supported publishing lists of all infected and source flocks, regardless of whether or not they participate in the SFCP. We have modified the rule to address this concern by requiring the scrapie status to be indicated on all certificates of animals moving for breeding or show purposes, discussed below under "Comments on Issuance of Certificates," and by defining *noncompliant flock* in §§ 54.1 and 79.1 as "(1) Any source or infected flock whose owner declines to enter into a flock plan or post-exposure management and monitoring plan agreement within 30 days of notification, or whose owner is not in compliance with either agreement; (2) any exposed flock whose owner fails to make animals available for testing within 60 days of notification, or as mutually agreed, or whose owner fails to submit required postmortem samples; (3) any flock whose owner or manager has misrepresented, or who employs a person who has misrepresented, the scrapie status of an animal or any other information on a certificate, permit, owner statement or other official document within the last 5 years; or (4) any flock whose owner or manager has moved, or who employs a person who has moved, an animal in violation of this part within the last 5 years." Publishing a list of noncompliant flocks, rather than lists of infected and source flocks, will protect the privacy of flock owners who comply with the regulations while listing those who do not and, therefore, present a risk of spreading scrapie.

Commenters also suggested we take steps to improve our ability to enforce the requirements of flock plans by taking action against persons who violate them. To accomplish this, we are slightly changing the definition of *flock plan* to require that a flock plan must be signed by the flock owner and by the accredited veterinarian, if any, employed by the flock owner. We believe signatures are desirable to document that participants in a flock plan have committed to follow its requirements, particularly now that nonperformance could cause a flock to be designated noncompliant. In the proposed definition of *flock plan*, the document did not have to be signed.

### *Comments on Issuance of Certificates*

As mentioned above, some commenters suggested that all infected and source flocks should be kept on a list that potential buyers could consult to obtain information about the scrapie status of animals they might buy. We believe this need for information regarding animals' exposure to scrapie can be met by changing the procedure for issuing certificates to require that certificates include a statement by the owner documenting any relevant information the owner has about the scrapie status of the animals, the exposure of the animals to scrapie, and the status of the animals' flock. This change would also address comments that suggested that certificates should contain more information about exposure of animals to scrapie.

Therefore, we are changing § 79.5, which concerns issuance of certificates, to require that a certificate must include: (1) A statement by the issuing veterinarian that the animals were not exhibiting clinical signs associated with scrapie at the time of examination and (2) an owner statement indicating whether the animal is or is not a scrapie-positive, suspect, high-risk or exposed animal and whether the animal originated in an infected, source, exposed or noncompliant flock. This added information will make the certificate more useful to persons acquiring these animals and to APHIS and State representatives enforcing the regulations, especially because the regulations require permits or prohibit the interstate movement of scrapie-positive, suspect, and high-risk animals, some exposed animals, and animals that originated in an infected or source flock.

### *Other and General Comments*

Several commenters recommended that we make the regulations consistent with the Office International des Epizooties (OIE) draft chapter on scrapie for the International Animal Health Code. While we believe that these regulations are in concordance with the spirit of the OIE draft chapter on scrapie, some requirements in the draft chapter are impractical for some segments of the U.S. sheep industry. Since the draft chapter is still being debated by the member countries, we have decided not to change our regulations in ways that will be costly to our industry without knowing what the final draft will include.

Several commenters supported the basic Consistent State requirements of reportability and movement restrictions but asked that the States be given up to 2 years to come into compliance with

the other requirements. We agree, and proposed this change in the August 15 proposal. No commenters objected to this change, and we have included a delayed compliance date for these requirements.

Several commenters stated that ewe lambs sent to feedlots should not be required to be identified. Their reasoning was that only a small percentage of ewe lambs are moved out of feedlots other than to slaughter, and that, in these cases, it would be appropriate to consider the feedlot to be their flock of origin. We disagree, because this would create a significant loophole which would encourage producers worried about their scrapie status to sell their breeding ewe lambs to feeders for resale to prevent tracebacks.

Several commenters asked that we add a medium risk or exposed flock classification for flocks with lower levels of risk, particularly those on pilot project flock plans. We agree and have added an exposed flock classification in § 79.4. We discussed the new definition of *exposed flock* above. This classification will identify animals with some degree of risk that might otherwise be exempted from necessary movement restrictions, e.g., as low-risk commercial sheep.

Several commenters recommended that we give designated scrapie epidemiologists (DSEs), rather than APHIS or State veterinarians, the responsibility for designating animals scrapie-positive, high-risk, or exposed, and for designating flocks as infected, source, or exposed flocks. We agree that a DSE has the appropriate level of technical expertise for making these determinations, and for making redesignations when needed, and have made this change in § 79.4(a). The commenters also suggested we give DSEs increased flexibility in addressing individual flock situations by customizing requirements for individual flock plans and post-exposure management plans and by conducting testing of flocks when test results could justify redesignation of a flock. We agree and have done this by allowing DSEs to determine the testing and monitoring needed for exposed flocks and by allowing them to modify flock plans and post-exposure management and monitoring plans under certain conditions to meet changing needs. These changes expanding the role of DSEs are in § 54.3(a) and in §§ 54.8(f), (h), and (i). We have also changed § 79.4 to allow DSEs that are engaged in designating or redesignating a flock's status to order testing of flock animals if the DSE determines such testing is

needed to properly designate a flock. In such cases the DSE will select animals for testing in a manner that will provide a 95 percent confidence of detecting scrapie at a prevalence of 1 percent. Testing may include live-animal testing using a live-animal official test, the culling and postmortem examination of genetically susceptible animals in the flock that cannot be evaluated by a live animal test, and postmortem examination of animals found dead or cull animals at slaughter.

One commenter stated that flock plans and post-exposure management and monitoring plans should allow APHIS or State representatives, when necessary, to restrict the removal of animals from flocks subject to those plans. Otherwise, animals might be removed from fear that they would be officially determined to be scrapie positive. We agree, and have added appropriate language to § 54.8(d).

Many commenters noted an error in the preamble that stated " \* \* \* imported lamb sells at a higher price than domestic lamb and mutton." In fact, domestic lamb and mutton sell at a higher price than imported lamb and mutton, and this has been corrected in our final regulatory flexibility analysis.

Several commenters supported our proposal to change the name of the Voluntary Scrapie Flock Certification Program to the Scrapie Flock Certification Program (SFCP), and a few commenters opposed the change. Those in favor recognized the trade benefits; those opposed were concerned that the program would no longer be voluntary. We have made no changes in rule based on this comment. Participation in the SFCP will remain voluntary.

Several commenters asked that we review our requirements for importing sheep and goats in light of this rulemaking to ensure equitable treatment. That is outside the scope of this rulemaking but will be considered in making policy and in future changes to the import regulations.

Several commenters expressed concern over how this regulation would affect large commercial range flocks. We agree that some of these concerns are valid and have made several changes to the rule to lessen adverse effects on these flocks. Some of the changes we have made to distinguish commercial flocks from other types were discussed above regarding the definitions of *commercial sheep or goat* and *low-risk commercial sheep*. We have also made changes affecting both intrastate and interstate movement of commercial sheep and goats. These changes, to both the interstate movement restrictions in § 79.3 and the requirements for

Consistent States in § 79.6, include: (1) Allowing Consistent States that have had no cases of scrapie in commercial flocks to exempt them from identification while in intrastate movement under 18 months of age; (2) allowing commercial sheep and goats to be identified with brands or ear notches in interstate movement; (3) reducing the recordkeeping and identification requirements for commercial flocks if they become infected; (4) not designating flocks as infected if the positive animal is a purchased ram; (5) allowing the interstate movement of all animals under 18 months of age in slaughter channels without identification; and (6) allowing increased options for commercial flocks if they are designated infected, source, or exposed and by giving greater latitude to DSEs to modify flock plans and post-exposure management and monitoring plans.

Several commenters recommended that we differentiate between blackfaced and whitefaced sheep based on the higher incidence of reported scrapie cases in blackfaced sheep. We agree in part with this concept and have changed §§ 79.3(a)(7) and (c)(5) of the interstate movement restrictions chart to distinguish between exposure to whitefaced and blackfaced sheep.

A commenter expressed concern over the number of signs that could potentially result in an animal being designated a suspect animal. We believe that this will not be a problem because the definition of *suspect animal* in §§ 54.1 and 79.1 includes the condition "A sheep or goat that exhibits any of the following possible signs of scrapie and that has been determined to be suspicious for scrapie by an accredited veterinarian, or a State or APHIS representative." This requires not only that the animal exhibit at least one of the signs but that a veterinarian determine that it is suspicious for scrapie before it is officially designated a suspect animal for regulatory purposes. Anyone who suspects that an animal has scrapie is encouraged to report it to a State, Federal, or accredited veterinarian so that an official determination can be made. In some States, such reporting is a legal requirement.

Several commenters commented on the cost of identifying animals. APHIS will provide alphanumeric tags to accredited veterinarians and backtags to markets and dealers. Additionally, producers may acquire alphanumeric eartags and backtags from APHIS at no cost if they have their premises and the tag sequences recorded in the National Scrapie Database. Producers may also

purchase premises identification tags with assigned premises numbers from approved vendors. The requirements for vendors who wish to produce approved tags are contained in § 79.2(f).

Discussions with tag companies suggest that the cost of these tags will range from \$0.06 for metal tags to \$1.00 for highly tamper-resistant plastic flap tags. The type of approved tag used will be up to the producer and their flock identification needs. Also, we have eliminated the identification requirements for most sheep under 18 months of age and all slaughter goats, which substantially reduces the identification cost.

Many commenters also remarked about the cost of applying identification, in addition to the material cost of the tags. We agree that there will be a cost to producers and markets to apply identification and keep records. We have reduced this as much as possible by reducing the number of animals that must be identified, by allowing certificates and market and dealer records to record premises identification rather than individual identification under certain circumstances, and by allowing several options for identification to fit different producers' needs.

Some commenters were concerned that the rule does not indicate the penalties for failing to comply. The maximum criminal and civil penalties that may be imposed are listed in the statutes that are the legal authority behind our regulations. Listing penalty amounts in our regulations is not normal practice for APHIS. In response to this comment we have indicated some instances when violators will have privileges under this rule, such as the ability to apply official identification, revoked. Our intent to publish the identities of noncompliant flocks should also serve as a deterrent. Finally, action may be taken under civil and criminal law against violators of the regulations. Administrative penalties may include warnings, monetary penalties, or withdrawal of certified flock status.

One commenter indicated that this rule would preclude State scrapie control programs. The rule does not preclude States from designing their own scrapie programs for intrastate movements. It would require that the program either meet the minimum specified requirements or can be shown to be equally effective in preventing the interstate movement of scrapie from the State.

Some commenters expressed concern about the effect of burial or incineration on the environment, when animals are disposed of in accordance with the

requirements of §§ 54.7(b) or 54.8(f). APHIS believes that the regulations currently in place are adequate for safe, environmentally conscious disposal of this material.

All commenters that addressed disposal costs stated that APHIS should pay the disposal costs for indemnified animals. We agree that APHIS will pay the disposal costs of scrapie-positive and suspect animals that cannot be disposed of by slaughter, and we have changed § 54.7(d) of the rule to provide that APHIS may pay the reasonable costs of disposal for scrapie-positive and suspect animals that are indemnified. To obtain reimbursement for disposal costs, animal owners must obtain written approval of the disposal costs from APHIS, prior to disposal. This paragraph also states that the Administrator may also authorize payment of up to half the reasonable disposal costs for animals that are allowed to be destroyed by slaughter under this section but for which slaughter is not a practical or cost efficient means of disposal. However, § 54.7(d) provides that APHIS may pay more than one-half of the expenses when the Administrator determines that doing so will contribute to scrapie eradication. For reimbursement to be made, the owner of the animals must present the veterinarian in charge with a copy of either a receipt for expenses paid or a bill for services rendered. Any bill for services rendered by the owner must not be greater than the normal fee for similar services provided by a commercial hauler or disposal facility.

Some commenters misinterpreted the indemnity section and were unsure whether indemnity would be provided for both commercial and registered animals. Both the November 30 proposal and this rule provide indemnity for both types of animals, but in differing amounts.

One commenter expressed concern over permitting exposed and high-risk sheep to go to feedlots, because this might pose a risk of spreading scrapie. We agree that allowing high-risk animals, exposed pregnant animals, or exposed animals with a vaginal discharge to go to feedlots from which they might return to the farm would present a significant risk, and we have changed §§ 79.3(b)(3) and (c)(3) of the rule to restrict the movement of these animals to slaughter or to terminal feedlots.

One commenter questioned whether the statement in the November 30 proposal regarding Executive Order 12988 that stated the rule "preempts all State and local laws and regulations that are in conflict with this rule" was

accurate, or was needed. The commenter stated that while State restrictions on the interstate movement of sheep and goats that were less stringent than the requirements of the rule will be overruled by the Federal requirements, State restrictions that are stricter than the rule's requirements should be allowed, because they would serve to improve disease control and reduce risks. The commenter also expressed concern that the statement meant that a State could not require any conditions for movement of animals into the State over and above the Federal requirements.

Under Executive Order 12988, a Federal agency that formulates proposed regulations is required to specify in clear language the preemptive effect it intends to be given to its legislation or regulations. The executive order does not specify what that preemptive effect shall be. Historically, domestic animal health regulations of a State have not been challenged when they require conditions on interstate movement that are more stringent than those included in APHIS regulations. However, State regulations that conflict with or subvert Federal regulations concerning the interstate movement of animals and products that are promulgated for the purpose of the control of diseases of livestock and poultry are preempted by the Federal regulations. This is a matter of Constitutional law that we cannot change by regulation.

#### *Scrapie Pilot Projects Final Rule*

This final rule also republishes changes to parts 54 and 79 that were made by another final rule concerning scrapie pilot projects. That rule was published and effective on June 27, 2000 (Docket No. 99-067-2, 65 FR 39534-39536). That rule amended the regulations to exempt flocks from certain regulatory requirements when the flocks are participating in scrapie control pilot projects authorized by APHIS.

#### *Miscellaneous Changes*

We have also made miscellaneous minor changes to the November 30 and August 15 proposals in this final rule, such as correcting misspellings, revising sentences for clarity, and adding explanatory subject titles to some paragraphs of amendatory language.

Therefore, for the reasons given in the proposed rule and in this document, we are adopting the proposed rule as a final rule, with the changes discussed in this document.

#### *Executive Order 12866 and Regulatory Flexibility Act*

This rule has been reviewed under Executive Order 12866. The rule has been determined to be significant for the purposes of Executive Order 12866 and, therefore, has been reviewed by the Office of Management and Budget.

In accordance with 5 U.S.C. 603, we have performed a final regulatory flexibility analysis for this rule. The economic analysis for this rule is summarized below, and a full copy is available from Regulatory Analysis and Development, PPD, APHIS, 4700 River Road Unit 118, Riverdale, MD 20737-1238. The economic analysis provides a cost-benefit analysis as required by Executive Order 12866 and an analysis of impacts on small entities as required by the Regulatory Flexibility Act.

We are taking the actions described in this rule in order to strengthen scrapie control programs on the national level and to reduce the losses from scrapie to the sheep and goat industries. This action is considered necessary because not all State scrapie control programs may be effective in identifying animals that may be infected with scrapie and controlling their movement in intrastate and interstate commerce in a manner that will prevent the further spread of scrapie. Statutory authorities, including 21 U.S.C. 111, 114, 114a, and 134a-134h, authorize the Department of Agriculture to conduct programs for the control of communicable animal diseases and to restrict the interstate movement of animals that may spread disease.

As alternatives to this action, APHIS considered a complete ban on interstate movement of sheep and goats from States that do not have effective scrapie control programs. We also considered adding stricter certification, recordkeeping, and animal identification requirements for all sheep and goats moving interstate, without regard to the effectiveness of individual State scrapie programs. We also considered setting up a system to employ a prospective live-animal test in mandatory testing of sheep and goats before they could be sold for any commercial purpose, with mandatory destruction and disposal of animals that fail the test. All of these alternatives would impose more costs and recordkeeping requirements than the selected alternative, and we do not believe any of these alternatives would control scrapie more effectively than the selected alternative. A complete ban on movements from Inconsistent States would hurt the economies of those States, and while it would provide other

States with some protection against infection from Inconsistent States, it would not eradicate the reservoirs of scrapie in those States. The alternative of stricter recordkeeping and identification for all interstate movements would not be effective as long as some of the information to be recorded is unknown or dubious, as can frequently happen when the animal originates in a State with a weak scrapie program. The alternative of mandatory testing, and destruction of animals that fail, was discussed in the November 30 proposal. It is not a practical option because a live-animal test has not been validated and approved and is also impractical at this time for economic reasons.

This rule will result in the expenditure of indemnity funds by APHIS to compensate the owners of certain animals destroyed to prevent the spread of scrapie. This will also encourage certain States to improve the effectiveness of their State scrapie programs to avoid additional restrictions on the movement of sheep and goats from their States.

The budgetary effects on APHIS of this rule will fall into four categories, all within available funds: An increase in outlays for staff to work with States and producers as they adapt to the new scrapie program requirements, a new program for indemnity payments, the cost of providing official eartags and backtags, and the cost for disposal (usually by landfill or incineration) of scrapie-positive and suspect animals that are indemnified. The initial amount of indemnity payments (the first year) is estimated to be approximately \$761,245, based on an estimated 4,188 animals eligible for indemnity in known scrapie-infected and source flocks, but may be more if producer response to the availability of indemnity results in new admissions of infection that reveal additional cases of scrapie. The amount of indemnity paid should decline in subsequent years, although, if slaughter surveillance is initiated or if live-animal tests are approved and widely used, this decline may not occur for several years, depending on the number of scrapie-positive animals that are revealed by initial use of these tests. This indemnity program will be less costly than *some* previous indemnity programs since it focuses on eliminating individual infected and high-risk animals rather than entire flocks, a focus that should be aided in the near future by the availability of a validated live-animal test. If a live-animal test is accepted for official use, an increase in indemnity costs will be expected initially as new infected flocks are identified.



APHIS will bear the total reasonable cost for disposing of indemnified scrapie-positive and suspect animals, and will bear half the cost for disposal of certain other indemnified animals that are destroyed rather than sent to slaughter. The cost for disposal of each animal will range between a low of approximately \$15 (for simple burial in a landfill, the most common method) and a high of approximately \$100 (the maximum cost when incineration is required). The method used will vary depending on local disposal alternatives and requirements. The total cost for disposing of an estimated 3000 animals the first year would therefore fall in the range between \$30,000 and \$300,000, and would probably be on the order of \$150,000. The cost for disposing an estimated 4200 animals over the lifetime of the program is estimated to fall in the range between \$42,000 and \$420,000, probably on the order of \$210,000.

Although this rule lists all States as "Consistent States," any State that loses this status will bear additional costs to improve its State scrapie programs so that the producers in that State can avoid additional interstate movement restrictions established for States without effective intrastate control programs. However, the designation of all 50 States as Consistent States indicates that they have already dedicated the resources needed to conduct effective intrastate programs. The signing of the MOU will complete this process of designating a State as a Consistent State.

#### Overview of U.S. Sheep and Goat Industry Operations, Inventory and Trade

Much of the data used in this analysis is from the 1997 Census of Agriculture (USDA, National Agricultural Statistics Service), the last full census that is

available. Where possible, updated 1999 data from Agricultural Statistics 2000 (USDA, National Agricultural Statistics Service) are employed.

There were 7.026 million sheep and lambs in the United States in 1999. There were 5.163 million breeding sheep and lambs, of which 4.433 million were ewes and rams 1 year old or older.

In 1997, as shown in Table 1, small farms accounted for over 99 percent of all the farms raising sheep and lambs, while farms considered to be large accounted for less than 0.3 percent. About 85 percent of the farms had an inventory of less than 100 animals and accounted for about 17 percent of the total inventory of sheep and lambs. On the other hand, sheep operations with an inventory of 5,000 sheep or more represented less than 0.3 percent of the farms but accounted for nearly 26 percent of the total inventory.

TABLE 1.—SHEEP AND LAMBS: FARMS AND INVENTORY BY SIZE, 1997

Farm inventory	Number of farms	Farm share	Inventory share
1 to 24 .....	35584	0.54	0.045
25 to 99 .....	20461	0.31	0.123
100 to 299 .....	6010	0.09	0.123
300 to 999 .....	2429	0.04	0.158
1,000 to 2,499 .....	820	0.01	0.16
2,500 to 4,999 .....	297	0.005	0.128
5,000 or more .....	189	0.003	0.263
Total .....	65790		

Source: USDA, *Census of Agriculture* 1997.

Of the total number of operations, about 60 percent were full owners, about 32 percent were part owners, and about 8 percent were tenants.

Sheep are produced in all parts of the United States, although stock levels vary from State to State. Ten States accounted for nearly 73 percent of the total inventory, mostly in western and central areas. Northern and southeastern States have the smallest sheep populations, accounting only for 5.2 percent of the total.

There were about 1.99 million goats in the United States in 1997, of which 52 percent were goats other than Angora or milk goats, 41 percent were Angora goats and about 7 percent were milk goats. The State of Texas accounted for about 64.3 percent of the goat inventory. Other States where goats are raised include Arizona, California, Georgia, New Mexico, North Carolina, Oklahoma, and Tennessee. These States together represented another 14.2 percent of the U.S. goats holdings. An average holding was about 35 goats. All

goat holdings were considered to be small.

During 1999 the United States produced about 247 million pounds of mutton, lamb and goat meat. It exported 5.6 million pounds and imported about 111 million pounds valued at \$189.2 million. The United States exported 518,257 sheep and goats valued at \$21.99 million in 1999, of which 494,098 went to Mexico. The United States imported 53,165 sheep and goats valued at \$5.33 million in 1999, of which 53,126 were from Canada. The United States imported 111 million pounds of sheep and goat meat valued at \$190.2 million and exported 5.6 million pounds of sheep and goat meat valued at \$6.46 million in 1999. Most lamb and mutton imports came from Australia and New Zealand, countries recognized as being free from scrapie. The United States is a net importer of lamb and mutton.

#### Sheep and Goats Affected by Scrapie Interstate Movement Restrictions

Nearly 6.487 million lambs and sheep are marketed each year, of which 0.977 million are mature sheep and 5.51 million are lambs less than 18 months of age.<sup>1</sup> There are 15 States with 53 flocks that were on the infected or source flock list as of July 2000. Of these, 47 are infected flocks and 6 are source flocks. Also, 14 additional flocks contained a scrapie-positive animal during FY 2000 but were not considered infected or source flocks in July, either because they had not been formally categorized yet or because they had completed an approved flock plan. Infected and source flocks are potential candidates for destruction and indemnity payments.

Additionally, over the last 10 years (1990–1999), an annual average of 139 animals have been submitted for scrapie diagnosis, of which an annual average of

<sup>1</sup> USDA/NASS, *Agriculture Statistics* 2000, U.S. Government Printing Office, Washington DC, 2000.

61 (or 44 percent) were determined to be scrapie-positive animals. However, it is likely that the number of reported cases will increase as the indemnity payments become available. There are about 1.578 million breeding sheep and lambs in the 15 States in which positive cases have occurred in FY 2000 or in which a source or infected flock exists. These animals represent approximately 28 percent of all breeding sheep and lambs in the United States and have a market value of about \$150 million.

The average size of a flock in an operation in the 15 States was 125, with between 21 and 479 per operation. Approximately 82.9 percent of these sheep are marketed, in most cases across State lines. However, nearly 85 percent of the marketed sheep are lambs less than 18 months of age, and will be exempt from individual animal identification under this final rule.

**Indemnity Costs for Animals Destroyed Due to Scrapie**

The exact number of scrapie-positive and high-risk animals that will qualify

for indemnity payments is not known. However, an estimate of the number of animals potentially eligible for indemnity would be 50 percent (based on field estimates) of the animals in an average infected or source flock (based on past field experience). As noted above, there are currently 47 infected flocks and 6 source flocks, and 14 other flocks that currently or recently contained scrapie-positive animals. Thus, based on average flock size and the average percentage of high-risk animals in infected and source flocks, the number that can be estimated to qualify for indemnity payments during the first year would be 4,188 animals  $(=(53 + 14) \times 125 \times 0.50)$ . This estimate implies that about 0.144 percent of the total number of breeding sheep and goats in the 15 States that can potentially move interstate will be designated as high-risk animals and be eligible for indemnity. The proportion of more expensive registered animals was 74.38 percent (8,199/11,023)<sup>2</sup> Assuming a 75 percent registered to 25 percent nonregistered animal

composition, the respective indemnity payments approximately range between \$161 and \$322 for registered animals and between \$61 and \$122 for nonregistered animals. The payment for registered animals is the sum of the spot market price and the premium given in order to adjust for value of these animals. Thus, the \$322 per head payment for yearlings column includes the \$122 spot market price and the \$200 premium payment. Nonregistered animals get the spot market price. The estimated indemnity expenditure will be about \$761,245 (See table 2 for detail). If the producer response to indemnity payment availability is positive, resulting in an increased number of indemnity requests, the expenditure will increase accordingly. However, even if a much larger number of animals were to be indemnified, the destruction of all known infected animals will greatly advance the goal of scrapie eradication, and can only be positive in terms of long-term reduced expenditure.

TABLE 2.—THE INDEMNITY COST

Group	Registered (75%)			Non registered (25%)			Total
	Number	\$/Head	Cost	Number	\$/Head	Cost	
Yearlings (1 to 2 years)	431	\$322	\$138,782	144	\$122	\$17,568	\$156,350
Running ages:							
2 to under 4 years	647	290	187,630	216	90	19,440	207,070
4 to 6 years .....	647	190	122,930	216	90	19,440	142,370
Aged (>6 years) ....	431	161	69,391	144	61	8,784	78,175
Ewe lambs .....	985	175	172,375	327	75	4,905	177,280
Total .....	3,141	.....	691,108	1,047	.....	70,137	761,245

**Note:** This chart assumes a distribution based on 1999 flock data for the ages, and resultant indemnity status, of the 4,188 animals estimated to be eligible for indemnity. We also assumed 75 percent of these animals are registered. We also estimated that 80 percent of non-registered ewe lambs will go to slaughter, so indemnity cost for this class will be minimal.

**Costs to Producers and APHIS for Official Identification of Animals Moving Interstate**

The animal identification required by this rule will result in additional costs. Of the approximately 7.82 million sheep and lambs in the United States, about 6.487 million sheep and lambs (or 82.9 percent) are marketed. Nearly 85 percent of these sheep and lambs that could move interstate are lambs less than 18 months of age in slaughter channels, which will not require identification tags under the new rule. Of the 1.99 million goats (=809,391 angora+146,678 milk+1,033,730 goats), about 27.5 percent could potentially be moved interstate. This assumes that most angora goats do not move

interstate, but that about 20 percent of milk goats and 50 percent of other goats might move interstate. The cost of metal identification tags is between 4 cents and 6 cents per animal. Thus, assuming the total number of sheep and goats that will need identification tags is 1.52 million, the tag cost will be between \$60,800  $(=1,520,300 \times 0.04)$  and \$91,220  $(=1,520,300 \times 0.06)$ . If the time it takes the owner to apply the tag (about 2 minutes per animal) is valued at \$7.61 per hour (the revised average wage for livestock workers in January, 2000), this labor cost represents another \$385,600  $(=1,520,300 \times 2 \times \$7.61/60)$ . In some States, tags are provided by APHIS free to accredited veterinarians, while in others, they are purchased by accredited

veterinarians through the State. Generally, wherever APHIS directly distributes tags they are free; where States distribute them, there may be no charge, a small processing fee, or a fee covering the full cost of the tags, depending on State regulations. In this rule there is a mechanism for APHIS or the State to provide tags direct to producers. If owners elect to use backtags for direct movements of animals to slaughter instead of eartags, the costs will be less. In either case, owners will incur the costs of applying identification. The effect on goat owners will be less, since about 41 percent of goats are the angora type, which are raised for their mohair and are less frequently moved interstate. Also, the

<sup>2</sup> Based on the composition of 8,199 registered and 2,824 commercial animals that were

indemnified in 1990, as reported by APHIS personnel.

owners of goats that qualify as "low-risk goats" will not have to individually identify their animals. Thus, the total potential identification costs for goat owners will be between \$3,850 and \$5,570.

#### International Trade Effects

The United States has limited foreign trade both in live sheep and goats and their products. Australia, a potential major importer of U.S. sheep for breeding purposes, is scrapie-free and prohibits imports of sheep from the United States. Australia allows imports of live goats from the United States only if they undergo a 3-year quarantine upon arrival. Mexico allows the importation of U.S. sheep only if the sheep are from flocks enrolled in the Voluntary Scrapie Flock Certification Program. Canada allows the importation of U.S. sheep only if a certification statement can be made that no case of scrapie has been diagnosed in the flock of origin for the last 3 years and the animals for export are not the progeny of infected animals. In 1997, the total earnings from exports of live sheep, goats, and sheep and goat meat and meat products were approximately \$65 million. The United States is a net exporter of live animals, while it is a net importer of mutton, lamb and goat meat. Both the sources of imports and destinations of exports are concentrated in a few countries. Scrapie-free animals, and to some extent their products, are likely to be highly valued in the domestic and international markets. U.S. breeding stock that can be certified scrapie-free is expected to be in high demand internationally. While scrapie-free status would do little to enhance domestic or export consumption of U.S. mutton and lamb, the lack of scrapie-free status could seriously reduce demand for these products if public fears about transmissible spongiform encephalopathies ever become associated with U.S. sheep products.

The U.S. competitiveness in the domestic and international markets depends upon its reputation for producing high quality animals and products. The actual product, as well as the purchasers' perception of quality, contribute to continued market acceptance. Thus, efforts to eradicate scrapie and secure the health of U.S. sheep and goats will continue to serve the economic interests of the industry and Nation. This rule could give incentive for more rigorous efforts to find infection and proceed rapidly to eradicate infected animals in order to preserve a scrapie-free status.

This rule should benefit U.S. producers in a number of ways,

especially by avoiding a number of direct costs and market losses. Associations representing breeding sheep owners, slaughter sheep owners, and wool-production sheep owners have submitted comments supporting the approach of this rule and also stated their associations' opinion that the benefits of the program will greatly exceed the costs. Scrapie may cost the sheep industry as much as \$20.1 million per year in direct losses (\$10 million in lost breeding stock and embryo export sales, \$3.95 million in disposal costs for offal, and \$6.176 million to divert offal from ruminant food chains and in loss of offal export markets). Scrapie also costs an unknown amount in lost potential international markets and lost flock productivity. Additionally, the sheep industry currently loses sales to drug companies because the U.S. Food and Drug Administration requires scrapie-free sources of sheep or goat materials for pharmaceutical or biological products implanted or injected in humans.

Therefore, this rule should make the U.S. sheep industry more competitive, particularly in live sheep and goat exports, since current trade shows that the value of live animal exports is almost four times that of the meat in the global market. This rule also addresses consumer concerns about the presence of a transmissible spongiform encephalopathy in food. While there is no evidence that scrapie is a human health risk, and significant epidemiological evidence that it is not, there is a perception of risk.

In summary, this rule will further restrict the interstate movement of sheep and goats from States that do not follow effective management practices for scrapie. Interstate movement of sheep and goats is beneficial, as it reduces interstate price differences faced by consumers of livestock products and allows producers to seek the best available prices for their products. The rule will encourage States to carry out the necessary surveillance and quarantine activities quickly, thereby reducing the spread of the disease. The process outlined in the rule will encourage States to begin stringent surveillance procedures immediately to identify any additional infected flocks and help to realize the goal of eradicating scrapie from the United States. The rule will also encourage flock owners to participate in State scrapie programs or the Federal Scrapie Flock Certification Program, contributing further to the control of scrapie. Apart from the cost of program activities by APHIS and State agencies, and expenditure of indemnity funds by

APHIS, the cost of identifying animals for interstate movement is the primary cost imposed by this rule. This cost will impose some burden upon owners, which will be passed along to those who are interested in buying these animals, possibly reducing interstate commerce in sheep and goats slightly.

The changes to the regulations will result in new information collection or recordkeeping requirements, which have been approved by the Office of Management and Budget (see "Paperwork Reduction Act" below).

#### Executive Order 12372

This program/activity is listed in the Catalog of Federal Domestic Assistance under No. 10.025 and is subject to Executive Order 12372, which requires intergovernmental consultation with State and local officials. (See 7 CFR part 3015, subpart V.)

#### Executive Order 12612 and Federalism

It has been determined under section 6(a) of Executive Order 12612, "Federalism," that this rule does not have sufficient federalism implications to warrant the preparation of a federalism assessment. The provisions contained in this rule will not have a substantial direct effect on States or their political subdivisions or on the distribution of power and responsibilities among the various levels of government.

The Administrator has examined the federalism implications of the requirements in this rule; i.e., different interstate movement requirements for sheep and goats depending on whether they are moving from a Consistent State or an Inconsistent State. The Administrator believes that this action adheres to Constitutional principles for the exercise of Federal power and is clearly authorized by statutory authorities delegated to APHIS.

This action will not absolutely impose any new compliance costs on State or local governments, but it is true that this rule will strongly encourage some States to expend additional funds to upgrade their State programs for disease control in sheep and goats. Owners of sheep and goats in States that do not fund their programs to an extent that allows them to qualify as Consistent States would face additional restrictions on the interstate movement of their sheep and goats. However, this rule designates all States as Consistent States. If one or more States do not maintain Consistent State status, APHIS will review the effects on the particular States involved to determine whether the loss of that status will have a substantial direct effect on the States or their political

subdivisions or on the distribution of power and responsibilities among the various levels of government and, if necessary, prepare a federalism assessment.

This final rule was preceded by proposed rules and an advance notice of proposed rulemaking which sought comments from the public, industry, and State and local officials. Those documents specifically requested comments addressing "the alignment of Federal interstate movement restrictions with State standards."

Most States supported the proposal's intention to establish a system to certify that State programs for sheep and goats meet certain minimum standards, in order to provide a baseline of protection against the spread of disease when moving sheep and goats in interstate commerce. Very few officials commented that APHIS should accept any State animal health program without enforcing minimum standards. APHIS disagrees with this position because experience in animal health programs on a national level has shown that the absence of effective programs for scrapie in a few States can quickly cause animal disease problems and financial losses affecting many States as animals move in interstate commerce.

State and local governments had the opportunity to comment on the proposed rules that preceded this final rule, and we encouraged them to submit comments on federalism concerns or any other issues. As implementation of this rule proceeds, APHIS intends to continue active consultation with State animal health agencies and the elected officials of affected State and local governments.

#### Executive Order 12988

This final rule has been reviewed under Executive Order 12988, Civil Justice Reform. This rule: (1) Preempts all State and local laws and regulations that are in conflict with this rule; (2) has no retroactive effect; and (3) does not require administrative proceedings before parties may file suit in court challenging this rule.

#### Paperwork Reduction Act

The information collection requirements that were contained in the proposed rule have been approved under OMB control number 0579-0101. This final rule adds an additional 66,154 burden hours for respondents. Part of this increase is due to the fact that we underestimated the paperwork burden associated with the proposed rule, as several commenters pointed out, and part of the increase results from changes in this final rule that add

additional burden in order to improve the disease control effects of the rule and to make indemnity payments more equitable. Our changes in this final rule that made the definitions of *exposed animal*, *infected flock*, and *source flock* more science-based, and make the rule in general more risk-averse, will also result in more flocks being classified in these categories in the first year or two these regulations are in effect. However, regulated flocks should then decrease in number rapidly in subsequent years, compared to the decrease in numbers they would have experienced under the original proposed rule. In that sense, the changes in this final rule compress more of the paperwork burden into the first year or two of program operations, rather than adding more to the total burden. The paperwork burden estimated for this rule will also decrease significantly as soon as a valid live-animal test is in use, since such a test would have the general effect of reducing the number of animals subject to the regulations, and resolving suspect animal cases more quickly. While such a test is expected to be approved soon, we do not know exactly how soon, and therefore have estimated the paperwork burden without assuming the availability of such a test. Forthcoming advances in electronic animal identification methods should also reduce the paperwork burden estimated for this rule.

As noted above, this additional burden resulted partly from changes to the definitions of *exposed animal*, *infected flock*, and *source flock* that resulted in more animals placed in these categories, causing additional identification and recordkeeping. Additional burden also resulted from changes in the final rule that require flock owners to do more individual animal identification, and that allowed slaughter plants and livestock markets to act as an agent for the owner in applying required official identification. Also, the final rule expanded the use of owner statements in connection with the movement of animals, resulting in the preparation of more such owners statements each year. Finally, changes to the indemnity procedure shifted indemnity values from a fixed-price approach to a market value approach, requiring more paperwork to document market prices at any given time and to base some indemnities on examination of sale records of flock owners. In accordance with section 3507(d) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), this additional burden has been submitted for approval to the Office of Management and Budget

(OMB). When OMB notifies us of its decision, we will publish a document in the **Federal Register** providing notice of the assigned OMB control number and expiration date, or, if approval is denied, providing notice of what action we plan to take.

#### Unfunded Mandates Reform Act of 1995

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), Pub. L. 104-4, establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local, tribal governments, and the private sector. Under section 101 of the UMRA, APHIS generally must prepare a written statement, including a cost-benefit analysis, for proposed and final rules with "Federal mandates" that may result in expenditures by State, local, or tribal governments, in the aggregate, or by the private sector, of \$100 million or more in any one year. When such a statement is needed for a rule, section 205 of the UMRA generally requires APHIS to identify and consider a reasonable number of regulatory alternatives and adopt the least costly, more cost-effective, or least burdensome alternative that achieves the objectives of the rule.

This rule contains no Federal mandates (under the regulatory provisions of Title II of the UMRA) that may result in expenditures by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100 million or more in any one year. Thus, this rule is not subject to the requirements of sections 202 and 205 of the UMRA.

#### List of Subjects

##### 9 CFR Part 54

Animal diseases, Goats, Indemnity payments, Scrapie, Sheep.

##### 9 CFR Part 79

Animal diseases, Goats, Quarantine, Reporting and recordkeeping requirements, Scrapie, Sheep, Transportation.

Accordingly, we are amending 9 CFR chapter I as follows:

1. Part 54 is revised to read as follows:

#### PART 54—CONTROL OF SCRAPIE

##### Sec.

##### 54.1 Definitions.

##### 54.2 Cooperative agreements and memoranda of understanding with States.

#### Subpart A—Scrapie Indemnification Program

##### 54.3 Animals eligible for indemnity payments.

- 54.4 Application by owners for indemnity payments.
- 54.5 Certification by owners.
- 54.6 Amount of indemnity payments.
- 54.7 Procedures for destruction of animals.
- 54.8 Requirements for flock plans and post-exposure management and monitoring plans.
- 54.9 Waiver of requirements for scrapie control pilot projects.
- 54.10 Tests for scrapie.
- 54.11 Approval of laboratories to run official scrapie tests and official genotype tests.

#### Subpart B—Scrapie Flock Certification Program

- 54.20 Administration.
- 54.21 Participation.
- 54.22 State scrapie certification boards.

**Authority:** 21 U.S.C. 111, 114, 114a, and 134a–134h; 7 CFR 2.22, 2.80, and 371.4.

#### § 54.1 Definitions.

**Accredited veterinarian.** A veterinarian approved by the Administrator in accordance with part 161 of this chapter to perform functions specified in subchapters B, C, and D of this chapter.

**Administrator.** The Administrator of the Animal and Plant Health Inspection Service or any employee of the United States Department of Agriculture authorized to act for the Administrator.

**Animal.** A sheep or goat.

**Animal and Plant Health Inspection Service (APHIS).** The Animal and Plant Health Inspection Service of the United States Department of Agriculture.

**APHIS representative.** An individual employed by APHIS in animal health activities who is authorized by the Administrator to perform the function involved.

**Approved laboratory.** A laboratory approved by the Administrator in accordance with § 54.11 to conduct one or more scrapie tests, or genotype tests, on one or more tissues.

**Approved test.** A test for the diagnosis of scrapie approved by the Administrator for use in the scrapie eradication or certification program in accordance with § 54.10.

**Area veterinarian in charge.** The veterinary official of APHIS who is assigned by the Administrator to supervise and perform the official animal health work of APHIS in the State concerned.

**Breed association and registries.** Organizations listed in § 151.9 of this chapter that maintain the permanent records of ancestry or pedigrees of animals (including the animal's sire and dam), individual identification of animals, and ownership of animals.

**Certificate.** An official document issued in accordance with § 79.5 of this chapter by an APHIS representative,

State representative, or accredited veterinarian at the point of origin of an interstate movement of animals.

**Commingle, commingled, commingling.** Animals grouped together and having physical contact with each other, including contact through a fence, but not limited contacts. Commingling also includes sharing the same section in a transportation unit where there is physical contact.

**Designated scrapie epidemiologist.** An epidemiologist who has demonstrated the knowledge and ability to perform the functions required and who has been selected by the State animal health official and the area veterinarian in charge. The regional epidemiologist and the APHIS National Scrapie Program Coordinator must concur in the selection and appointment of the designated scrapie epidemiologist. The designated scrapie epidemiologist must satisfactorily complete training designated by APHIS.

**Destroyed.** (1) Euthanized by means other than slaughter, and the carcass disposed of, by means authorized by the Administrator; or

(2) In the case of exposed or high-risk animals that are not known to be infected, either euthanized or disposed of by slaughter; or

(3) Moved to a quarantined research facility if the movement has been approved by the Administrator.

**Electronic implant.** Any radio frequency identification implant device approved for use in the scrapie program by the Administrator. The Administrator will approve an electronic implant after determining that it is tamper resistant, not harmful to the animal, and readable by equipment available to APHIS and State representatives.

**Exposed animal.** (1) Any animal that has been in the same flock at the same time as a scrapie-positive female animal, excluding limited contacts; or

(2) Any animal born in a flock after a scrapie-positive animal was born into that flock or lambed in that flock, if born before that flock completes the requirements of a flock plan; or

(3) Any animal that was commingled with a scrapie-positive female animal during or up to 30 days after she lambed, kidded, or aborted, or while a visible vaginal discharge was present, or that was commingled with any other scrapie-positive female animal for 24 hours or more, including during activities such as shows and sales or while in marketing channels; or

(4) Any animal in a noncompliant flock.

**Exposed flock.** Any flock in which a scrapie-positive animal was born or

lambed. Any flock that currently contains a female high-risk, exposed, or suspect animal, or that once contained a female high-risk, exposed, or suspect animal that lambed in the flock and from which tissues were not submitted for official testing and found negative. A flock that has completed a post-exposure management and monitoring plan following the exposure will no longer be an exposed flock.

**Flock.** All animals that are maintained on a single premises and all animals under common ownership or supervision on two or more premises with animal interchange between the premises. Changes in ownership of part or all of a flock do not change the identity of the flock or the regulatory requirements applicable to the flock. Animals maintained temporarily on a premises for activities such as shows and sales or while in marketing channels are not a flock. More than one flock may be maintained on a single premises if:

(1) The flocks are enrolled as separate flocks in the SFCP; or

(2) A State or APHIS representative determines, based upon examination of flock records, that:

(i) There is no interchange of animals between the flocks;

(ii) The flocks never commingle and are kept at least 30 feet apart at all times or are separated by a solid wall through, over, or under which fluids cannot pass and through which contact cannot occur;

(iii) The flocks have separate flock records and identification;

(iv) The flocks have separate lambing facilities, including buildings and pastures, and a pasture or building used for lambing by one flock is not used by the other flock at any time; and

(v) The flocks do not share equipment without cleaning and disinfection in accordance with § 54.7(e). Additional guidance on acceptable means of cleaning and disinfection is also available in the Scrapie Flock Certification Program standards and the Scrapie Eradication Uniform Methods and Rules.

**Flock of origin.** The flock in which an animal most recently resided in which it either was born, gave birth, or was used for breeding purposes. The determination of an animal's flock of origin may be based either on the physical presence of the animal in the flock, the presence of official identification on the animal traceable to the flock, the presence of other identification on the animal that is listed on the bill of sale, or other evidence, such as registry records.

**Flock plan.** A written flock management agreement signed by the owner of a flock, the accredited veterinarian, if one is employed by the owner, and a State or APHIS representative in which each participant agrees to undertake actions specified in the flock plan to control the spread of scrapie from, and eradicate scrapie in, an infected flock or source flock or to reduce the risk of the occurrence of scrapie in a flock that contains a high-risk or an exposed animal. As part of a flock plan, the flock owner must provide the facilities and personnel needed to carry out the requirements of the flock plan. The flock plan must include the requirements in § 54.8(a) through (f).

**Flock sire.** A sexually intact male animal that has ever been used for breeding in a flock.

**High-risk animal.** A sexually intact animal, excluding male sheep that have tested RR at codon 171 and AA at codon 136 using an official genotype test, that is:

- (1) The progeny of a scrapie-positive dam; or
- (2) Born in the same flock during the same lambing season as progeny of a scrapie-positive dam, unless the progeny of the scrapie-positive dam are from separate contemporary lambing groups; or
- (3) Born in the same flock during the same lambing season that a scrapie-positive animal was born, or during any subsequent lambing season, if born before that flock completes the requirements of a flock plan; or
- (4) An exposed female sheep that has not tested QR, HR, or RR at codon 171 using an official genotype test.

**Infected flock.** The flock of origin of a female animal that a State or APHIS representative has determined to be a scrapie-positive animal; or any flock in which a State or APHIS representative has determined that a scrapie-positive female animal has resided unless an epidemiologic investigation conducted by a State or APHIS representative shows that the animal did not lamb or abort in the flock. A flock will no longer be considered an infected flock after it has completed the requirements of a flock plan.

**Limited contacts.** Incidental contacts between animals from different flocks off the flock's premises such as at fairs, shows, exhibitions and sales; between ewes being inseminated, flushed, or implanted; or between rams at ram test or collection stations. Embryo transfer and artificial insemination equipment and surgical tools must be sterilized between animals for these contacts to be considered limited contacts. Limited

contacts do not include any contact, incidental or otherwise, with animals in the same flock or with a female animal during or up to 30 days after she lambed, kidded or aborted or when there is any visible vaginal discharge. Limited contacts do not include any activity where uninhibited contact occurs, such as sharing an enclosure, sharing a section of a transport vehicle, or residing in other flocks for breeding or other purposes. Examples of limited contacts may be found in the Scrapie Flock Certification Program standards.

**Live-animal screening test.** Any test for the diagnosis of scrapie in a live animal that is approved by the Administrator as usually reliable but not definitive for diagnosing scrapie, and that is conducted in a laboratory approved by the Administrator.<sup>1</sup>

**Mortgage.** Any mortgage, lien, or other security or interest held by any person other than the one claiming indemnity.

**National Scrapie Database.** A database designated by the Administrator in which APHIS and State animal health agencies cooperatively enter data concerning scrapie outbreaks, flocks and premises affected by scrapie, individual animal identification and premises identification data, and other data to support the Scrapie Eradication Program and the Scrapie Flock Certification Program.

**National Veterinary Services Laboratories (NVSL).** The National Veterinary Services Laboratories, APHIS, U.S. Department of Agriculture, or an NVSL cooperating or contract laboratory.

**Noncompliant flock.** (1) Any source or infected flock whose owner declines to enter into a flock plan or post-exposure management and monitoring plan agreement within 30 days of being so

<sup>1</sup> The names and addresses of laboratories approved by the Administrator to conduct live-animal screening tests will be published in the Notices Section of the **Federal Register**. A list of approved laboratories is also available upon request from the Animal and Plant Health Inspection Service, Veterinary Services, National Animal Health Programs Staff, 4700 River Road Unit 43, Riverdale, MD 20737-1235. State, Federal, and university laboratories will be approved by the Administrator when he or she determines that the laboratory: (a) Employs personnel trained by the National Veterinary Services Laboratories assigned to supervise the testing; (b) follows standard test protocols; (c) meets check test proficiency requirements; and (d) will report all test results to State and Federal animal health officials. Before the Administrator may withdraw approval of any laboratory for failure to meet any of these conditions, the Administrator must give written notice of the proposed withdrawal to the director of the laboratory and must give the director an opportunity to respond. If there are conflicts as to any material fact, a hearing will be held to resolve the conflicts.

designated, or whose owner is not in compliance with either agreement;

(2) Any exposed flock whose owner fails to make animals available for testing within 60 days of notification, or as mutually agreed, or whose owner fails to submit required postmortem samples;

(3) Any flock whose owner has misrepresented, or who employs a person who has misrepresented, the scrapie status of an animal or any other information on a certificate, permit, owner statement, or other official document within the last 5 years; or

(4) Any flock whose owner or manager has moved, or who employs a person who has moved, an animal in violation of this chapter within the last 5 years.

**Official genotype test.** Any test to determine the genotype of a live or dead animal that is conducted at either an approved laboratory or at the National Veterinary Services Laboratories, when the animal is officially identified and the samples used for the test are collected and shipped to the laboratory by either an accredited veterinarian or a State or APHIS representative

**Official test.** Any test for the diagnosis of scrapie in a live or dead animal that is approved by the Administrator for that use and conducted either at an approved laboratory or at the National Veterinary Services Laboratories.

**Owner.** A person, partnership, company, corporation, or any other legal entity who has legal or rightful title to animals, whether or not they are subject to a mortgage.

**Post-exposure management and monitoring plan.** A written agreement signed by the owner of a flock, any accredited veterinarian employed by the owner, and a State or APHIS representative in which each participant agrees to undertake actions specified in the agreement to monitor for the occurrence of scrapie in the flock for at least 5 years after the last high-risk or scrapie-positive animal is removed from the flock or after the last exposure of the flock to a scrapie-positive animal, unless otherwise specified by a State or APHIS representative. As part of a post-exposure management and monitoring plan, the flock owner must provide the facilities and personnel needed to carry out the requirements of the plan. The plan must include the requirements in § 54.8.

**Scrapie control pilot project.** A pilot project authorized by the Administrator in writing, designed to test or improve program procedures or to facilitate research, in order to control and eradicate scrapie. In addition to APHIS, participants may include State animal

health agencies, flock owners, and other parties as necessary.

**Scrapie Eradication Program.** The cooperative State-Federal program administered by APHIS and Consistent States to control and eradicate scrapie.

**Scrapie Eradication Uniform Methods and Rules (UM&R).** Cooperative procedures and standards adopted by APHIS and Consistent States for controlling and eradicating scrapie. The UM&R will be reviewed at least annually by representatives of the livestock industry and appropriate State and Federal agencies and the public and will be revised, and published as needed by APHIS.

**Scrapie Flock Certification Program (SFCP).** The cooperative Federal-State-industry voluntary program for the control of scrapie conducted in accordance with this subpart.

**Scrapie Flock Certification Program standards.** Cooperative procedures and standards adopted by APHIS and State scrapie certification boards for reducing the incidence and controlling the spread of scrapie through flock certification.<sup>2</sup>

**Scrapie-positive animal.** An animal for which a diagnosis of scrapie has been made by the National Veterinary Services Laboratories or another laboratory authorized by the Administrator to conduct scrapie tests in accordance with this part, through:

(1) Histopathological examination of central nervous system (CNS) tissues from the animal for characteristic microscopic lesions of scrapie;

(2) The use of proteinase-resistant protein analysis methods including but not limited to immunohistochemistry and/or western blotting on CNS and/or peripheral tissue samples from a live or a dead animal for which a given method has been approved by the Administrator for use on that tissue;

(3) Bioassay;

(4) Scrapie associated fibrils (SAF) detected by electron microscopy; or

(5) Any other test method approved by the Administrator in accordance with § 54.10.<sup>3</sup>

<sup>2</sup> Individual copies of the Scrapie Flock Certification Program standards may be obtained on the World Wide Web at URL <http://www.aphis.usda.gov/vs/scrapie>, or from the Animal and Plant Health Inspection Service, National Animal Health Programs Staff, 4700 River Road Unit 43, Riverdale, MD 20737-1235.

<sup>3</sup> The names and addresses of laboratories approved by the Administrator to conduct tests are published in the Notices Section of the **Federal Register**. A list of approved laboratories is also available upon request from the Animal and Plant Health Inspection Service, Veterinary Services, National Animal Health Programs Staff, 4700 River Road Unit 43, Riverdale, MD 20737-1235. State, Federal, and university laboratories will be approved by the Administrator when he or she determines that the laboratory: (a) Employs

**Separate contemporary lambing groups.** To be a separate contemporary lambing group, the group must be maintained separately such that the animals cannot come into physical contact with other lambs, kids, ewes or does or birth fluids or placenta from other ewes or does. This separate maintenance must preclude contact through a fence, during lambing and for 60 days following the date the last lamb or kid is born in a lambing season, and must preclude using the same lambing facility as other ewes or does, unless the lambing facility is cleaned and disinfected under supervision by an APHIS representative, State representative, or an accredited veterinarian between lambings in accordance with § 54.7(e). Additional guidance on acceptable means of cleaning and disinfection is also available in the Scrapie Flock Certification Program standards and the Scrapie Eradication Uniform Methods and Rules. The flock owner must maintain adequate records to document which animals were maintained in each contemporary lambing group and to document when cleaning and disinfection was performed and who supervised it.

**Slaughter channels.** Animals in slaughter channels include any animal that is sold, transferred, or moved either directly to a slaughter facility, to an individual for custom slaughter, or for feeding for the express purpose of improving the animals' condition for movement to slaughter. Any sexually intact animal that is commingled with breeding animals or that has been bred is not in slaughter channels. When selling animals for slaughter, owners should note on the bill of sale that the animals are sold only for slaughter.

**Source flock.** A flock in which a State or APHIS representative has determined that at least one animal was born that was diagnosed as a scrapie-positive animal at an age of 72 months or less. The determination that an animal was born in a flock will be based on such information as the presence of official identification on the animal traceable to the flock, the presence of other identification on the animal that is

personnel trained by the National Veterinary Services Laboratories assigned to supervise the testing; (b) follows standard test protocols; (c) meets check test proficiency requirements; and (d) will report all test results to State and Federal animal health officials. Before the Administrator may withdraw approval of any laboratory for failure to meet any of these conditions, the Administrator must give written notice of the proposed withdrawal to the director of the laboratory and must give the director an opportunity to respond. If there are conflicts as to any material fact, a hearing will be held to resolve the conflict.

listed on the bill of sale, or other evidence, such as registry records, to show that a scrapie-positive animal was born in the flock, combined with the absence of records indicating that the animal was purchased from outside and added to the flock. If DNA from the animal was previously collected by an accredited veterinarian and stored at an approved genotyping laboratory, or if DNA collection and storage are required for breed registration and the breed registration has appropriate safeguards in place to ensure the integrity of the banking process, the owner may request verification of the animal's identity based on DNA comparison if adequate records and identification have been maintained by the owner and the repository to show that the archived DNA is that of the animal that has been traced to the flock. The owner will be responsible for all costs for the DNA comparison. A flock will no longer be a source flock after it has completed the requirements of a flock plan.

**State.** Each of the 50 States, the District of Columbia, the Northern Mariana Islands, Puerto Rico, and all territories or possessions of the United States.

**State representative.** An individual 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 the function involved.

**Suspect animal.** An animal will be designated a suspect animal in accordance with § 79.4 of this chapter if it is:

(1) A sheep or goat that exhibits any of the following possible signs of scrapie and that has been determined to be suspicious for scrapie by an accredited veterinarian or a State or APHIS representative: 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, or swaying of back end; increased sensitivity to noise and sudden movement; tremor, "star gazing," head pressing, recumbency, or other signs of neurological disease or chronic wasting.

(2) A sheep or goat that has tested positive for scrapie or for the proteinase resistant protein associated with scrapie on a live-animal screening test or any other test, unless the animal is designated a scrapie-positive animal.

(3) A sheep or goat that has tested inconclusive or suggestive on an official test for scrapie.

**Unofficial test.** Any test for the diagnosis of scrapie or for the detection



of the proteinase resistant protein associated with scrapie in a live or dead animal that either has not been approved by the Administrator or that was not conducted at an approved laboratory or at the National Veterinary Services Laboratories.

#### **§ 54.2 Cooperative agreements and memoranda of understanding with States.**

APHIS will execute cooperative agreements and/or memoranda of understanding with the animal health agency of any State in order to cooperatively administer the Scrapie Eradication Program and the Scrapie Flock Certification Program within that State. These agreements will describe the respective roles of APHIS and State personnel in implementing the Scrapie Eradication Program and the Scrapie Flock Certification Program. Each agreement may specify the financial, material, and personnel resources to be committed to these programs and other scrapie control measures by APHIS and the State; assign specific activities related to the control of scrapie within a State to APHIS or State personnel; establish schedules for APHIS representatives or State representatives to visit flocks; establish procedures for maintaining and sharing program records specified in this part, and specify other responsibilities of State representatives and APHIS representatives in support of the Scrapie Eradication Program and the Scrapie Flock Certification Program.

(Approved by the Office of Management and Budget under control number 0579-0101)

### **Subpart A—Scrapie Indemnification Program**

#### **§ 54.3 Animals eligible for indemnity payments.**

(a) Indemnity may be paid for an animal only after the owner of the animal has applied for indemnification and been approved in accordance with § 54.4. Indemnity may be paid only for the following:

- (1) Destruction of high-risk animals;
- (2) Destruction of animals based on an epidemiologic investigation, when the Administrator determines that the destruction of these animals will contribute to the eradication of scrapie;
- (3) Destruction of live scrapie-positive animals;
- (4) Destruction of animals that test positive on a live-animal screening test; and
- (5) Destruction of suspect animals that are destroyed at the request of an APHIS representative.

(b) No indemnity will be paid for an animal if the owner of the animal fails to provide APHIS, within 30 days of request, animal registration certificates, sale and movement records, or other records requested in accordance with § 54.5. No indemnity will be paid until the premises, including all structures, holding facilities, conveyances, and materials contaminated because of occupation or use by the depopulated animals, have been properly cleaned and disinfected in accordance with § 54.7(e). Additional guidance on acceptable means of cleaning and disinfection is also available in the Scrapie Flock Certification Program standards and the Scrapie Eradication Uniform Methods and Rules. Premises or portions of premises may be exempted from the cleaning and disinfecting requirements if a designated scrapie epidemiologist determines, based on epidemiologic investigation, that cleaning and disinfection of such buildings, holding facilities, conveyances, or other materials on the premises will not significantly reduce the risk of the spread of scrapie, either because effective disinfection is not possible or because the normal operations on the premises prevent transmission of scrapie. No indemnity will be paid to an owner if the owner assembled or increased his flock for the purpose of collecting or increasing indemnity.

#### **§ 54.4 Application by owners for indemnity payments.**

(a) Normally, an application for indemnification will be initiated by a State or APHIS representative who is working with the owner of a flock that has already been determined to be an infected flock or source flock, or that is already under a State movement restriction. In such cases, the flock owner will confirm information about the flock's eligibility for indemnity that is contained in the application submitted by the State or APHIS representative. However, the owner of any flock may apply directly to receive indemnification by submitting to the Administrator a written request containing the following information:

- (1) Name, address, and social security number of the flock owner;
- (2) Number and breed(s) of animals in the flock, including a current inventory;
- (3) Location of flock premises;
- (4) Reasons the owner believes animals in his or her flock may be eligible for indemnification, including any diagnosis of scrapie made for animals in the flock; any signs of scrapie observed in the flock by the owner; and any movement of animals into the flock

from flocks infected with or exposed to scrapie;

(5) A copy of the registration papers issued in the name of the owner for any registered animals in the flock (registration papers are not required for the payment of indemnity for animals that are not registered). If the registration papers are unavailable, the owner may choose to accept a lesser indemnity in accordance with § 54.6(b)(2) or the area veterinarian in charge may grant a 60-day extension or the Administrator may grant an extension longer than 60 days for the presentation of registration papers; and

(6) Signed release letters addressed to any sheep or goat registry associations that maintain records of the owner's sheep or goats requesting the associations to release to APHIS all records maintained by the association on sheep or goats currently or formerly owned by the applicant.

(b) APHIS will evaluate each application to determine whether the owner's flock contains animals eligible for indemnity in accordance with § 54.3.

#### **§ 54.5 Certification by owners.**

Before any indemnity is paid to an owner, the owner must sign a written agreement with APHIS, certifying the following:

(a) The owner will make available for review upon request by a State or APHIS representative all bills of sale, pedigree registration certificates, and other records regarding movement of animals into and from the flock;

(b) If the owner maintains any flock after the payment of indemnity or acquires a new flock that is housed on the same premises within 5 years after the last high-risk or scrapie-positive animal is removed, the owner will maintain the flock in accordance with a post-exposure management and monitoring plan for 5 years;

(c) If the animal for which indemnity is paid is subject to any mortgage, the owner consents to the payment of the indemnity, up to the value of the mortgage, to the person(s) holding the mortgage;

(d) That the animal may be removed to a U.S. Department of Agriculture facility or a quarantined research facility, slaughtered, or euthanized and necropsied and tissues removed for diagnostic or other purposes.

#### **§ 54.6 Amount of indemnity payments.**

(a) Indemnity paid for sheep in accordance with § 54.3 will be set based on the following price reports published by the Agricultural Marketing Service (AMS). If pricing information is unavailable from these markets during a

given week or month or if the numbers of animals sold are too low to give an accurate market value, the preceding week or month's value will be used. The AMS reports from the most recent week or month prior to the date APHIS offers to pay an owner indemnity shall be used to calculate the indemnity for that owner's sheep:

(1) The weekly weighted average Choice/Prime slaughter lamb price per pound at Greeley, CO;

(2) The weekly weighted average Utility slaughter ewe price per pound at San Angelo, TX;

(3) The monthly weighted average commercial western ewe lamb replacement price per head;

(4) The monthly weighted average commercial western yearling ewe replacement price per head;

(5) The monthly weighted average commercial western running age ewe price per head.

(6) The monthly weighted average commercial western aged ewe price per head.

(b) For animals under 1 year of age, the basic indemnity shall equal the price per pound from paragraph (a)(1) of this section times the greater of 50 lbs or the actual weight of the animal; except that, for ewe lambs under 1 year of age, the indemnity shall equal the per-head price from paragraph (a)(3) of this section if that price is higher. For sexually intact sheep 8 years of age or older and castrated animals 1 year of age or older, the basic indemnity shall equal the price per pound from paragraph (a)(2) of this section times 150, based on an average weight of 150 lbs. For sexually intact sheep at least 1 year of age and under 2 years of age, the indemnity shall equal the greater of the price per head from paragraph (a)(4) of this section, or the price per pound from paragraph (a)(2) of this section times 150, based on an average weight of 150 lbs. For sexually intact sheep at least 2 years of age and under 6 years of age, the basic indemnity shall equal the greater of the price per head from paragraph (a)(5) of this section or the price per pound from paragraph (a)(2) of this section times 150, based on an average weight of 150 lbs. For sexually intact sheep at least 6 years of age and under 8 years of age, the basic indemnity will equal the greater of the price per head from paragraph (a)(6) of this section or the price per pound from paragraph (a)(2) of this section times 150, based on an average weight of 150 lbs. A premium shall be added to the basic indemnity for each registered animal, equal to \$100 for each registered animal under 1 year of age, \$200 for each registered animal at least 1 year of

age and under 4 years of age, and \$100 for each registered animal at least 4 years of age and under 8 years of age. An additional premium of \$50 will be added to the basic indemnity for each flock sire. The owner must provide adequate records to qualify for these premiums. When the animals to be indemnified are goats, or are sheep that fall outside the classes covered previously in this paragraph, the Administrator may take into consideration the producer's purchase records and sales records for the preceding 12 to 24 months in determining the indemnity amount, but the indemnity shall not exceed the maximum indemnity calculated for registered sheep in accordance with this section.

(1) If records and identification are inadequate to determine the actual age of animals, an APHIS or State representative will count all sexually intact animals that are apparently under 1 year of age, and those that are apparently at least 1 and under 2 years of age, based on examination of their teeth, and the indemnity for these animals will be calculated. The total number of these animals will be subtracted from the total number of sexually intact animals in the group to be indemnified, and indemnity for the remainder will be calculated based on the assumption that the remainder of the flock is 80 percent aged 2 to 6 years and 20 percent aged 6 to 8 years.

(2) Any animal that is not registered at the time indemnity is first offered, but is eligible to be registered, will receive the registered animal premium reduced by \$50.

(c) For animals destroyed by slaughter, the owner will retain the salvage value (the amount paid by a slaughter plant for the animal) of the animals in lieu of receiving the base indemnity. If the salvage value, less transport costs, is less than the base indemnity, APHIS will pay the owner the difference. APHIS will also indemnify the owner in the amount of any registered animal or flock sire premiums for which the animal qualifies.

(d) If the owner disagrees with the average weight estimate, he may have the sheep weighed at a public scale at his own expense, provided that the sheep may not come in contact with other sheep or goats during movement to the public scales, and will be paid based on the actual weight times the AMS weekly average price.

(e) Indemnity will be paid to an owner only for animals actually in a flock at the time indemnity is first offered. Animals removed from the flock

as part of a post-exposure management and monitoring plan will be paid indemnity based on the AMS average prices at the time an APHIS representative designates the animals for removal.

#### **§ 54.7 Procedures for destruction of animals.**

(a) Scrapie-positive and suspect animals for which indemnification is sought must be destroyed on the premises where they are held, pastured, or penned at the time indemnity is approved or moved to an approved research facility, unless the APHIS representative involved approves in advance of destruction moving the animals to another location for destruction. Animals that are not scrapie-positive or suspect animals for which indemnification is sought may be:

(1) Slaughtered when moved in accordance with part 79 of this chapter and with the prior written approval of the APHIS representative involved;

(2) Destroyed on the premises where they are held, pastured, or penned at the time indemnity is approved;

(3) Moved to an approved research facility; or

(4) Moved to another location for destruction if an APHIS representative approves the movement in advance.

(b) The carcasses of animals destroyed in accordance with this section are authorized by the Administrator to be buried, incinerated, or disposed of by other methods in accordance with local, State, and Federal laws. The carcasses of scrapie-positive and suspect animals may not be processed for human or animal food.

(c) The destruction of animals and disposition of their carcasses in accordance with this part must be monitored by an APHIS representative who will prepare and transmit to the Administrator a report identifying the animals and showing their disposition.

(d) APHIS may pay the reasonable costs of disposal for scrapie-positive and suspect animals that are indemnified. To obtain reimbursement for disposal costs, animal owners must obtain written approval of the disposal costs from APHIS, prior to disposal. The Administrator may also authorize payment of up to half the reasonable disposal costs for animals that are eligible to be destroyed by slaughter under this section but for which slaughter is not a practical or cost efficient means of disposal; *Provided that*, APHIS may pay more than one-half of the expenses when the Administrator determines that doing so will contribute to scrapie eradication. For

reimbursement to be made, the owner of the animals must present the area veterinarian in charge with a copy of either a receipt for expenses paid or a bill for services rendered. Any bill for services rendered by the owner must not be greater than the normal fee for similar services provided by a commercial hauler or disposal facility.

(e) *Cleaning and disinfection of premises and equipment.* When required, cleaning and disinfection shall be conducted under the supervision of a State or APHIS representative as follows. Additional guidance on acceptable means of cleaning and disinfection is also available in the Scrapie Flock Certification Program standards and the Scrapie Eradication Uniform Methods and Rules:

(1) *Drylot areas.* When required, remove the manure and top 1–2 inches of soil to reduce contamination. Bury, till under, or compost the removed material in areas not accessed by domestic animals or wildlife.

(2) *Cement, wood, metal, and other non-earth surfaces, tools, equipment, instruments, feed, hay, bedding, and other materials.* Remove all organic material and compost or incinerate.

Clean and wash all surfaces, tools, equipment, and instruments using hot water and detergent. Allow all surfaces, tools, equipment, and instruments to dry completely before disinfecting and sanitizing using the following methods:

(i) Incinerate items by high-temperature incineration methods;

(ii) Autoclave instruments, small tools, and other items at 136 °C for 1 hour;

(iii) To clean dry surfaces, apply a 2-percent chlorine bleach solution at room temperature (at least 18.3 °C for 1 hour, or apply a 1-molar solution of sodium hydroxide (approximately 5 oz. of sodium hydroxide dissolved in 1 gallon water) at room temperature for at least 1 hour. Note: A 2-molar solution is more effective than a 1-molar solution and should be used when circumstances permit.

#### **§ 54.8 Requirements for flock plans and post-exposure management and monitoring plans.**

(a) The owner of the flock or his or her agent must identify all animals 1 year of age or over within the flock. All animals less than 1 year of age must be identified when a change of ownership occurs, with the exception of those animals under 1 year of age moving within slaughter channels that must be identified in accordance with §§ 79.2 and 79.3 of this chapter. The form of identification must be an electronic implant, flank tattoo, ear tattoo, or

tamper-resistant ear tag approved for this use by APHIS. In the case of goats, the form of identification may alternatively be a tail fold tattoo. The official identification must provide a unique identification number that is applied by the owner of the flock or his or her agent and must be linked to that flock in the National Scrapie Database.

(b) Upon request by a State or APHIS representative, the owner of the flock or his or her agent must have an accredited veterinarian collect tissues from animals for scrapie diagnostic purposes and submit them to a laboratory designated by a State or APHIS representative.

(c) Upon request by a State or APHIS representative, the owner of the flock or his or her agent must make animals in the flock and the records required to be kept as a part of these plans available for inspection.

(d) The owner of the flock or his or her agent must meet requirements found necessary by a State or APHIS representative to monitor for scrapie and to prevent the recurrence of scrapie in the flock and to prevent the spread of scrapie from the flock. These other requirements may include, but are not limited to: Utilization of a live-animal screening test; restrictions on the animals that may be moved from the flock; segregated lambing; cleaning and disinfection of lambing facilities; and/or education of the owner of the flock and personnel working with the flock in techniques to recognize clinical signs of scrapie and to control the spread of scrapie.

(e) The owner of the flock or his or her agent must immediately report the following animals to a State representative, APHIS representative, or an accredited veterinarian, and not remove them from a flock without written permission of a State or APHIS representative:

(1) Any sheep or goat exhibiting 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, swaying of back end; increased sensitivity to noise and sudden movement; tremor, “star gazing,” head pressing, recumbency, or other signs of neurological disease or chronic wasting illness; and

(2) Any sheep or goat in the flock that has tested positive for scrapie or for the proteinase resistant protein associated with scrapie on a live-animal screening test or any other test.

(f) *Requirements for flock plans only.*

(1) An epidemiologic investigation must be conducted to identify high-risk and

exposed animals that currently reside in the flock or that previously resided in the flock, and all high-risk animals, scrapie-positive animals, and suspect animals must be removed from the flock. The animals must be removed either by movement to an approved research facility or by euthanization and disposal of the carcasses by burial, incineration, or other methods in accordance with local, State, and Federal laws, or, in the case of high-risk animals, by movement to slaughter in accordance with the provisions of part 79 of this chapter, or upon request in individual cases by another means determined by the Administrator to be sufficient to prevent the spread of scrapie;

(2) The premises of a flock under a flock plan must be cleaned and disinfected in accordance with § 54.7(e). Additional guidance on acceptable means of cleaning and disinfection is also available in the Scrapie Flock Certification Program standards and the Scrapie Eradication Uniform Methods and Rules. Premises or portions of premises may be exempted from the cleaning and disinfecting requirements if a designated scrapie epidemiologist determines, based on epidemiologic investigation, that cleaning and disinfection of such buildings, holding facilities, conveyances, or other materials on the premises will not significantly reduce the risk of the spread of scrapie, either because effective disinfection is not possible or because the normal operations on the premises prevent transmission of scrapie. No area where a scrapie-positive animal lambled or aborted may be exempted;

(3) The owner of the flock, or his or her agent, must request breed associations and registries, livestock markets, and packers to disclose records to APHIS representatives or State representatives, to be used to identify source flocks and trace exposed animals, including high-risk animals; and

(4) The flock owner must agree to conduct post-exposure management and monitoring.

(g) *Requirements for post-exposure management and monitoring plans only:* The plan must require that a State or APHIS representative inspect the flock and flock records at least once every 12 months. The owner of the flock or his or her agent must maintain, and keep for a minimum of 5 years after an animal dies or is otherwise removed from a flock, the following records for each animal in the flock:

(1) Any identifying marks or tags present on the animal, including the

animal's individual official identification number from its electronic implant, flank tattoo, ear tattoo, tamper resistant ear tag, or, in the case of goats, tail fold tattoo, and any secondary form of identification the owner of the flock may choose to maintain;

(2) Sex, year of birth, breed, and when possible to determine, the following: sire, dam, and offspring of the animal;

(3) Date of acquisition and previous flock, if the animal was not born in the flock; and

(4) Disposition of the animal, including the date and cause of death, if known, or date of removal from the flock and name and address of the person to whom the animal was transferred.

(h) *Modification of flock plans and post-exposure management and monitoring plans.* A designated scrapie epidemiologist may modify the requirements of a flock plan or post-exposure management and monitoring plan to accommodate the situation of a particular flock if the modified plan requires:

(1) That a State or APHIS representative inspect the flock and flock records at least once every 12 months;

(2) The testing of animals at a level that will result in 99 percent confidence of detecting a 1 percent prevalence in the flock (for flock plans only);

(3) The official identification of all animals upon leaving the premises of the flock for purposes other than slaughter and of all animals over 18 months of age (as evidenced by the eruption of the second incisor) in slaughter channels; and

(4) Recordkeeping including:

(i) For acquired animals, the date of acquisition, name and address of the person from whom the animal was acquired, any identifying marks or tags present on the animal including the animal's individual official identification number from its electronic implant, flank tattoo, ear tattoo, tamper resistant ear tag, or, in the case of goats, tail fold tattoo, and any secondary form of identification the owner of the flock may choose to maintain.

(ii) For animals leaving the premises of the flock, the disposition of the animal, including, for those animals that are required to be identified, any identifying marks or tags present on the animal, including the animal's individual official identification number from its electronic implant, flank tattoo, ear tattoo, tamper resistant ear tag, or, in the case of goats, a tail fold tattoo, and any secondary form of identification the

owner of the flock may choose to maintain, the date and cause of death, if known, or date of removal from the flock and name and address of the person to whom the animal was transferred.

(iii) Maintenance of these records for 5 years.

(5) Requirements equivalent to those contained in paragraphs (b), (c), (d), and (e) of this section.

(i) *Post-exposure management and monitoring plans for exposed flocks that were not source flocks and in which a scrapie infected animal did not lamb.* A designated scrapie epidemiologist shall determine the testing and monitoring requirements for these flocks based on the exposure risk of the individual flock.

#### **§ 54.9 Waiver of requirements for scrapie control pilot projects.**

The Administrator may waive the following requirements of this part for participants in a scrapie control pilot project by recording the requirements waived in the scrapie control pilot project plan:

(a) The determination that an animal is a high-risk animal, if the scrapie control pilot project plan contains testing or other procedures that indicate that an animal, despite meeting the definition of high-risk animal, is unlikely to spread scrapie; and

(b) The requirement that high-risk animals must be removed from a flock if the scrapie control pilot project plan contains alternative procedures to prevent the further spread of scrapie without removing high-risk animals from the flock.

#### **§ 54.10 Tests for scrapie.**

(a) The Administrator may approve new tests for the diagnosis of scrapie conducted on live or dead animals for use in the Scrapie Eradication Program. The Administrator will base the approval or disapproval of a test on the evaluation by APHIS and, when appropriate, outside scientists, of:

(1) A standardized test protocol that must include a description of the test, a description of the reagents, materials, and equipment used for the test, the test methodology, and any control or quality assurance procedures;

(2) Data to support reproducibility, that is, the ability to reproduce the same result repeatedly on a given sample;

(3) Data to support suitability, that is, data to show that similar results can be produced when the test is run at other laboratories;

(4) Data to support the sensitivity and specificity of the test; and

(5) Any other data requested by the Administrator to determine the suitability of the test for program use.

(b) To be approved, a scrapie test must be able to be replicated at the National Veterinary Services Laboratories, or another reliable, timely, and cost effective method of check testing must be available to APHIS.

(c) A test or combination of tests may be approved for the identification of suspect animals, for the identification of scrapie-positive animals, or for other purposes such as flock certification. For a test to be approved for the identification of scrapie-positive animals, the test must have a specificity comparable to the specificity of the currently approved tests. For a test to be approved as a live animal screening test for the identification of suspect animals, the test must be usually reliable but need not be definitive for diagnosing scrapie.

(d) Specific guidelines for use of approved scrapie tests within the Scrapie Eradication Program or Scrapie Flock Certification Program will be added to this part as tests are approved and will also be contained in the Scrapie Eradication UM&R and the Scrapie Flock Certification Program standards based on the characteristics of the test, including specificity, sensitivity, and predictive value.

(e) If an owner elects to have an unofficial test conducted on an animal for scrapie, or for the proteinase resistant protein associated with scrapie, and that animal tests positive to such a test, the animal will be designated a suspect animal, unless:

(1) The test was run as part of a bona fide research protocol designed to evaluate an unapproved test in which the owner is not informed of the test result; or

(2) The test protocol includes appropriate measures to prevent the spread of scrapie.

#### **§ 54.11 Approval of laboratories to run official scrapie tests and official genotype tests.**

(a) State, Federal, and university laboratories, or in the case of genotype tests, private laboratories will be approved by the Administrator when he or she determines that the laboratory:

(1) Employs personnel assigned to supervise the testing who are qualified to conduct the test based on education, training, and experience and who have been trained by the National Veterinary Services Laboratories (NVSL) or who have completed equivalent training approved by NVSL;

(2) Has adequate facilities and equipment to conduct the test;

(3) Follows standard test protocols;  
(4) Meets check test proficiency requirements;

(5) Meets recordkeeping requirements;  
(6) Will retain records, slides, blocks, and other specimens from all cases for at least 1 year and from positive cases for 5 years;

(7) Will allow APHIS to inspect the laboratory without notice during normal business hours; and

(8) Will report all test results to State and Federal animal health officials within agreed timeframes. An inspection may include, but is not limited to, review and copying of records, examination of slides, observation of the test being conducted, and interviewing of personnel.

(b) A laboratory may request approval to conduct one or more types of scrapie test or genotype test on one or more types of tissue. To be approved, a laboratory must meet the requirements in paragraph (a) of this section for each type of test and for each type of tissue for which they request approval.

(c) The Administrator may withdraw approval of any laboratory for failure to meet any of the conditions required by paragraph (a) of this section. The Administrator shall give written notice of the proposed withdrawal to the director of the laboratory and shall give the director an opportunity to respond. If there are conflicts as to any material fact concerning the reason for withdrawal, a hearing will be held to resolve the conflicts.

## Subpart B—Scrapie Flock Certification Program

### § 54.20 Administration.

The Scrapie Flock Certification Program is a cooperative effort between APHIS; members of the sheep and goat industry, including owners of flocks, slaughtering and rendering establishments, and breed associations and registries; accredited veterinarians; and State governments. APHIS coordinates with State scrapie certification boards and State animal health agencies to encourage flock owners to certify their flocks as free of scrapie by being in continuous compliance with the Scrapie Flock Certification Program standards.

### § 54.21 Participation.

Any owner of a sheep or goat flock may apply to enter the Scrapie Flock Certification Program by sending a written request to a State scrapie certification board or to the area veterinarian in charge. A notice containing a current list of flocks participating in the Scrapie Flock

Certification Program, and the certification status of each flock, may be obtained from the APHIS web site at URL <http://www.aphis.usda.gov/vs/scrapie>. A list of noncompliant flocks may also be obtained from this site, and either list may be obtained by writing to the Animal and Plant Health Inspection Service, National Animal Health Programs Staff, VS, APHIS, 4700 River Road Unit 43, Riverdale, MD 20737–1235.

(Approved by the Office of Management and Budget under control number 0579–0101)

### § 54.22 State scrapie certification boards.

An area veterinarian in charge, after consulting with a State representative and industry representatives, may appoint a State scrapie certification board for the purpose of coordinating activities for the Scrapie Flock Certification Program, including making decisions to admit flocks to the Scrapie Flock Certification Program and to change flock status in accordance with the Scrapie Flock Certification Program standards. These boards are not appointed for the purpose of providing APHIS with consensus advice or policy recommendations. No more than one State scrapie certification board may be formed in each State. Each State scrapie certification board shall include as members the area veterinarian in charge, one or more State representatives, one or more accredited veterinarians, when possible, and one or more owners of flocks, and, at the discretion of the area veterinarian in charge, may include other members.

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2. Part 79 is revised to read as follows:

## PART 79—SCRAPIE IN SHEEP AND GOATS

### Sec.

#### 79.1 Definitions.

#### 79.2 Identification of sheep and goats in interstate commerce.

#### 79.3 General restrictions.

#### 79.4 Designation of scrapie-positive animals, high-risk animals, exposed animals, suspect animals, exposed flocks, infected flocks, noncompliant flocks, and source flocks; notice to owners.

#### 79.5 Issuance of certificates.

#### 79.6 Standards for States to qualify as Consistent States.

#### 79.7 Waiver of requirements for scrapie control pilot projects.

**Authority:** 21 U.S.C. 111–113, 115, 117, 120, 121, 123–126, 134b, and 134f; 7 CFR 2.22, 2.80, and 371.4.

### § 79.1 Definitions.

*Accredited veterinarian.* A veterinarian approved by the

Administrator in accordance with part 161 of this chapter to perform functions specified in subchapters B, C, and D of this chapter.

*Administrator.* The Administrator of the Animal and Plant Health Inspection Service or any employee of the United States Department of Agriculture authorized to act for the Administrator.

*Animal.* A sheep or goat.

*Animal and Plant Health Inspection Service (APHIS).* The Animal and Plant Health Inspection Service of the United States Department of Agriculture.

*APHIS representative.* An individual employed by APHIS in animal health activities who is authorized by the Administrator to perform the function involved.

*Approved laboratory.* A laboratory approved by the Administrator in accordance with § 54.11 of this chapter to conduct one or more scrapie tests, or genotype tests, on one or more tissues.

*Area veterinarian in charge.* The veterinary official of APHIS who is assigned by the Administrator to supervise and perform the official animal health work of APHIS in the State concerned.

*Blackfaced sheep.* Any purebred suffolk, hampshire, shropshire or cross thereof, any non-purebred sheep known to have suffolk, hampshire, or shropshire ancestors, and any non-purebred sheep of unknown ancestry with a black face, except commercial hair sheep.

*Breed association and registries.* Organizations listed in § 151.9 of this chapter that maintain the permanent records of ancestry or pedigrees of animals (including the animal's sire and dam), individual identification of animals, and ownership of animals.

*Certificate.* An official document issued in accordance with § 79.5 by an APHIS representative, State representative, or accredited veterinarian at the point of origin of an interstate movement of animals.

*Commercial hair sheep.* Any commercial sheep with hair rather than wool that is either a full-blooded hair sheep or that resulted from the cross of a hair sheep with a whitefaced wool sheep.

*Commercial sheep or goat.* Any animal from a flock from which animals are moved only either directly to slaughter or through slaughter channels to slaughter or any animal that is raised only for meat or fiber production and that is not registered with a sheep or goat registry or used for exhibition.

*Commingle, commingled.* Animals grouped together and having physical contact with each other, including contact through a fence,

but not limited contacts. Commingling also includes sharing the same section in a transportation unit where there is physical contact.

**Consistent State.** (1) A State that the Administrator has determined conducts an active State scrapie control program that either:

(i) Meets the requirements of § 79.6; or  
(ii) Effectively enforces a State designed plan that the Administrator determines is at least as effective in controlling scrapie as the requirements of § 79.6.

(2) The Administrator has determined the following States to be Consistent States: Alabama, Alaska, Arizona, Arkansas, California, Colorado, Connecticut, Delaware, Florida, Georgia, Hawaii, Idaho, Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Montana, Nebraska, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, South Dakota, Tennessee, Texas, Utah, Vermont, Virginia, Washington, West Virginia, Wisconsin, and Wyoming.

**Designated scrapie epidemiologist.** An epidemiologist who has demonstrated the knowledge and ability to perform the functions required and who has been selected by the State animal health official and the area veterinarian in charge. The regional epidemiologist and the APHIS National Scrapie Program Coordinator must concur in the selection and appointment of the designated scrapie epidemiologist. The designated scrapie epidemiologist must satisfactorily complete training designated by APHIS.

**Direct movement to slaughter.** Transported to a facility for slaughter, without stops or unloading except for feeding and watering during which the animals are not commingled with any other animals.

**Electronic implant.** Any radio frequency identification implant device approved for use in the scrapie program by the Administrator. The Administrator will approve an electronic implant after determining that it is tamper resistant, not harmful to the animal, and readable by equipment available to APHIS and State representatives.

**Exposed animal.** (1) Any animal that has been in the same flock at the same time as a scrapie-positive female animal, excluding limited contacts; or

(2) Any animal born in a flock after a scrapie-positive animal was born into that flock or lambed in that flock, if born

before that flock completes the requirements of a flock plan; or

(3) Any animal that was commingled with a scrapie-positive female animal during or up to 30 days after she lambed, kidded, or aborted, or while a visible vaginal discharge was present, or that was commingled with any other scrapie-positive female animal for 24 hours or more, including during activities such as shows and sales or while in marketing channels; or

(4) Any animal in a noncompliant flock.

**Exposed flock.** Any flock in which a scrapie-positive animal was born or lambed. Any flock that currently contains a female high-risk, exposed, or suspect animal, or that once contained a female high-risk, exposed, or suspect animal that lambed in the flock and from which tissues were not submitted for official testing and found negative. A flock that has completed a post-exposure management and monitoring plan following the exposure will no longer be an exposed flock.

**Flock.** All animals that are maintained on a single premises and all animals under common ownership or supervision on two or more premises with animal interchange between the premises. Changes in ownership of part or all of a flock do not change the identity of the flock or the regulatory requirements applicable to the flock. Animals maintained temporarily on a premises for activities such as shows and sales or while in marketing channels are not a flock. More than one flock may be maintained on a single premises if:

(1) The flocks are enrolled as separate flocks in the SFCP; or

(2) A State or APHIS representative determines, based upon examination of flock records, that:

(i) There is no interchange of animals between the flocks;

(ii) The flocks never commingle and are kept at least 30 feet apart at all times or are separated by a solid wall through, over, or under which fluids cannot pass and through which contact cannot occur;

(iii) The flocks have separate flock records and identification;

(iv) The flocks have separate lambing facilities, including buildings and pastures, and a pasture or building used for lambing by one flock is not used by the other flock at any time; and

(v) The flocks do not share equipment without cleaning and disinfection in accordance with § 54.7(e) of this chapter. Additional guidance on acceptable means of cleaning and disinfection is also available in the Scrapie Flock Certification Program

standards and the Scrapie Eradication Uniform Methods and Rules.

**Flock of origin.** The flock in which an animal most recently resided in which it either was born, gave birth, or was used for breeding purposes. The determination of an animal's flock of origin may be based either on the physical presence of the animal in the flock, the presence of official identification on the animal traceable to the flock, the presence of other identification on the animal that is listed on the bill of sale, or other evidence, such as registry records.

**Flock plan.** A written flock management agreement signed by the owner of a flock, the accredited veterinarian, if one is employed by the owner, and a State or APHIS representative in which each participant agrees to undertake actions specified in the flock plan to control the spread of scrapie from, and eradicate scrapie in, an infected flock or source flock or to reduce the risk of the occurrence of scrapie in a flock that contains a high-risk or an exposed animal. As part of a flock plan, the flock owner must provide the facilities and personnel needed to carry out the requirements of the flock plan. The flock plan must include the requirements in § 54.8(a)(f) of this chapter.

**High-risk animal.** A sexually intact animal, excluding male sheep that have tested RR at codon 171 and AA at codon 136 using an official genotype test, that is:

(1) The progeny of a scrapie-positive dam; or

(2) Born in the same flock during the same lambing season as progeny of a scrapie-positive dam, unless the progeny of the scrapie-positive dam are from separate contemporary lambing groups; or

(3) Born in the same flock during the same lambing season that a scrapie-positive animal was born, or during any subsequent lambing season, if born before that flock completes the requirements of a flock plan; or

(4) An exposed female sheep that has not tested QR, HR, or RR at codon 171 using an official genotype test.

**Inconsistent State.** Any State other than a Consistent State.

**Infected flock.** The flock of origin of a female animal that a State or APHIS representative has determined to be a scrapie-positive animal; or any flock in which a State or APHIS representative has determined that a scrapie-positive female animal has resided unless an epidemiologic investigation conducted by a State or APHIS representative shows that the animal did not lamb or abort in the flock. A flock will no longer

be considered an infected flock after it has completed the requirements of a flock plan.

*Interstate commerce.* Trade, traffic, transportation, or other commerce between a place in a State and any place outside of that State, or between points within a State but through any place outside that State.

*Limited contacts.* Incidental contacts between animals from different flocks off the flock's premises such as at fairs, shows, exhibitions and sales; between ewes being inseminated, flushed, or implanted; or between rams at ram test or collection stations. Embryo transfer and artificial insemination equipment and surgical tools must be sterilized between animals for these contacts to be considered limited contacts. Limited contacts do not include any contact, incidental or otherwise, with animals in the same flock or with an animal during or up to 30 days after she lambed, kidded or aborted or when there is any visible vaginal discharge. Limited contacts do not include any activity where uninhibited contact occurs, such as sharing an enclosure, sharing a section of a transport vehicle, or residing in other flocks for breeding or other purposes. Examples of limited contacts may be found in the Scrapie Flock Certification Program standards.

*Live-animal screening test.* Any test for the diagnosis of scrapie in a live animal that is approved by the Administrator as usually reliable but not definitive for diagnosing scrapie, and that is conducted in a laboratory approved by the Administrator.<sup>1</sup>

*Low-risk commercial sheep.* Commercial whitefaced, whitefaced cross, or commercial hair sheep from a flock with no known risk factors for scrapie, including any exposure to female blackfaced sheep, that are identified with a legible permanent

brand or ear notch pattern registered with an official brand registry and that are not scrapie-positive, suspect, high-risk, or exposed animals and are not animals from an infected, source, or exposed flock. The term brand includes official brand registry brands on ear tags in those States whose brand law or regulation recognizes brands placed on ear tags as official brands. Low-risk commercial sheep may only exist in a State where scrapie has not been diagnosed in the previous 10 years in commercial whitefaced, whitefaced cross, or commercial hair sheep that were not commingled with female blackfaced sheep.

*Low-risk goat.* A goat that is not a scrapie-positive, suspect, high-risk, or exposed animal, that has not been commingled with sheep, and that is from:

(1) A State in which scrapie has not been identified in a goat during the previous 10 years;

(2) A State in which scrapie has been identified in a goat during the previous 10 years, but the scrapie-positive goat was not born in the State and resided in the State for less than 54 months and did not kid while in the State; or,

(3) A State in which scrapie has been identified in a goat during the previous 10 years, and the scrapie-positive goat was commingled with sheep, but flock records allowed a complete epidemiologic investigation to be completed and all resulting infected, source, and exposed goat herds have completed flock plans and are in compliance with post-exposure monitoring plans.

*National Scrapie Database.* A database designated by the Administrator in which APHIS and State animal health agencies cooperatively enter data concerning scrapie outbreaks, flocks and premises affected by scrapie, individual animal identification and premises identification data, and other data to support the Scrapie Eradication Program and the Scrapie Flock Certification Program.

*Noncompliant flock.* (1) Any source or infected flock whose owner declines to enter into a flock plan or post-exposure management and monitoring plan agreement within 30 days of being so designated, or whose owner is not in compliance with either agreement;

(2) Any exposed flock whose owner fails to make animals available for testing within 60 days of notification, or as mutually agreed, or whose owner fails to submit required postmortem samples;

(3) Any flock whose owner has misrepresented, or who employs a

person who has misrepresented, the scrapie status of an animal or any other information on a certificate, permit, owner statement, or other official document within the last 5 years; or

(4) Any flock whose owner or manager has moved, or who employs a person who has moved, an animal in violation of this chapter within the last 5 years.

*Official eartag.* An identification eartag approved by APHIS as being sufficiently tamper-resistant for the intended use and providing unique identification for each animal. An official eartag may conform to the alphanumeric National Uniform Eartagging system or another system approved by APHIS, or it may bear a premises identification number that either contains or is used in conjunction with the producer's livestock production numbering system to provide a unique identification number.

*Official genotype test.* Any test to determine the genotype of a live or dead animal that is conducted at either an approved laboratory or at the National Veterinary Services Laboratories, when the animal is officially identified and the samples used for the test are collected and shipped to the laboratory by either an accredited veterinarian or a State or APHIS representative.

*Official identification.* Identification mark or device approved by APHIS for use in the Scrapie Eradication Program. Examples are listed in § 79.2(a)(2).

*Official test.* Any test for the diagnosis of scrapie in a live or dead animal that is approved by the Administrator for that use and conducted either at an approved laboratory or at the National Veterinary Services Laboratories.

*Owner.* A person, partnership, company, corporation, or any other legal entity who has legal or rightful title to animals, whether or not they are subject to a mortgage.

*Owner statement.* A written statement by the owner that includes the owner's name, signature, address, and phone number, date the animals left the flock of origin, the premises identification number assigned to the premises, the number of animals, the premises portion of the premises identification if premises identification is used, and a statement that the animals were either born or were used for breeding purposes on the premises to which the premises identification is assigned.

*Ownership brand.* A unique permanent legible brand or ear notch pattern applied to an animal that indicates ownership by a particular person when the brand pattern is registered with a State's official brand recording agency.

<sup>1</sup> The names and addresses of laboratories approved by the Administrator to conduct live-animal screening tests will be published in the Notices Section of the **Federal Register**. A list of approved laboratories is also available upon request from the Animal and Plant Health Inspection Service, Veterinary Services, National Animal Health Programs Staff, 4700 River Road Unit 43, Riverdale, MD 20737-1235. State, Federal, and university laboratories will be approved by the Administrator when he or she determines that the laboratory: (a) Employs personnel trained by the National Veterinary Services Laboratories assigned to supervise the testing; (b) follows standard test protocols; (c) meets check test proficiency requirements; and (d) will report all test results to State and Federal animal health officials. Before the Administrator may withdraw approval of any laboratory for failure to meet any of these conditions, the Administrator will give written notice of the proposed withdrawal to the director of the laboratory, and will give the director an opportunity to respond. If there are conflicts as to any material fact, a hearing will be held to resolve the conflicts.



**Permit.** An official document issued in connection with the interstate movement of animals (VS Form 1-27 or a State form that contains the same information) that is issued by an APHIS representative, State representative, or an accredited veterinarian authorized to sign such permits. A new permit is required for each change in destination for an animal. A permit lists the owner's name and address; points of origin and destination; number of animals covered; purpose of the movement; whether the animals are from an exposed, noncompliant, infected, or source flock; whether the animal is a high-risk, exposed, scrapie-positive, or scrapie suspect animal; transportation vehicle license number or other identification number; and seal number (if a seal is required). A permit also lists all official identification on the animals covered, including the official eartag number, individual animal registered breed association registration tattoo, individual animal registered breed association registration brand, United States Department of Agriculture backtag (when applied serially, only the beginning and the ending numbers need be recorded), individual animal registered breed association registration number, or any other form of official identification present on the animal.

**Premises identification.** An APHIS approved eartag, backtag, or legible tattoo bearing the premises identification number, consisting of the State postal abbreviation or code followed by a unique alphanumeric number or name, assigned by a State or Federal animal health official to the premises of the flock of origin for the sheep or goats that, in the judgment of the State animal health official or area veterinarian in charge, is epidemiologically distinct from other premises, or a legible permanent brand or ear notch pattern registered with an official brand registry. Premises identification may be used when official individual animal identification is required, if the premises identification method either includes a unique animal number or is used in conjunction with the producer's livestock production numbering system to provide a unique identification number and where, if brands or ear notches are used, the animals are accompanied by an official brand inspection certificate. Clearly visible and/or legible paint brands may be used on animals moving directly to slaughter and on animals moving for grazing or other management purposes without change in ownership.

**Scrapie Eradication Program.** The cooperative State-Federal program

administered by APHIS and Consistent States to control and eradicate scrapie.

**Scrapie Eradication Uniform Methods and Rules (UM&R).** Cooperative procedures and standards adopted by APHIS and Consistent States for controlling and eradicating scrapie. The UM&R will be reviewed at least annually by representatives of the livestock industry, appropriate State and Federal agencies, and the public and will be drafted, revised, and published as needed by APHIS.

**Scrapie Flock Certification Program (SFCP).** The cooperative Federal-State-industry voluntary program for the control of scrapie conducted in accordance with subpart B of part 54 of this chapter.

**Scrapie Flock Certification Program standards.** Cooperative procedures and standards adopted by APHIS and State Scrapie Certification Boards for reducing the incidence and controlling the spread of scrapie through flock certification.<sup>2</sup>

**Scrapie-positive animal.** An animal for which a diagnosis of scrapie has been made by the National Veterinary Services Laboratories or another laboratory authorized by the Administrator to conduct scrapie tests in accordance with this chapter, through:

(1) Histopathological examination of central nervous system (CNS) tissues from the animal for characteristic microscopic lesions of scrapie;

(2) The use of proteinase-resistant protein analysis methods including but not limited to immunohistochemistry and/or western blotting on CNS and/or peripheral tissue samples from a live or a dead animal for which a given method has been approved by the Administrator for use on that tissue;

(3) Bioassay;

(4) Scrapie associated fibrils (SAF) detected by electron microscopy; or

(5) Any other test method approved by the Administrator in accordance with § 54.10 of this chapter.<sup>3</sup>

<sup>2</sup> Individual copies of the SFCP standards may be obtained on the World Wide Web at URL <http://www.aphis.usda.gov/vs>, or from the Animal and Plant Health Inspection Service, National Animal Health Programs Staff, 4700 River Road Unit 43, Riverdale, MD 20737-1235.

<sup>3</sup> The names and addresses of laboratories approved by the Administrator to conduct tests are published in the Notices Section of the **Federal Register**. A list of approved laboratories is also available upon request from the Animal and Plant Health Inspection Service, Veterinary Services, National Animal Health Programs Staff, 4700 River Road Unit 43, Riverdale, MD 20737-1235. State, Federal, and university laboratories will be approved by the Administrator when he or she determines that the laboratory: (a) Employs personnel trained by the National Veterinary Services Laboratories assigned to supervise the

**Separate contemporary lambing groups.** To be a separate contemporary lambing group, the group must be maintained separately such that the animals cannot come into physical contact with other lambs, kids, ewes or does or birth fluids or placenta from other ewes or does. This separate maintenance must preclude contact through a fence, during lambing and for 60 days following the date the last lamb or kid is born in a lambing season, and must preclude using the same lambing facility as other ewes or does, unless the lambing facility is cleaned and disinfected under supervision by an APHIS representative, State representative, or an accredited veterinarian between lambings in accordance with § 54.7(e) of this chapter. Additional guidance on acceptable means of cleaning and disinfection is also available in the Scrapie Flock Certification Program standards and the Scrapie Eradication Uniform Methods and Rules. The flock owner must maintain adequate records to document which animals were maintained in each contemporary lambing group and to document when cleaning and disinfection was performed and who supervised it.

**Slaughter channels.** Animals in slaughter channels include any animal that is sold, transferred, or moved either directly to a slaughter facility, to an individual for custom slaughter, or for feeding for the express purpose of improving the animals' condition for movement to slaughter. Any sexually intact animal that is commingled with breeding animals or that has been bred is not in slaughter channels. When selling animals for slaughter, owners should note on the bill of sale that the animals are sold only for slaughter.

**Source flock.** A flock in which a State or APHIS representative has determined that at least one animal was born that was diagnosed as a scrapie-positive animal at an age of 72 months or less. The determination that an animal was born in a flock will be based on such information as the presence of official identification on the animal traceable to the flock, the presence of other identification on the animal that is listed on the bill of sale, or other evidence, such as registry records, to

testing; (b) follows standard test protocols; (c) meets check test proficiency requirements; and (d) will report all test results to State and Federal animal health officials. Before the Administrator may withdraw approval of any laboratory for failure to meet any of these conditions, the Administrator must give written notice of the proposed withdrawal to the director of the laboratory and must give the director an opportunity to respond. If there are conflicts as to any material fact, a hearing will be held to resolve the conflict.

show that a scrapie-positive animal was born in the flock, combined with the absence of records indicating that the animal was purchased from outside and added to the flock. If DNA from the animal was previously collected by an accredited veterinarian and stored at an approved genotyping laboratory, or if DNA collection and storage are required for breed registration and the breed registration has appropriate safeguards in place to ensure the integrity of the banking process, the owner may request verification of the animal's identity based on DNA comparison if adequate records and identification have been maintained by the owner and the repository to show that the archived DNA is that of the animal that has been traced to the flock. The owner will be responsible for all costs for the DNA comparison. A flock will no longer be a source flock after it has completed the requirements of a flock plan.

**State.** Each of the 50 States, the District of Columbia, the Northern Mariana Islands, Puerto Rico, and all territories or possessions of the United States.

**State representative.** An individual 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 the function involved.

**Suspect animal.** An animal will be designated a suspect animal in accordance with § 79.4 if it is:

(1) A sheep or goat that exhibits any of the following possible signs of scrapie and that has been determined to be suspicious for scrapie by an accredited veterinarian or a State or APHIS representative: 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, or swaying of back end; increased sensitivity to noise and sudden movement; tremor, "star gazing," head pressing, recumbency, or other signs of neurological disease or chronic wasting.

(2) A sheep or goat that has tested positive for scrapie or for the proteinase resistant protein associated with scrapie on a live-animal screening test or any other test, unless the animal is designated a scrapie-positive animal.

(3) A sheep or goat that has tested inconclusive or suggestive on an official test for scrapie.

**Terminal feedlot.** (1) A dry lot approved by a State or APHIS representative or an accredited veterinarian authorized to perform this function where animals are separated

from all other animals by at least 30 feet at all times or are separated by a solid wall through, over, or under which fluids cannot pass and contact cannot occur and from which animals are moved only to another terminal feedlot or directly to slaughter; or

(2) A pasture when approved by and maintained under the supervision of the State and in which only nonpregnant animals are permitted, where there is no direct fence-to-fence contact with another flock, and from which animals are moved only to another terminal feedlot or directly to slaughter.

(3) Records of all animals entering and leaving a terminal feedlot must be maintained for 1 year after the animal leaves the feedlot and must include the person from whom the animals were acquired and the slaughtering facility in which they were slaughtered. Records must be made available for inspection by an APHIS or State representative upon request.

**Unofficial test.** Any test for the diagnosis of scrapie or for the detection of the proteinase resistant protein associated with scrapie in a live or dead animal that either has not been approved by the Administrator or that was not conducted at an approved laboratory or at the National Veterinary Services Laboratories.

#### **§ 79.2 Identification of sheep and goats in interstate commerce.**

(a) No sheep or goat that is required to be individually identified or premises identified by § 79.3 may be sold, transported, received for transportation, or offered for sale or transportation in interstate commerce unless each sheep or goat is identified in accordance with this section.

(1) The sheep or goat must be identified to its flock of origin and, for an animal born after January 1, 2002, to its flock of birth, by the owner of the flock or his or her agent; at whichever of the following points in commerce comes first, *Except that*; animals born after January 1, 2002, may be moved interstate direct to slaughter without identification to flock of birth until June 1, 2003, and animals that cannot be identified to their flock of origin because Consistent States have exempted them from flock of origin identification in intrastate commerce in accordance with § 79.6(a)(10)(i) may be moved interstate with only individual animal identification traceable to the State of origin and to the owner of the animals at the time they were so identified:

(i) The point of first commingling of the sheep or goats in interstate

commerce with sheep or goats from any other flock of origin;

(ii) Upon unloading of the sheep or goats in interstate commerce at any livestock market, except a market described in paragraph (a)(1)(iii) of this section;

(iii) Upon leaving a livestock market that has been approved in accordance with this chapter to handle sheep and goats in interstate commerce and that has agreed to act as an agent for the owner to apply official identification to the animals. In such cases the animals must be:

(A) Moved to the market and maintained until officially identified in distinguishable groups identifiable to their flocks of origin and when required their flock of birth by means of partitions or other such maintenance; and,

(B) Accompanied by an owner statement that contains the information needed to officially identify the animals to their flock of origin and, when required, their flock of birth;

(iv) Upon transfer of ownership of the sheep or goats in interstate commerce;

(v) In the case of animals shipped directly to slaughter at a slaughter plant that has agreed to act as an agent for the owner to apply official identification to the animals, upon arrival of the sheep or goats in interstate commerce at the slaughter plant. In such cases the animals must be:

(A) Moved to the slaughter plant and maintained until officially identified in distinguishable groups identifiable to their flocks of origin and when required their flock of birth by means of partitions or other such maintenance; and,

(B) Accompanied by an owner statement that contains the information needed to officially identify the animals to their flock of origin and, when required, their flock of birth. If the slaughter plant has agreed to allow APHIS to conduct slaughter sampling, animals need not be identified if they arrive at the plant on days that an APHIS designated sampler is not available at the plant to collect samples; or

(vi) Prior to moving a sheep or goat across a State line, unless the animals are moving to an approved livestock market in accordance with paragraph (a)(1)(iii) of this section or to an approved slaughter plant in accordance with paragraph (a)(1)(v) of this section.

(2) The sheep or goats must be identified by one of the following means of identification, and must remain so identified until they reach their final destination:

(i) Electronic implants for animals required to be identified by the SFCP, when used in a flock participating in the SFCP and when accompanied by a certificate or owner statement that includes the electronic implant numbers and the name of the chip manufacturer;

(ii) Official eartags, including tags approved for use in the SFCP or APHIS-approved premises identification number eartags when combined with a unique animal identification number;

(iii) United States Department of Agriculture backtags or official premises identification backtags that include a unique animal identification number, when used on sheep or goats moving directly to slaughter and when applied within 3 inches of the poll on the dorsal surface of the head or neck;

(iv) Legible official registry tattoos that have been recorded in the book of record of a sheep or goat registry association when the animal is accompanied by either a registration certificate or a certificate of veterinary inspection. These tattoos may also be used as premises identification if they contain a unique premises prefix that has been linked in the National Scrapie Database with the assigned premises identification number of the flock of origin;

(v) Premises identification eartags or tattoos, if the premises identification method includes a unique animal number or is combined with a flock eartag that has a unique animal number and the animal is accompanied by an owner statement; or

(vi) Premises identification when premises identification is allowed by § 79.3 and the animal is accompanied by an owner statement.

(3) The owner of the flock of origin is responsible for the identification of animals required to be identified by this section. No person who buys or sells, for his or her own account or as the agent of the buyer or seller, transports, receives for transportation, offers for sale or transportation, or otherwise handles sheep or goats in interstate commerce shall receive or otherwise handle any animal in interstate commerce that has not been identified as required by this section. If an animal loses its identification to its flock of origin while in interstate commerce it is the responsibility of the person who has control or possession of the animal to identify the animal prior to commingling it with any other animals. This shall be done by applying individual animal identification to the animal as required in paragraph (a)(2) of this section and recording the means of identification and the corresponding animal identification number. If the

flock of origin cannot be determined, all possible flocks of origin shall be listed on the record.

(b) Serial numbers for use in official identification will be assigned to each person who applies to the State animal health official or the area veterinarian in charge for the State in which that person maintains his or her place of business. Serial numbers of official eartags will be assigned to each accredited veterinarian or State or APHIS representative who requests official eartags from the State animal health official or the area veterinarian in charge, whoever is responsible for issuing official eartags in that State. The official responsible for issuing eartags in a State may assign serial numbers of official eartags to other responsible persons, such as 4-H leaders, if the State animal health official and the area veterinarian in charge agree that such assignments will improve scrapie control and eradication within the State. Persons assigned serial numbers may either directly apply eartags to animals, or may reassign eartag numbers to producers. If these persons reassign eartag numbers, they must maintain appropriate records that permit traceback of animals to their flock of origin, or flock of birth when required. Premises identification eartag, backtag, and tattoo numbers (series of alphanumeric USDA tags and backtags may be assigned as premises identification if they are linked to the premises in the National Scrapie Database) will be assigned to animal owners by the State animal health official or the area veterinarian in charge, whoever is responsible for assigning premises codes in that State. Persons assigned serial numbers of United States Department of Agriculture backtags, official sheep and goat tattoos, official eartags, and premises identification numbers must:

(1) If the person assigned the numbers is a flock owner, so that the assigned numbers are directly linked to the flock of origin in the national scrapie database, record the following information on a document:

(i) The premises identification number or serial numbers;

(ii) The number of animals so identified;

(iii) The date the animals were identified;

(iv) For animals born after January 1, 2002, that were not born in the flock of origin and that are not identified to the previous flock of origin, the individual identification number applied and the name, street address, including the city and State, or the township, county, and State, and the telephone number, if the

telephone number is available, of the flock of birth if known.

(2) If the person assigned the numbers is a veterinarian, extension agent, auction market operator, dealer, or any person other than the owner of the flock of origin, record the following information on a document:

(i) All serial numbers applied to a sheep or goat;

(ii) Any other serial numbers and approved identification appearing on the sheep or goat;

(iii) The street address, including the city and State, or the township, county, and State, of the premises where the approved means of identification was applied;

(iv) The date the identification was applied;

(v) The name, street address, including the 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 who owns or possesses the sheep or goat, and

(vi) For animals born after January 1, 2002, that were not born in the flock of origin and that are not identified to the previous flock of origin, the individual identification number applied and the name, street address, including the city and State, or the township, county, and State, and the telephone number if the telephone number is available, of the flock of birth if known.

(vii) The serial numbers, the manufacturer, and the type and color of all official tags received. Usually maintaining the tag invoice will meet this requirement.

(3) Maintain these records for 5 years; and

(4) Make these records available for inspection and copying during ordinary business hours (8 a.m. to 5:30 p.m., Monday through Friday) upon request by any authorized employee of the United States Department of Agriculture or the State, and presentation of his or her official credentials.

(5) Any person who fails to comply with these requirements shall not be assigned serial numbers of United States Department of Agriculture backtags, official sheep and goat tattoos, official eartags, or premises identification numbers. If a person who is not in compliance with these requirements has already been assigned such serial numbers, the Administrator may withdraw the assignment by giving notice to such person. After such notice the person shall be subject to criminal and civil penalties if he continues to use those assigned serial numbers.

(c) No person shall apply a premises identification number or a brand or ear notch pattern to an animal that did not originate on the premises to which the number was assigned by a State or APHIS representative or to which the brand or ear notch pattern has been assigned by an official brand registry. This includes individual identification such as USDA tags and backtags that have been assigned to a premises for use as premises identification and registration tattoos that contain prefixes that have been assigned to a premises for use as premises identification. This does not preclude the owner of a flock from using a premises identification number tag assigned to that flock on an animal owned by him that resides in that flock but that was born or previously resided on a different premises as long as the records required in paragraph (b)(1)(iv) of this section are maintained.

(d) Each person who buys or sells, for his or her own account or as the agent of the buyer or seller, transports, receives for transportation, offers for sale or transportation, or otherwise handles sheep or goats in interstate commerce must ensure that the animals are identified as required in this part and must keep records relating to the transfer of ownership, shipment, or handling of the sheep or goats, such as yarding receipts, sale tickets, invoices, and waybills.

(1) If official individual animal identification is required, the records must include 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; and a copy of any documents required to accompany the animal including any certificate, owner statement, letter, or permit; and

(i) For animals not in slaughter channels the records must include all serial numbers and other approved means of identification appearing on the sheep or goat. This requirement may usually be met by maintaining a copy of the certificate that accompanied the animals. The premises number may be recorded instead of the individual numbers in the case of animals identified with premises identification if:

(A) The premises identification meets the requirements of paragraph (a)(2)(v) of this section for individual animal identification; or

(B) The animals are allowed to move interstate with only premises identification in accordance with § 79.3.

(ii) For animals in slaughter channels that are identified with individual animal identification traceable to the flock of origin or that are identified to the flock of origin with official premises identification that meets the requirements for individual animal identification, no additional records are required;

(iii) For animals in slaughter channels that are identified with individual animal identification traceable to a previous flock but not to the flock of origin, or that are identified with official premises identification that meets the requirements for individual animal identification that is traceable to a previous flock but not to the flock of origin, the records must include all serial numbers and other approved means of identification appearing on the sheep or goat;

(iv) For animals that are not required to be identified until they reach their final destination, the records must include the final destination.

(2) If official premises identification is required or allowed, the records must include:

(i) The premises identification number(s) and the number of animals identified with each premises number;

(ii) Copies of any required documents such as the brand inspection certificate, an owner's statement, an accredited veterinarian's statement, or a health certificate;

(iii) 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.

(3) Each person required to keep records under this paragraph must maintain the records for at least 5 years after the person has sold or otherwise disposed of the sheep or goat to another person, and for such further period as the Administrator may require by written notice to the person, for purposes of any investigation or action involving the sheep or goat identified in the records. The person must make the records available for inspection and copying during ordinary business hours (8 a.m. to 5:30 p.m., Monday through Friday) by any authorized employee of the United States Department of Agriculture or the State, upon that employee's request and presentation of his or her official credentials.

(e) No person may remove or tamper with any means of identification

required to be on sheep or goats pursuant to this section while the animals are in interstate commerce, and, at the time of slaughter, animal identification must be maintained throughout postmortem inspection in accordance with regulations of the Food Safety and Inspection Service, U.S. Department of Agriculture, in chapter III of this title.

(f) *Requirements for approval of official premises and individual identification tags.* (1) The Administrator may approve tag companies to produce official premises and/or individual identification tags for use on sheep or goats. Tags may be plastic or metal and must be an appropriate size for use in sheep and goats. Tags must be able to legibly accommodate the required alphanumeric sequences. Tags must resist removal and be difficult to place on another animal once removed, but need not be tamper-proof. Tags must be readily distinguishable as USDA official sheep and goat tags, must carry the alphanumeric sequences, symbols, or logos specified by APHIS, and must have a means of discouraging counterfeiting, such as use of a unique copywrited logo or trade mark. Tags for use only on animals in slaughter channels must be marked with the words "Meat" or "For Slaughter Only," or else must be used in conjunction with an ear tattoo of the word "Meat."

(2) Written requests for approval of official premises identification tags for sheep and goats should be sent to the Animal and Plant Health Inspection Service, Veterinary Services, National Animal Health Programs Staff, Attention: National Scrapie Program Coordinator, 4700 River Road Unit 43, Riverdale, MD 20737-1235. The request must include:

(i) Data supporting the durability of the tag and durability and legibility of the identification numbers and high retention rates of the tags in animals, preferably sheep and/or goats. Preference will be given to tags with high legibility and retention rates in sheep and goats that minimize injury to the ear.

(ii) A signed statement agreeing to:

(A) Send official eartags only to a State or APHIS representative, to a flock owner at the address to which the premises number or tag sequence was assigned by a State or APHIS representative, or as directed by APHIS;

(B) Provide a monthly report by State of all tags produced, including the tag sequences produced and the person's and address to which the tags were shipped; and

(C) When required by APHIS, enter the sequences of tags shipped into the National Scrapie Database through a web page interface or other means specified by APHIS.

(iii) Twenty-five sample tags. Additional tags must be submitted if requested by APHIS.

(3) Approval to produce official premises and/or individual identification tags will be valid for 1 year and must be renewed annually. The Administrator may also grant approval to produce tags for periods of less than 1 year in cases where all of the submissions required by this section have not been received or evaluated but there is substantial evidence that the tags meet the requirements of this section. The Administrator may decline to renew a company's approval if the tags do not show adequate retention and durability in field use or if any of the requirements of this section are not met

by the tag company. If a company's tags do not show adequate retention and durability in field use or if any of the requirements of this section are not met by the tag company, the approval may be withdrawn with 60 days written notice. Any person who is approved to produce official premises or individual identification tags in accordance with this section and who knowingly produces tags that are not in compliance with the requirements of this section, and any person who is not approved to produce such tags but does so, shall be subject to such civil penalties and such criminal liabilities as are provided by 18 U.S.C. 1001, 21 U.S.C. 122 and 134e, or other applicable Federal statutes. Such action may be in addition to, or in lieu of, withdrawal of approval to produce tags.

(g) *New types of identification.*

Written requests for approval of sheep or goat identification devices and

markings not listed in paragraph (a)(2) of this section should be sent to the Animal and Plant Health Inspection Service, Veterinary Services, National Animal Health Programs Staff, 4700 River Road Unit 43, Riverdale, MD 20737-1235. If the Administrator determines that the devices and markings will provide a means of tracing sheep and goats in interstate commerce, a proposal will be published in the **Federal Register** to add the devices and markings to the list of approved means of sheep and goat identification.

**§ 79.3 General restrictions.**

The following prohibitions and movement conditions apply to the interstate movement of sheep and goats, and no sheep or goat may move interstate except in compliance with them.

**INTERSTATE MOVEMENT GENERAL RESTRICTIONS FOR SHEEP AND GOATS**

Note: A CONSISTENT STATE is one whose intrastate identification, reporting, and movement restrictions for infected and source flocks and high-risk animals are consistent with the APHIS standards for State scrapie programs.

Type of interstate movement	Moved from INCONSISTENT state	Moved from CONSISTENT state
(a) Sale or other movement of breeding animals, show animals or any other animal not specifically addressed in this chart. General Condition: No animal may be removed from slaughter channels in interstate commerce if it was sold at a slaughter-only auction, is identified with a tag or ear tattoo marked "meat" or "slaughter only," or was sold with a bill of sale marked for slaughter only, and other animals may be removed from slaughter channels in interstate commerce only if they are identified to their flock of birth.—		
(1) High-risk, scrapie-positive, or suspect animals, or animals from a noncompliant flock.	Prohibited <sup>1</sup> .....	Prohibited <sup>1</sup>
(2) Non-high-risk animals from an infected or source flock that are not scrapie-positive or suspect animals.	Prohibited <sup>1</sup> .....	Prohibited, <sup>1</sup> except as allowed in an approved scrapie control pilot project flock plan and must meet the requirements for exposed animals.
(3) Sexually intact exposed animals that are not scrapie-positive, suspect, or high-risk animals and are not animals from an infected or source flock.	Flock must be enrolled in the Complete Monitored category of the Scrapie Flock Certification Program or equivalent APHIS recognized program, have official individual animal identification, and a permit. <sup>2</sup> For any female exposed sheep the results of an official genotype test must be included on or attached to the permit and must be QR or RR at codon 171. For any female animal moving for exhibition, the permit must include a statement by both the owner and the accredited veterinarian that the animal has not lambed or aborted within 30 days of being exhibited and is not due to lamb within 30 days of being exhibited and that there is no visible vaginal discharge. For any animal born after 1-1-2002, the certificate must include the flock of birth and the flock of origin, if different.	Official individual animal identification and a permit. <sup>2</sup> For any female exposed sheep the results of an official genotype test must be included on or attached to the permit and must be QR or RR at codon 171. For any female animal moving for exhibition, the permit must include a statement by both the owner and an accredited veterinarian that the animal has not lambed or aborted within 30 days of being exhibited and is not due to lamb within 30 days of being exhibited and that there is no visible vaginal discharge. For any animal born after 1-1-2002, the permit must include the flock of birth and the flock of origin, if different.

## INTERSTATE MOVEMENT GENERAL RESTRICTIONS FOR SHEEP AND GOATS—Continued

Note: A CONSISTENT STATE is one whose intrastate identification, reporting, and movement restrictions for infected and source flocks and high-risk animals are consistent with the APHIS standards for State scrapie programs.

Type of interstate movement	Moved from INCONSISTENT state	Moved from CONSISTENT state
(4) (i) Sexually intact sheep except as allowed in (a)(7). (ii) Sexually intact goats, except for low-risk goats.	Flock must be enrolled in the Complete Monitored category of the Scrapie Flock Certification Program or equivalent APHIS-recognized program, have official individual animal identification, and a certificate. For any animal born after 1–1–2002, the certificate must include the flock of birth and the flock of origin, if different.	Official individual animal identification and a certificate. For any animal born after 1–1–2002, the certificate must include the flock of birth and the flock of origin, if different.
(5) Sexually intact low-risk goats .....	Official individual animal identification and a certificate. For any animal born after 1–1–2002, the certificate must include the flock of birth and the flock of origin, if different.	Official individual animal identification and a certificate. For any animal born after 1–1–2002, the certificate must include the flock of birth and the flock of origin, if different.
(6) Castrated animals that are not scrapie-positive or suspect animals.	Official individual animal identification and a certificate.	None, except for exposed animals that must have official individual animal identification.
(7) Low-risk commercial sheep .....	Official individual animal identification and a certificate, and the flock must be enrolled in the Complete Monitored category of the Scrapie Flock Certification Program or an equivalent APHIS-recognized program. For any animal born after 1–1–2002, the certificate must include the flock of birth and the flock of origin, if different.	(i) Official premises identification that is a permanent brand or ear notch pattern registered with an official brand registry; (ii) A brand inspection certificate; (iii) An owner statement dated within 30 days stating that the animals were born in the flock, that the flock does not contain any animal exhibiting signs of scrapie, that to the best of his or her knowledge the flock has no risk factors for or exposure to scrapie, and that the flock has never contained: (A) Any animal diagnosed as having scrapie; (B) any female blackfaced sheep; or (C) any female blackfaced cross sheep that were not born in the flock; and (iv) An accredited veterinarian's statement issued within 12 months of the date of movement indicating that, to the best of his or her knowledge, the flock has no known risk factors for or exposure to scrapie, and that he or she has inspected the flock and it does not contain: (A) Any animal exhibiting signs of scrapie; (B) any female blackfaced sheep; or (C) any female blackfaced cross sheep that were not born in the flock. The statements must include the owner's name, address, and the premises identification number and a drawing of the owner's registered brand or ear notch pattern.
(8) Commercial low-risk goats. ....	Official individual animal identification and a certificate. For any animal born after 1–1–2002, the certificate must include the flock of birth and the flock of origin, if different.	None.
(b) Sale or other movement directly to slaughter, through slaughter channels to slaughter, or to feedlots for later movement to slaughter of animals that are under 18 months of age as evidenced by eruption of the second incisor, not pregnant, and have not lambed or kidded. General Condition: No animal may be removed from slaughter channels in interstate slaughter channels in interstate commerce if it was sold at a slaughter-only auction, is identified with a tag or ear tattoo marked "meat" or "slaughter only," or was sold with a bill of sale marked for slaughter only, and other animals may be removed from slaughter channels in interstate commerce only if they are identified to their flock of birth.—		
(1) Scrapie-positive or suspect animal .....	Prohibited <sup>1</sup> .....	Prohibited. <sup>1</sup>

## INTERSTATE MOVEMENT GENERAL RESTRICTIONS FOR SHEEP AND GOATS—Continued

Note: A CONSISTENT STATE is one whose intrastate identification, reporting, and movement restrictions for infected and source flocks and high-risk animals are consistent with the APHIS standards for State scrapie programs.

Type of interstate movement	Moved from INCONSISTENT state	Moved from CONSISTENT state
(2) Sexually intact high-risk animals and sexually intact animals from infected or source flocks that are not scrapie-positive or suspect animals.	Official individual animal identification and a permit, or a permit and an indelible "S" mark on the left jaw, or sealed conveyance and a permit. (Note: these animals may only be permitted to slaughter or to terminal feedlots. <sup>3</sup> )	Official individual animal identification and a permit, or a permit and an indelible "S" mark on the left jaw, or sealed conveyance and a permit. (Note: these animals may only be permitted to slaughter or to terminal feedlots. <sup>3</sup> )
(3) Exposed sexually intact animals that are not scrapie-positive, suspect, or high-risk animals and that are not animals from an infected or source flock.	Official individual animal identification for any animal that is not moving directly to slaughter or to a terminal feedlot. <sup>3, 4</sup> (Note: pregnant animals and animals with a visible vaginal discharge may only be permitted to slaughter or to terminal feedlots.)	Official individual animal identification for any animal that is not moving direct to slaughter or to a terminal feedlot. <sup>3, 4</sup> (Note: Pregnant animals and animals with a visible vaginal discharge may only be permitted to slaughter or to terminal feedlots.)
(4) Sexually intact sheep that are not scrapie-positive, suspect, high-risk, or exposed animals and are not animals from an infected or source flock.	Official premises identification or official individual animal identification for any animal that is not moving direct to slaughter or to a terminal feedlot. <sup>3</sup>	None.
(5) Sheep enrolled in the selective monitored or complete monitored category of the SFCP that are not scrapie-positive, suspect, high-risk, or exposed animals.	None .....	None.
(6) Castrated animals that are not scrapie-positive, or suspect animals.	None .....	None.
(7) Sexually intact goats that are not scrapie-positive, suspect, high-risk, or exposed animals and are not animals from an infected or source flock.	None .....	None.
(c) Sale or other movement directly to slaughter, through slaughter channels to slaughter, or to feedlots for later movement to slaughter of animals that are over 18 months of age, as evidenced by eruption of the second incisor, or that are pregnant or that have lambed or kidded. General Condition: No animal may be removed from slaughter channels in interstate commerce if it was sold at a slaughter-only auction, is identified with a tag or ear tattoo marked "meat" or "slaughter only," or was sold with a bill of sale marked for slaughter only, and other animals may be removed from slaughter channels in interstate commerce only if they are identified to their flock of birth.—		
(1) Scrapie-positive or suspect animal .....	Prohibited <sup>1</sup> .....	Prohibited. <sup>1</sup>
(2) Sexually intact high-risk animals and sexually intact animals from an infected or source flock that are not scrapie-positive, or suspect animals.	Official individual animal identification and a permit, or a permit and an indelible "S" mark on the left jaw, or sealed conveyance and a permit. (Note: these animals may only be permitted to slaughter or to terminal feedlots. <sup>3</sup> )	Official individual animal identification and a permit, or a permit and an indelible "S" mark on the left jaw, or sealed conveyance and a permit. (Note: These animals may only be permitted to slaughter or to terminal feedlots. <sup>3</sup> )
(3) Sexually intact exposed animals that are not scrapie-positive, suspect, or high-risk animals and are not animals from an infected or source flock.	Official individual animal identification and a permit, or a permit and an indelible "S" mark on the left jaw, or sealed conveyance and a permit when moving directly to slaughter. (Note: pregnant animals and animals with a visible vaginal discharge may only be permitted to slaughter or to terminal feedlots. <sup>3, 4</sup> )	Official individual animal identification. (Note: pregnant animals and animals with a visible vaginal discharge may only be moved directly to slaughter or to terminal feedlots. <sup>3, 4</sup> )
(4) Sheep over 18 months of age that are not scrapie-positive, suspect, sexually intact high-risk, or sexually intact exposed animals and that are not sexually intact animals from an infected or source flock.	Official individual animal identification and a certificate. <sup>4</sup>	Official individual animal identification. <sup>4</sup>
(5) Low-risk commercial sheep .....	Official individual animal identification and a certificate <sup>4</sup> .	(i) Official premises identification that is a permanent legible brand or ear notch pattern registered with an official brand registry or, in the case of animals moving directly to slaughter, may be a legible paint brand registered with an official brand registry; (ii) A brand inspection certificate;



## INTERSTATE MOVEMENT GENERAL RESTRICTIONS FOR SHEEP AND GOATS—Continued

Note: A CONSISTENT STATE is one whose intrastate identification, reporting, and movement restrictions for infected and source flocks and high-risk animals are consistent with the APHIS standards for State scrapie programs.

Type of interstate movement	Moved from INCONSISTENT state	Moved from CONSISTENT state
		(iii) An owner statement dated within 30 days of the movement stating that the flock does not contain any animal exhibiting signs of scrapie, and that, to the best of his or her knowledge, the flock has no risk factors for or exposure to scrapie and has never contained: (A) Any animal diagnosed as having scrapie; (B) any female blackfaced sheep; or (C) any female blackfaced cross sheep that was not born in the flock;
		(iv) An accredited veterinarian's statement issued within 12 months of the date of movement indicating that, to the best of his or her knowledge, the flock has no known risk factors for or exposure to scrapie, and that he or she has inspected the flock and it does not contain: (A) Any animal exhibiting signs of scrapie; (B) any female blackfaced sheep; or (C) any female blackfaced cross sheep that was not born in the flock. The statements must include the owner's name, address, and the premises identification number and a drawing of the owner's registered brand or ear notch pattern. <sup>4</sup>
(6) Goats that are not scrapie-positive, suspect, sexually intact high-risk, or sexually intact exposed animals and that are not sexually intact animals from an infected or source flock.	None .....	None.
(d) Movement of animals for grazing or other management purposes without change of ownership.—		
(1) Scrapie-positive, suspect, or sexually intact high-risk animals.	Prohibited <sup>1</sup> .....	Prohibited. <sup>1</sup>
(2) Non-high-risk animals from an infected or source flock.	Prohibited <sup>1</sup> .....	Prohibited, <sup>1</sup> except as allowed in an approved scrapie control pilot project flock plan and must meet the requirements for exposed animals.
(3) Sexually intact exposed animals that are not scrapie-positive, suspect, or high-risk animals and that are not animals from an infected or source flock.	Official individual animal identification and a permit. <sup>2</sup> For any female exposed sheep the results of an official genotype test must be included on or attached to the permit and must be QR or RR at codon 171.	Official individual animal identification and a permit. <sup>2</sup> For any female exposed sheep the results of an official genotype test must be included on or attached to the permit and must be QR or RR at codon 171.
(4) Sexually intact sheep or sexually intact goats that have been commingled with sheep and that are not scrapie-positive, suspect, high-risk, or exposed animals and are not animals from an infected or source flock.	Official premises identification and a certificate..	None.
(5) Sexually intact goats that have not been commingled with sheep and that are not scrapie-positive, suspect, high-risk, or exposed animals and are not animals from an infected or source flock.	None .....	None.
(6) Castrated animals that are not scrapie-positive or suspect animals and are not an animal from an infected or source flock.	None .....	None.

<sup>1</sup> Animals prohibited movement may be moved interstate only if they are moving interstate for destruction or research as approved by the Administrator.

<sup>2</sup> A copy of the permit must be sent to the State veterinarian and the AVIC of the receiving State prior to movement of animals.

<sup>3</sup> No exposed or high-risk animal from any State or any animal from an Inconsistent State shall be removed from slaughter channels once it has entered interstate commerce.

<sup>4</sup> Official individual animal identification or official premises identification is not required for these slaughter animals if the animals are kept as a group on the same premises on which they were born or used for breeding purposes and are not commingled with animals from another premises at any time, including throughout the feeding, marketing, and slaughter process.

**§ 79.4 Designation of scrapie-positive animals, high-risk animals, exposed animals, suspect animals, exposed flocks, infected flocks, noncompliant flocks, and source flocks; notice to owners.**

(a) *Designation.* A designated scrapie epidemiologist will designate an animal to be a scrapie-positive animal, high-risk animal, exposed animal, or suspect animal after determining that the animal meets the criteria of the relevant definition in § 79.1.

(1) A State or APHIS veterinarian will designate an animal to be a suspect animal after determining that the animal meets the criteria of the relevant definition in § 79.1.

(2) A designated scrapie epidemiologist will designate a flock to be a source, infected, or exposed flock after reviewing sale, movement, and breeding records that indicate the flock meets the criteria of the relevant definition in § 79.1.

(i) A designated scrapie epidemiologist may conduct testing of animals if he or she determines such testing is needed to properly designate a flock to be a source, infected, or exposed flock. The designated scrapie epidemiologist will select animals for testing in a manner that will provide a 95 percent confidence of detecting scrapie at a prevalence of 1 percent or, when flock records are adequate and all exposed animals that lambed in the flock are available for testing, may limit the testing to all exposed and suspect animals. Flocks meeting the definition of infected or source flocks that are designated as exposed flocks must complete a post exposure monitoring and management plan. Testing may include live-animal testing using a live-animal official test, an official genotype test, the culling and postmortem examination and testing of genetically susceptible animals in the flock that cannot be evaluated by a live animal test, and postmortem examination and testing of animals found dead or cull animals at slaughter.

(ii) If an owner does not make his or her animals available for testing within 60 days of notification or as mutually agreed or fails to submit required postmortem samples, the flock will be designated a source, infected, or exposed flock, whichever definition applies. Any flock that is pending designation must comply with the movement restrictions for infected flocks.

(3) A designated scrapie epidemiologist will designate a flock to be a noncompliant flock after determining that the flock meets the definition of a noncompliant flock in § 79.1.

(b) *Redesignation.* (1) A designated scrapie epidemiologist may reclassify an animal designated a high-risk animal as an exposed animal after receiving negative results from an official test or in accordance with an approved Scrapie Control Pilot Project.

(2) A State or APHIS veterinarian may remove the suspect animal designation from an animal that had clinical signs of scrapie and that did not test positive for scrapie or for the proteinase resistant protein associated with scrapie upon determination that it is alive and no longer exhibits such signs, or that the signs are not caused by scrapie.

(3) A designated scrapie epidemiologist may remove the suspect animal designation from an animal that has tested positive for scrapie or for the proteinase resistant protein associated with scrapie on an unofficial test based on knowledge of the test used or based on an epidemiologic investigation which may include additional testing of the suspect animal and or animals that have been commingled with the suspect animal.

(4) A designated scrapie epidemiologist may remove the suspect animal designation from an animal that tested positive on a live-animal screening test based on an epidemiologic investigation which includes additional official testing of the suspect animal and when appropriate, animals that have been commingled with the suspect animal.

(5) A designated scrapie epidemiologist may remove the exposed flock designation after completing an epidemiologic investigation or upon completion of a post-exposure management and monitoring plan. As part of the epidemiologic investigation the designated scrapie epidemiologist may conduct testing of animals if he or she determines such testing is needed to properly redesignate the flock. The designated scrapie epidemiologist will select animals for testing in a manner that will provide a 95 percent confidence of detecting scrapie at a prevalence of 1 percent or, when flock records are adequate and all exposed animals that lambed in the flock are available for testing, may limit the testing to all exposed and suspect animals. Testing may include live-animal testing using a live-animal official test, an official genotype test, the culling and postmortem examination and testing of genetically susceptible animals in the flock that cannot be evaluated by a live animal test, and postmortem examination and testing of animals found dead or cull animals at slaughter. A designated scrapie epidemiologist shall redesignate an

exposed flock as a noncompliant flock if the owner fails to make his animals available for testing within 60 days of notification or as mutually agreed or fails to submit required postmortem samples.

(6) Based on an epidemiologic investigation and testing, a designated scrapie epidemiologist may redesignate an infected flock or source flock as an exposed flock. The designated scrapie epidemiologist may only use this option when the epidemiologic investigation reveals that the scrapie exposure was minor or could not be confirmed due to inadequate records. The designated scrapie epidemiologist will select animals for testing in a manner that will provide a 95 percent confidence of detecting scrapie at a prevalence of 1 percent or, when flock records are adequate and all exposed animals that lambed in the flock are available for testing, may limit the testing to all exposed and suspect animals. Testing may include live-animal testing using a live-animal official test, an official genotype test, the culling and postmortem examination and testing of genetically susceptible animals in the flock that cannot be evaluated by a live animal test, and postmortem examination and testing of animals found dead or cull animals at slaughter. Infected or source flocks that are redesignated as exposed flocks must complete a post exposure monitoring and management plan. If an owner does not make his or her animals available for testing within 60 days of notification or as mutually agreed or fails to submit required postmortem samples, the flock designation will remain unchanged.

(7) A designated scrapie epidemiologist may remove the noncompliant flock designation after reviewing any required testing of the flock and determining that the flock has complied with the required testing or no longer meets the definition of a noncompliant flock.

(8) A designated scrapie epidemiologist may redesignate an exposed animal, exposed flock, or infected flock by removing that designation after completing an epidemiologic investigation and determining that the exposure was limited to a scrapie-positive male animal that was not born in the flock (the owner must have adequate records and animal identification to show that the scrapie-positive male animal was purchased).

(c) *Notice to owner.* As soon as possible after making such a determination, a State or APHIS representative will attempt to notify the owner(s) of the flock(s) in writing that

their flock contained or contains a scrapie-positive animal, a suspect animal, a high-risk animal or an exposed animal, or that the flock is an infected, source, exposed, or noncompliant flock or that the flock is pending designation as an infected, source, exposed, or noncompliant flock. The notice will include:

- (1) A description of the interstate movement restrictions and identification requirements;
- (2) Reporting requirements;
- (3) Sample submission requirements for suspect and high-risk animals contained in this part;
- (4) Options for controlling the spread of scrapie from, and eradicating scrapie in, an infected flock or source flock or to reduce the risk of the occurrence of scrapie in a flock that contains a high-risk or an exposed animal; and
- (5) In the case of flocks that are pending designation the notification shall include the testing options available to them and the designation their flock will receive if they decline to test.

#### **§ 79.5 Issuance of certificates.**

(a) Certificates are required as specified by § 79.3 for certain interstate movements of animals. A certificate must show the official ear tag number, individual animal registered breed association registration tattoo, individual animal registered breed association registration brand, individual animal registered breed association registration number, and any other official individual identification of each animal to be moved; *provided that*, in the case of animals identified with premises identification<sup>4</sup> that is assigned to the flock of origin and that meets the requirements for individual animal identification, the premises number may be recorded instead of the individual identification numbers. A certificate must also show the number of animals covered by the certificate; the purpose for which the animals are to be moved; the points of origin and destination; the consignor, and the consignee. Certificates must indicate the flock of birth for any breeding sheep born after January 1, 2002, that are covered by the certificate. The certificate must include a statement by the issuing accredited or State or Federal veterinarian that the animals were not exhibiting clinical signs associated with scrapie at the time

of examination and an owner statement indicating whether the animal is or is not a scrapie-positive, suspect, high-risk or exposed animal and whether it originated in an infected, source, exposed, or noncompliant flock. Except as provided in paragraphs (b) and (c) of this section, all of the information required by this paragraph must be typed or written on the certificate. Note that in accordance with § 79.3(a), (b), and (c), scrapie-positive, suspect, and high-risk animals, some exposed animals, and animals that originated in an infected or source flock require permits rather than certificates.

(b) *Animal identification documents attached to certificates.* As an alternative to typing or writing individual animal identification on a certificate, another document may be used to provide this information, but only under the following conditions:

- (1) The document must be a State form or APHIS form that requires individual identification of animals;
- (2) A legible copy of the document must be stapled to the original and each copy of the certificate;
- (3) Each copy of the document must identify each animal to be moved with the certificate, but any information pertaining to other animals, and any unused space on the document for recording animal identification, must be crossed out in ink; and
- (4) The following information must be typed or written in ink in the identification column on the original and each copy of the certificate and must be circled or boxed, also in ink, so that no additional information can be added:

- (i) The name of the document; and
- (ii) Either the serial number on the document or, if the document is not imprinted with a serial number, both the name of the person who prepared the document and the date the document was signed.

(c) *Ownership brands documents attached to certificates.* As an alternative to typing or writing ownership brands on a certificate, an official brand inspection certificate may be used to provide this information, but only under the following conditions:

- (1) A legible copy of the official brand inspection certificate must be stapled to the original and each copy of the certificate;
- (2) Each copy of the official brand inspection certificate must show the ownership brand of each animal to be moved with the certificate, but any other ownership brands, and any unused space for recording ownership brands, must be crossed out in ink; and

(3) The following information must be typed or written in ink in the official identification column on the original and each copy of the certificate and must be circled or boxed, also in ink, so that no additional information can be added:

- (i) The name of the attached document; and
- (ii) Either the serial number on the official brand inspection certificate or, if the official brand inspection certificate is not imprinted with a serial number, both the name of the person who prepared the official brand inspection certificate and the date it was signed.

#### **§ 79.6 Standards for States to qualify as Consistent States.**

(a) In reviewing a State for Consistent State status, the Administrator will evaluate the State statutes, regulations, and directives pertaining to animal health activities; reports and publications of the State animal health agency; and a written statement from the State animal health agency describing State scrapie control activities and certifying that these activities meet the requirements of this section. In determining whether a State is a Consistent State, the Administrator will determine whether the State:

(1) Has the authority, based on State law or regulation, to restrict the movement of all scrapie-infected and source flocks.

(2) Has the authority, based on State law or regulation, to require the reporting of any animal suspected of having scrapie and test results for any animals tested for scrapie to State or Federal animal health authorities.

(3) Has, in cooperation with APHIS personnel, drafted and signed a memorandum of understanding between APHIS and the State that delineates the respective roles of each in the National Scrapie Program implementation.

(4) Has placed all known scrapie-infected and source flocks under movement restrictions, with movement of animals only to slaughter, to feedlots under permit and movement restrictions that ensure later movement to slaughter, for destruction, or for research. Scrapie-positive and suspect animals may be moved only for transport to an approved research facility or for purposes of destruction.

(5) Has effectively implemented policies to:

(i) Investigate all animals reported as scrapie suspect animals within 7 days of notification;

(ii) Designate a flock's status, within 15 days of notification that the flock contains a scrapie-positive animal, based on an investigation by State or

<sup>4</sup> Ownership brands may be used on certificates for sheep and goats moved interstate when premises identification is required under this part, provided the ownership brands are legible and are registered with the official brand recording agency and the animals are accompanied by a brand inspection certificate.

Federal animal health authorities and in accordance with this part;

(iii) Restrict the movement, in accordance with paragraph (a)(4) of this section, of newly designated scrapie-infected and source flocks within 7 days after they are designated in accordance with § 79.4;

(iv) Relieve infected and source flock movement restrictions only after completion of a flock plan created in accordance with § 54.14 of this chapter or a flock plan created in accordance with an approved scrapie control pilot project, or as permitted by the conditions of such a flock plan, and after agreement by the owner to comply with a 5-year post-exposure management and monitoring plan;

(v) Conduct an epidemiologic investigation of source and infected flocks that includes the designation of high-risk and exposed animals and that identifies animals to be traced;

(vi) Conduct tracebacks of scrapie-positive animals and traceouts of high-risk and exposed animals and report any out-of-State traces to the appropriate State within 45 days of receipt of notification of a scrapie-positive animal; and

(vii) Conduct tracebacks based on slaughter sampling within 15 days of receipt of notification of a scrapie-positive animal at slaughter.

(6) Effectively monitors and enforces quarantines.

(7) Effectively enforces State reporting laws and regulations for scrapie.

(8) Has designated at least one APHIS or State animal health official to coordinate scrapie program activities in the State and to serve as the designated scrapie epidemiologist in the State.

(9) Has educated those engaged in the interstate movement of sheep and goats regarding the identification and recordkeeping requirements of this part.

(10) Has provided APHIS with a plan and timeline for complying with the following additional requirements, which must be met within 2 years of designation of the State as a Consistent State<sup>5</sup>:

(i) Requires, based on State law or regulation, and effectively enforces official identification upon change of ownership of all animals of any age not in slaughter channels and any sheep

over 18 months of age as evidenced by eruption of the second incisor such that the animal may be traced to its flock of birth; provided that:

(A) A State may exempt commercial goats in intrastate commerce that have not been in contact with sheep from this identification requirement if there has been in that State no case of scrapie in a commercial goat in the past 10 years that originated in that State and cannot be attributed to exposure to infected sheep, and there are no exposed commercial goat herds in that State; and

(B) A State may exempt commercial whitefaced sheep or commercial hair sheep under 18 months of age in intrastate commerce from this identification requirement if there has been in that State no case of scrapie in the exempted class that originated from that State, and there are no exposed commercial whitefaced or hair sheep flocks in that State that have been exposed by a female animal.

(C) States that exempt these types of commercial animals must put in place the regulations necessary to require identification of these animals within 90 days of these conditions no longer existing.

(ii) Maintains in the National Scrapie Database administered by APHIS, or in a State database approved by the Administrator as compatible with the National Scrapie Database, the State's:

(A) Premises information and assigned premises numbers and individual identification number sequences assigned for use as premises identification;

(B) Individual animal information on all scrapie-positive, suspect, high-risk, and exposed animals in the State;

(C) Individual animal information on all out-of-State animals to be traced; and

(D) Accurate flock status data.

(iii) Requires official individual identification of any live scrapie-positive, suspect, or high-risk animal of any age and of any sexually intact exposed animal of more than 1 year of age or any sexually intact exposed animal of less than 1 year of age upon change of ownership (except for exposed animals moving in slaughter channels at less than 1 year of age), whether or not the animal resides in a source or infected flock.

(iv) Effectively enforces movement restrictions on all scrapie-positive, suspect, and high-risk animals

throughout their lives unless they are moved in accordance with § 79.3.

(v) Requires that tissues from all scrapie-positive or suspect animals and female high-risk animals that have lambed (when they have died or have been destroyed) be submitted to a laboratory authorized by the Administrator to conduct scrapie tests and requires complete destruction of the carcasses of scrapie-positive and suspect animals.

(vi) Prohibits any animal from being removed from slaughter channels unless it is identified to the flock of birth, is not from an Inconsistent State, and is not scrapie-exposed or from an infected or source flock.

(b) If the Administrator determines that statutory changes are needed to bring a State into full compliance, the Administrator may grant up to a 2-year extension to allow a State to acquire additional authorities before removing a State's Consistent Status. The decision to grant an extension will be based on the State's ability to prevent the movement of scrapie-infected animals out of the State and on the progress being made in making the needed statutory changes.

#### **§ 79.7 Waiver of requirements for scrapie control pilot projects.**

(a) The Administrator may waive the following requirements of this part for participants in a scrapie control pilot project by recording the requirements waived in the scrapie control pilot project plan:

(1) The determination that an animal is a high-risk animal, if the scrapie control pilot project plan contains testing or other procedures that indicate that an animal, despite meeting the definition of high-risk animal, is unlikely to spread scrapie; and

(2) The requirement that high-risk animals must be removed from a flock, if the scrapie control pilot project plan contains alternative procedures to prevent the further spread of scrapie without removing high-risk animals from the flock.

(b) [Reserved]

Done in Washington, DC, this 9th day of August 2001.

**Bill Hawks,**

*Under Secretary for Marketing and Regulatory Programs.*

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<sup>5</sup> This provision would apply until January 1, 2003. Any State designated as a Consistent State after that date would have to meet all requirements prior to designation.