



DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Parts 54 and 79

[Docket No. APHIS-2007-0127]

RIN 0579-AC92

Scrapie in Sheep and Goats

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Proposed rule.

SUMMARY: We are proposing to amend the scrapie regulations by changing the risk groups and categories established for individual animals and for flocks, increasing the use of genetic testing as a means of assigning risk levels to animals, reducing movement restrictions for animals found to be genetically less susceptible or resistant to scrapie, and simplifying, reducing, or removing certain recordkeeping requirements. We also propose to provide designated scrapie epidemiologists with more alternatives and flexibility when testing animals in order to determine flock designations under the regulations. We propose to change the definition of high-risk animal, which will change the types of animals eligible for indemnity, and to pay higher indemnity for certain pregnant ewes and early maturing ewes. The proposed changes would also make the identification and recordkeeping requirements for goat owners consistent with those for sheep owners. These changes would affect sheep and goat producers, persons who handle sheep and goats in interstate commerce, and State governments.

DATES: We will consider all comments that we receive on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments by either of the following methods:

- Federal eRulemaking Portal: Go to <http://www.regulations.gov/#!docketDetail;D=APHIS-2007-0127>.
- Postal Mail/Commercial Delivery: Send your comment to Docket No. APHIS-2007-0127, Regulatory Analysis and Development, PPD, APHIS, Station 3A-03.8, 4700 River Road Unit 118, Riverdale, MD 20737-1238.

Supporting documents and any comments we receive on this docket may be viewed at <http://www.regulations.gov/#!docketDetail;D=APHIS-2007-0127> or in our reading room, which is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 799-7039 before coming.

FOR FURTHER INFORMATION CONTACT: Dr. Diane Sutton, National Scrapie Program Coordinator, Sheep, Goat, Cervid & Equine Health Center, Surveillance, Preparedness and Response Services, VS, APHIS, 4700 River Road Unit 43, Riverdale, MD 20737-1235; (301) 851-3509.

SUPPLEMENTARY INFORMATION:

Background

Scrapie is a member of a class of diseases called transmissible spongiform encephalopathies (TSEs). Scrapie is a degenerative and eventually fatal disease affecting the central nervous systems of sheep and goats. 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 parts 54 and 79 (referred to below as the scrapie regulations), which respectively describe program procedures and restrict the interstate movement of certain sheep and goats. APHIS also administers the voluntary Scrapie Flock Certification Program (the SFCP),¹ described in regulations at 9 CFR part 54, and produces program standards documents titled “Scrapie Program Standards Volume 2: Scrapie Free Flock Certification Program (SFCP)” and “Scrapie Eradication Uniform Methods and Rules” (UM&R). Copies of the SFCP Standards and the UM&R are available on the APHIS Web site at http://www.aphis.usda.gov/animal_health/animal_diseases/scrapie/downloads/sfcp.pdf and http://www.aphis.usda.gov/animal_health/animal_diseases/scrapie/downloads/umr_scrapie.pdf, respectively, or by contacting the individual listed under FOR FURTHER INFORMATION CONTACT. The UM&R has been updated to be consistent with these proposed changes and has been renamed the Scrapie Program Standards Volume 1: National Scrapie Eradication Program. A draft of this document is available on the APHIS Web site at <http://www.aphis.usda.gov/animal-health/scrapie>. Comments on this document are being accepted concurrently with this proposed rule.

The last major revision of the scrapie regulations occurred on August 21, 2001, when we published in the Federal Register (66 FR 43964, Docket No. 97-093-5) a final rule amending part 79 by imposing additional restrictions on the interstate movement of sheep and goats. We also added new requirements with regard to the identification, recordkeeping, and health status of sheep and goats in order to provide a more effective national program for surveillance of scrapie

¹ Formerly the Scrapie Flock Certification Program; this proposal would add the word “Free” to the program’s name.

and for the tracing of animals affected with scrapie. In our August 2001 final rule, we also amended part 54 by reinstating a scrapie indemnification program for sheep and goats. Those changes to parts 54 and 79 were designed, in part, to provide a national standard for the control and eradication of scrapie, and to reflect our commitment to eliminating scrapie from the United States.

The changes we are proposing in this document are based on our evaluation of input that we have received from the regulated industry and the States since the implementation of the August 2001 final rule. A number of regulatory changes have been suggested, including changes to the risk groups and categories established for individual animals and flocks, increased use of genetic testing as a means of assigning risk levels to flocks and animals, reduced movement restrictions for animals found to be genetically less susceptible or resistant to scrapie, and simplification and reduction of recordkeeping requirements. States have also requested that we provide designated scrapie epidemiologists (DSEs) with more alternatives and flexibility in determining how many and which animals in a flock must be tested in order to determine the flock's status under the regulations. We are also proposing changes to the procedures for paying indemnity for animals, based on input from industry on how to equitably decide which animals should qualify and how payment amounts should be set. This proposed rule addresses all of these areas.

The scrapie regulations are quite complex, and understanding them is easier when a few overarching principles are kept in mind. One of these principles is trace back, which in this case means that whenever a sheep or goat is positively diagnosed with scrapie, APHIS or a State will investigate the past movements of the animal to identify other animals and flocks that may have been exposed to the scrapie-positive animal. A second principle is trace forward, which means

that whenever an exposed sheep or goat is identified as having left an infected or source flock, APHIS or a State will investigate the movements of the animal to locate the animal for genetic and/or scrapie testing and to identify other animals and flocks that may have been exposed to scrapie through the lambing of or contact with the lambing area of the potentially infected animal. This is done so that genetic and/or scrapie testing can be done to determine if any of the animals are or could be infected.

This proposal would improve the ability of APHIS and States to trace animals. It would do this by changing requirements for records needed to trace animals, and by adding provisions to link official individual animal identification applied by persons other than the flock owner to the flock of origin in the National Scrapie Database rather than just the person who applied the official identification. The current regulations address trace forward primarily in § 54.8(f) regarding the responsibility of flock owners to disclose records to APHIS representatives or State representatives for the purpose of tracing animals, in § 79.2(b) regarding the responsibility of persons applying ear tags to maintain appropriate records that permit traceback of animals, and in § 79.6(a)(5) regarding State responsibilities to do epidemiologic investigations of source and infected flocks that include tracing animals. The proposed rule would ensure that better records are available for tracing animals, by adding requirements in new § 54.8(b), Records for flocks under a flock plan or PEMMP, § 79.2(f), Records required of persons who purchase, acquire, sell, or dispose of animals and § 79.2(g), Records required of persons who apply official identification to animals.

In addition to improving the utility of records for tracing animals, the proposed rule would reduce some recordkeeping, primarily by eliminating the requirement in many cases to read and record individual identification that was applied before a new owner or shipper receives

the animal. Further, by making the regulations easier to understand we hope to eliminate cases where owners and markets unnecessarily keep records or apply unneeded identification or fail to do so when required through lack of understanding. Also, in cases where genetic testing allows us to determine that all exposed animals in a flock are genetically resistant, use of genetic testing would allow some flocks to avoid being placed under a flock plan or post-exposure management and monitoring plan (PEMMP), thus avoiding the substantial recordkeeping requirements for such flocks imposed by § 54.8.

The proposal to enhance use of the National Scrapie Database would also aid trace back and trace forward. Proposed § 54.11 would ensure official test results are recorded in the database and proposed § 79.2(b) addresses linking animal identification numbers for sheep and goats in interstate commerce to flock of origin in the database.

A third guiding principle in both the current and proposed regulations is flock risk level, which considers whether a flock has ever included an animal that is eventually diagnosed with scrapie or that was exposed to scrapie. If so, there is a risk that other animals from that flock may have scrapie. The flock risk level varies according to many factors. For example, the flock risk level would be very high if an animal that was born in the flock and spent its life in the flock until it was sold was diagnosed with scrapie shortly after being sold. In contrast, a flock's risk level would be lower if only one purchased exposed animal lambed in the flock, spent only a short time in the flock, and then was sent to slaughter without testing. A final guiding principle is that testing has limits to its practical utility. Scrapie is a long incubation disease, which makes it impossible to detect early infection with currently available tests. While there are now tests to diagnose scrapie using samples from both live and dead animals, it is almost never practical or cost effective for APHIS to simply test every animal in a sizeable flock in order to determine

whether the flock contains infected animals. The current live animal test for scrapie requires a biopsy of the lymphoid tissue from the animal's third eyelid, rectum, tonsil, or a lymph node. Difficulties in sample collection and processing and the relatively small amount of third eyelid or rectal lymphoid tissue in some animals can result in significant numbers of "no tests" (i.e., tests that are not successfully completed because of insufficient follicles in the sample or other reasons), and the test is very labor intensive and expensive. Also, a single rectal biopsy or third eyelid test using biopsies from both third lids appears to have a diagnostic sensitivity of approximately 87 percent compared to postmortem immunohistochemistry testing on obex and lymph node when used in sheep over 14 months of age, which means the rectal biopsy or third eyelid test will not identify at least 13 percent of infected animals. Also, since scrapie is a long incubation disease, it typically takes 14 months or more after the animal becomes infected before these tests can detect the infection. This means that both the inherent diagnostic sensitivity of the tests and the number of animals tested that became infected less than 14 months ago affect testing accuracy, and as a result the percentage of infected animals not identified by the tests will be significantly higher than 13 percent.

Those principles are all important factors in the design of the current scrapie regulations. Many of the changes we are proposing in this document incorporate an additional guiding principle, genetic resistance and susceptibility, discussed in detail below.

Current Understanding of Genetic Resistance and Susceptibility to Scrapie

The Scrapie Ovine Slaughter Surveillance study² conducted by APHIS (referred to below as the SOSS study) provides useful baseline information on the prevalence of scrapie in the

² The SOSS study and related information is available from the person identified under FOR FURTHER INFORMATION CONTACT or at http://www.aphis.usda.gov/animal_health/nahms/sheep/index.shtml.

United States and the relationship of different sheep genotypes to scrapie susceptibility. Some of the findings of that study are summarized below. Please refer to the study for complete details, including methodology and standard error rates.

Beginning April 1, 2002, and continuing through March 31, 2003, the SOSS study collected samples from 12,508 mature sheep at 22 slaughter plants and 1 large livestock market. Samples from 33 animals tested positive for scrapie. The overall weighted national prevalence of scrapie in mature cull sheep was estimated to be 0.20 percent.

To evaluate the potential relationship between scrapie susceptibility and certain genotypes, approximately one-fourth of the negative samples (i.e., those in which the scrapie prion protein [PrPsc] was not detected) and all 33 of the scrapie-positive samples were submitted for genetic testing.

Susceptibility to scrapie has been linked to certain codons in the sheep genotype. A codon is a set of three nucleotides that encode for a specific amino acid. Codons that encode for amino acids at positions 136 and 171 in the prion protein (PrP) have been associated with scrapie susceptibility in sheep in the United States. However, codon 171 is thought to be the major determinant of scrapie susceptibility in the United States.

Codon values are stated as the diploid PrP genotype for the encoded amino acids. The relevant amino acid single-letter abbreviations are Q (glutamine) and R (arginine) for codon 171, and A (alanine) and V (valine) for codon 136. So, for example, a sheep genotype that codes for glutamine in both of its alleles at codon 171 would be described as QQ. A very small number of sheep code for histidine (H) or lysine (K) at codon 171 and for threonine (T) at codon 136. The presence of histidine at 171 is presently thought to be similar to Q for scrapie resistance. Lysine at 171 has recently been found in a few Barbados sheep and T at 136 has been found in one

sheep breed outside the United States, but the effects of these variations on scrapie resistance has not been fully studied. For this reason H or K at codon 171 is treated the same as Q and T at codon 136 is treated the same as V.

The following is a simplified summary of the current knowledge of how genotype affects susceptibility to scrapie. Two codons of the sheep genotype, codons 136 and 171, are especially important to scrapie susceptibility or resistance. In general, a glutamine (Q) at codon 171 of the PrP allele is associated with susceptibility to scrapie. Sheep with two alleles with Q at codon 171 (QQ) are markedly susceptible; sheep with only one (QR) are rarely susceptible. Sheep that have two alleles with arginine at codon 171 (RR) appear to be very resistant. No cases of classical scrapie have been reported in 171 (RR) sheep in the United States and are rare in other countries.

Codon 136 also has significant effects on scrapie susceptibility or resistance. There are at least two field strains of classical scrapie in the United States. When the strain to which a flock was exposed can be inferred, and the genotypes of sheep in the flock are known, this information can be used to depopulate only those exposed animals susceptible to the strain involved. The more prevalent strain, valine-independent scrapie, accounts for at least 93 percent of scrapie cases and affects sheep with either valine (V) or alanine (A) at codon 136, but only very rarely affects sheep that also have at least one allele with arginine (R) at codon 171.

The less common strain of classical scrapie in the United States, valine-associated scrapie, has only been reported in sheep with at least one allele with V at codon 136, and it is significantly more likely than the other strain to affect sheep with a single allele with R at codon 171, since it affects sheep that are AV at codon 136 and QR at codon 171.

An important observation about the genetic results of the SOSS study is that 100 percent of the scrapie-positive sheep were coded QQ for codon 171. Other scientific studies and subsequent data collected by USDA confirm that U.S. sheep that test positive for scrapie coded QQ or QH for codon 171 in more than 99 percent of the cases. As illustrated by the following tables adapted from the SOSS study, approximately 40 percent of sheep in the United States were coded QQ for codon 171.

Genotype Distribution in the General Sheep Population		
Codon 136	Codon 171	Percent
	QQ	40
	QR	44
	RR	16
		Total: 100
AA		90
AV		9
VV		1
		Total: 100

Genotype Distribution in the Scrapie-Positive Sheep		
Codon 136	Codon 171	Percent
	QQ	100
		Total: 100
AA		91
AV		6
No test*		3
		Total: 100
*Samples could not be genotyped because of insufficient DNA or other reasons		

The genotype of a sheep with respect to codons 136 and 171 can be represented by two pairs of letters; for example AA RR would indicate a sheep where both 136 codons are coded for alanine and both 171 codons are coded for arginine. This representation is used to discuss the scrapie susceptibility implications of different sheep genotypes.

QQ sheep (AA QQ, AV QQ, and VV QQ) are susceptible to the more common U.S. scrapie strain and, if infected, can transmit the disease to susceptible flock mates. AA QQ sheep appear to be resistant to the less common valine-associated strain which affects AV QQ, VV QQ, and AV QR sheep. All genotypes of sheep and goats appear to be susceptible to non-classical scrapie. The United States has had 14 cases of non-classical scrapie in sheep.

In contrast, AA RR sheep are nearly completely resistant to, and are unlikely to carry or transmit classical scrapie. Only two sheep with classical scrapie that were AA RR have been reported worldwide.

AA QR sheep are rarely susceptible to classical scrapie. In rare cases, AA QR sheep in Europe have become infected, and there have been two unconfirmed and three confirmed reports in AA QR U.S. sheep. It is unknown whether infected AA QR sheep can transmit the disease. The risk from exposed AA QR sheep is probably minor, since infected AA QR sheep are rare and it is less common for the scrapie prion protein to be found outside the brain of these sheep. However, AA QR sheep are susceptible to non-classical scrapie.

AV QR sheep are somewhat susceptible to the valine associated scrapie strain. As of June 30, 2015, 11 confirmed positive AV QR sheep have been identified in the United States. The risk from exposed AV QR sheep is probably small, since infected AV QR sheep are uncommon, making up less than 1 percent of the scrapie-positive U.S. sheep that have been genotyped, and it is less common for the scrapie prion protein to be found outside the brains of these sheep. AV QR sheep are significantly less susceptible to the scrapie strains that affect them than are the QQ sheep that are affected by these strains.

Implications of Genetic Resistance and Susceptibility for Scrapie Program Design

The observations discussed above, in conjunction with APHIS and State experience in conducting scrapie control pilot projects,³ suggest ways to improve the scrapie regulations' effectiveness and to reduce their costs by creating new risk categories for sheep and goats based on their scrapie resistance or susceptibility, and taking these risk categories into account when imposing regulatory restrictions on animals. In general, the animals that could have their status affected by genotype test results are exposed or potentially exposed animals. Most of the changes in this area would flow from the establishment of four new categories of exposed animals. Ordered by lowest to highest risk, these categories are: Genetically resistant exposed sheep, genetically less susceptible exposed sheep, low-risk exposed animal, and genetically susceptible exposed animals. As defined in the regulations, the terms exposed sheep and exposed animal both include embryos.

We would define genetically resistant sheep to include most sheep and sheep embryos with the RR genotype. The exception would be if a sheep with the RR genotype is ever epidemiologically linked to a scrapie-positive RR sheep or to a scrapie type that affects RR sheep. A genetically resistant sheep that was exposed to scrapie would be a genetically resistant exposed sheep. Genetically less susceptible sheep would include most sheep (or sheep embryos) with the AA QR or AV QR genotype. A low-risk exposed animal would be a sheep or goat deemed to present significantly lower risks than a typical exposed animal due to the nature of either the exposure or the animal. The exact definitions for these categories are discussed in more detail below. Flexibility has been written into these definitions to allow the Administrator

³ Pilot projects have tested, among other things, live animal scrapie tests, alternatives for improving field data collection for animals and flocks, innovative animal ID devices, use of genotype to classify the risk of exposed sheep and new devices and procedures for collecting tissue samples for DNA testing.

to adjust the classification of animals based on the strain involved and the genotype of the animal as additional research becomes available.

Genetically susceptible animals would include all goats, any sheep with a genotype other than QR or RR (such as QQ, HH, QH, QK, KK or KH), and any sheep with an unknown or undetermined genotype (i.e., sheep that have not been officially genotyped or sheep that have been tested with inconclusive results). At present, all goats would be considered genetically susceptible because there is insufficient understanding of genetically based scrapie resistance in goats to reliably assign goat risk categories based on genetics. If ongoing and future research provides new information about the genetic resistance of sheep or goats to scrapie that would allow other useful distinctions in risk between different genotypes of sheep or goats, APHIS will take such research results into account in the design of the Scrapie Eradication Program. The Scrapie Eradication Program is the cooperative State-Federal-Industry program administered by APHIS and States to control and eradicate scrapie, encompassing the SFCP, Federal and State regulations regarding the identification and movement of sheep and goats and the control of scrapie, and other associated efforts.

In order to assign individual sheep to one of these genetic susceptibility categories, APHIS has established procedures to ensure that genotype tests conducted as part of the Scrapie Eradication Program are reliable. We propose to amend the definition of official genotype test to read “A test to determine the genotype of a live or dead animal conducted at either the National Veterinary Services Laboratories or at an approved laboratory. The test subject must be an animal that is officially identified and the test accurately recorded on an official form supplied or approved by APHIS, with the samples collected and shipped to the laboratory using a shipping method specified by the laboratory by:

- (1) An accredited veterinarian;
- (2) A State or APHIS representative; or
- (3) The animal's owner or owner's agent, using a tamper-resistant sampling kit approved by APHIS for this purpose.”

The primary change from the previous definition is that new paragraph (3) would allow owners to collect samples for official genotype tests and to clarify that when a sample is submitted it must be accompanied by a properly completed official form. We believe this would make it more convenient and less expensive for owners to obtain genotype testing; however, it is also critical that the sample is from an animal that is officially identified and that the sample maintains its identity and its association with the correct animal throughout the process of collection and submission. We propose to stress that the form must be properly completed due to the significant percentage of forms submitted to approved laboratories that are incomplete or undecipherable. To protect against error and tampering, we propose to allow owners or owner agents⁴ to collect samples for official genotype testing only by using an APHIS-approved tamper-resistant sampling kit. This kit would be an official identification device that, when it is attached to the animal, collects and ejects a tissue sample in a sealed container. Both the tissue sample container and the official identification device that remains attached to the animal would bear the same identification number, reliably associating the tissue with the correct animal. We propose to add a new term to part 54, tamper-resistant sampling kit, defined as “A device or method for collecting DNA samples from sheep or goats that is approved by the Administrator and that identifies both the sample and the animal at the time the sample is collected. These

⁴ APHIS or State representatives or accredited veterinarians would not have to use tamper-resistant sampling kits when collecting samples.

devices or methods must ensure that the sample, its corresponding label, and the official ID device or method applied to the animal meets the requirements of § 79.2(k) and that the sample is from the same animal to which the official ID device or method was applied. The kit must include an APHIS-approved official form or another form, device, or method acceptable to APHIS for transmitting the information required to APHIS and the approved laboratory.” This definition is intended to allow the market to develop innovative approaches to the task by allowing the Administrator to approve a wide variety of potential kits. APHIS also employs this approach of encouraging market innovation and approving successful methods in our proposed changes to § 54.10, “Program approval of tests for scrapie,” and § 54.11, “Approval of laboratories to run official scrapie tests and official genotype tests,” which are discussed later in this document.

Note that in addition to approving tamper-resistant sampling kits, test methodologies, and laboratories that may perform tests, APHIS reserves the right to require confirmatory genotype testing. This is an additional safeguard that may be used to ensure result validity when evaluating official genotype test results, e.g., when the result of the genotype test is inconclusive for codon 136 or 171 or as part of a standard quality assurance procedure.

We propose to amend the regulations in several ways to provide for the use of the genotype information, and, with the resulting capability to classify exposed animals as genetically susceptible, genetically less susceptible, or genetically resistant, would be able to more precisely classify the risk that an individual exposed animal may spread scrapie. We would incorporate genetic susceptibility into the definitions of exposed animal and high-risk animal, reducing the percentage of animals subject to the most severe regulatory restrictions, including euthanasia and destruction. We would also modify § 79.3 to consider genetic susceptibility in its

restrictions on exposed animal movement, so that the animals most resistant to scrapie face fewer restrictions than other exposed animals. Laboratories that perform official genotype tests already enter the results in the National Scrapie Database to maximize the availability and usefulness of genotype information, and we propose to include this data entry requirement in § 54.11, the section concerning approval of laboratories to perform the test. We also propose to add a requirement to § 79.5(a)(3) that Interstate Certificates of Veterinary Inspections (ICVIs) or permits used for interstate movement of breeding animals record the animals' genetic susceptibility category if known. We would take genetic susceptibility into account when writing flock plans and PEMMPs. Finally, to make the most effective use of limited indemnity funds, when paying indemnity for exposed animals we would generally only pay indemnity for exposed sheep that are officially genotyped and designated genetically susceptible exposed sheep. We would only pay indemnity for non-genotyped sheep in circumstances such as when the Administrator determines that waiting for genotype test results could result in the exposure of more animals, or when the cost of testing the sheep and indemnifying only those that are genetically susceptible would approach or exceed the cost of indemnity for all the exposed sheep involved. We would not require that goats be genotyped to be eligible for indemnity because, as discussed above, present understanding of genetically based scrapie resistance in goats does not allow us to reliably assign goat risk categories based on genetics.

Under the regulations, animals for which indemnity is paid must be destroyed. The current definition of destroyed includes euthanasia and disposal of the carcass by means authorized by the Administrator, or movement to a quarantined research facility when so ordered by the Administrator. Currently the definition also states that if the animal to be destroyed is an exposed or high-risk animal that is not known to be infected, it may be either euthanized or

disposed of by slaughter. The World Organization for Animal Health guidelines for scrapie control recommend that the carcasses of scrapie affected animals be completely destroyed to reduce potential scrapie exposure through consumption of feed containing animal proteins. Also, in recent years the Food and Drug Administration (FDA) and USDA have increased their efforts to reduce potential animal or human exposure to TSEs through consumption of feed or food containing animal proteins. Changes in this area have included⁵ additional restrictions to prevent inclusion of certain tissues from cattle (specified risk materials) that present a particular risk of containing BSE from being used in animal or human food. In support of this effort, we propose to no longer allow the carcasses of any sheep or goats indemnified and destroyed under the regulations to be used for feed or food.

APHIS indemnified and destroyed 235 sheep and goats during the first 6 months of 2014 under the regulations, of which 133 were destroyed by slaughter. This change would therefore divert on average approximately 266 sheep and goats per year from slaughter channels; however, it is expected that as the program progresses the number of animals indemnified will decrease and thus the number of animals diverted will decrease. Postmortem testing of mature scrapie exposed sheep and goats in FY 2013 and FY 2014 resulted in 5.6 and 2.7 percent of the animals testing positive for scrapie, respectively. In FY 2014, a large scrapie source flock with a very low prevalence accounted for about half of the animals depopulated in FY 2014. If this flock is excluded, the percent of exposed animals that tested positive is approximately 4.8 percent. Therefore, this change would likely keep approximately 12 to 15 scrapie-positive animals from food or feed uses each year.

⁵ See, e.g., the FSIS rule "Prohibition of the Use of Specified Risk Materials for Human Food and Requirements for the Disposition of Non-Ambulatory Disabled Cattle" (72 FR 38700; July 13, 2007) and the FDA rule "Substances Prohibited From Use in Animal Food or Feed" (73 FR 22719, April 25, 2008).

To accomplish this change, we propose to revise the definition of destroyed to read as follows: “Euthanized and the carcass disposed of by means authorized by the Administrator that will prevent its use as feed or food, or moved to a quarantined research facility if the movement has been approved by the Administrator.” This proposed change would work in concert with the proposed movement restriction in § 79.3(c), that indemnified high-risk animals or indemnified sexually intact genetically susceptible exposed animals, which pose the most risk, may only be moved for destruction. These changes would ensure that the riskiest animals are kept from slaughter, without precluding movement under permit to slaughter of less risky genetically susceptible exposed animals that are not indemnified. This would allow animals from flocks under investigation that are not yet known to be infected and lambs that are likely too young to have developed significant scrapie agent presence to continue to move to slaughter.

In the following sections, we discuss in detail how genotype information would affect the regulations’ definitions, movement restrictions, indemnity provisions, and other requirements.

Changes to Flock and Animal Designation Categories

We propose to make several changes to the definition of the term exposed flock and to define two new terms, flock under investigation and classification or reclassification investigation. As currently defined, the term exposed flock is rather broad and encompasses notably different risk levels. For example, a flock could be designated exposed because an animal that may be scrapie-positive lambled in the flock, which is probably the event that has the single highest probability of transmitting scrapie to other animals. However, a flock could also be designated as exposed if a single animal in the flock was once briefly in a different flock that contained a scrapie-positive animal.

The current definition of exposed flock was written before effective live-animal tests for scrapie were available and before genetic testing was widely accepted for evaluating risk. Now that such tests are available and accepted, sometimes flocks that would be designated exposed under the current definition could avoid such a designation under the revisions we propose. For example, an investigator may know that a flock has a risk factor, and that we should pay attention to the flock, but cannot determine the actual risk without testing the animal that caused the potential exposure or, in its absence, other animals in the flock. Live animal tests are now available to aid in this determination.

To address these problems, we are developing a new category, flock under investigation. A flock under investigation is a flock that may have become scrapie infected by exposure to a scrapie-positive, high-risk, or scrapie-suspect animal, however, further investigation of animal records and/or testing of animals in the flock may be necessary to make the final determination. A flock under investigation may be cleared by demonstrating that it was not in fact exposed, or by taking steps to ensure that, whether or not the flock was exposed, there is no significant possibility that animals in the flock were infected as a result of the exposure. Such steps could include genotyping some or all of the animals in the flock, then removing and destroying and/or testing the genetically susceptible animals and/or having the flock comply with a PEMMP.

Creating the category of flock under investigation would leave the category of exposed flock to apply to only those flocks where there has been exposure or potential exposure that could not be adequately assessed, and/or the risks of exposure have not been sufficiently mitigated, so there is some significant continuing risk that a scrapie-positive animal might be detected in the flock. An exposed flock could be a flock under investigation whose owner declined to complete the genotyping or scrapie testing needed to complete the investigation, or

declined to remove one or more genetically susceptible exposed animals or suspect animals identified during the investigation. Thus, the category of exposed flock would generally apply to flocks where the owner has decided to accept some level of continuing scrapie risk, rather than undertake the actions that would resolve the remaining risk.

Specifically, we propose to define these two categories as follows. A flock under investigation would be any flock in which an APHIS or State representative has determined that a scrapie suspect, positive, or high-risk animal resides or may have resided. (Note that mere removal of any suspect or high-risk animals is not sufficient grounds to end investigation of the flock.) A flock would no longer be a flock under investigation if it is redesignated in accordance with § 79.4. A flock may be redesignated for various reasons, including a determination that it is an infected flock, source flock, or exposed flock, or that tissues from the suspect and high-risk animals were submitted for official testing and no evidence of scrapie is found, or because the flock completed any genotyping and live-animal or post-mortem scrapie testing required by the DSE and is in compliance with a PEMMP if one is required by the DSE.

An exposed flock would be any flock that was designated an infected or source flock that has completed a flock plan and that retained a female genetically susceptible exposed animal. The definition would also include any flock under investigation that retains a female genetically susceptible exposed animal or a suspect animal, or whose owner declines to complete genotyping and live-animal and/or post-mortem scrapie testing required by the investigator, and any noncompliant flock or any flock for which a PEMMP is required that is not in compliance with the conditions of the PEMMP. A flock will no longer be considered an exposed flock if it is redesignated in accordance with § 79.4.

We also propose to change the definition for noncompliant flock to recognize the role of the new category flock under investigation. The current definition refers to source, infected, or exposed flocks that are not in compliance with the regulations; we propose to also include flocks under investigation that are not in compliance.

We would also add a new defined term, classification or reclassification investigation, to consolidate descriptions of epidemiological investigation activities that were formerly located in several places in the regulations. This defined term would not impose new requirements, but would instead help the reader understand what epidemiological considerations a DSE would employ when determining the designation of an animal or flock under the Scrapie Eradication Program. The new term would be defined as follows: “An epidemiological investigation conducted or directed by a DSE for the purpose of designating or redesignating the status of a flock or animal. In conducting such an investigation, the DSE will evaluate the available records for flocks and individual animals and conduct or direct any testing needed to assess the status of a flock or animal. The status of an animal or flock will be determined based on the applicable definitions in this section and, when needed to make a designation under § 79.4, official genotype test results, exposure risk, scrapie type involved, and/or results of official scrapie testing on live or dead animals.”

We also propose to revise the definition of exposed animal so that it employs the concepts of genetic resistance or susceptibility discussed above. It also includes a standard for estimating a probable date of infection for a flock, which is relevant to identifying which animals were exposed. Where epidemiologic investigation is inconclusive, we use a probable date of infection 2 years before the birth of the oldest scrapie-positive animal in the flock. The 2-year range is used because the oldest positive animal was likely infected at or near birth by another

positive animal that died and that positive animal likely exposed up to two previous lamb crops before she died since most positive animals die 3-to-4 years after infection. The revised definition we propose for exposed animal would read “Any animal or embryo that: (1) Has been in a flock or in an enclosure off the premises of the flock with a scrapie-positive female animal, (2) resides in a noncompliant flock, or (3) has resided on the premises of a flock before or while it was designated an infected or source flock and before a flock plan was completed. An animal shall not be designated an exposed animal if it only resided on the premises before the date that infection was most likely introduced to the premises as determined by a Federal or State representative. If the probable date of infection cannot be determined based on the epidemiologic investigation, a date 2 years before the birth of the oldest scrapie-positive animal(s) will be used. If the actual birth date is unknown, the date of birth will be estimated based on examination of the teeth and any available records. If an age estimate cannot be made, the animal will be assumed to have been 48 months of age on the date samples were collected for scrapie diagnosis. Exposed animals will be further designated as genetically resistant exposed sheep, genetically less susceptible exposed sheep, genetically susceptible exposed animals, or low-risk exposed animals. An animal will no longer be an exposed animal if it is redesignated in accordance with § 79.4.”

We also propose to add definitions of several terms related to genetic susceptibility and resistance that appear in the defined term exposed animal. These new terms reflect the fact, as discussed above, that the genetic resistance or susceptibility of an exposed animal affects the risk level of that exposed animal. Therefore, we propose to add the following definitions.

We would define genetically less susceptible exposed sheep as “Any sheep or sheep embryo that is:

- An exposed sheep or sheep embryo of genotype AA QR, unless it is epidemiologically linked to a scrapie-positive RR or AA QR sheep or to a scrapie type to which AA QR sheep are not less susceptible where Q represents any genotype other than R at codon 171; or
- An exposed sheep or sheep embryo of genotype AV QR, unless it is epidemiologically linked to a scrapie-positive RR or QR sheep, to a flock that the DSE has determined may be affected by valine associated scrapie (based on an evaluation of the genotypes of the scrapie-positive animals linked to the flock), or to another scrapie type to which AV QR sheep are not less susceptible where Q represents any genotype other than R at codon 171 and V represents any genotype other than A at codon 136; or
- An exposed sheep or sheep embryo of a genotype that has been exposed to a scrapie type to which the Administrator has determined that genotype is less susceptible but not resistant.”

We would define genetically resistant exposed sheep as “Any exposed sheep or sheep embryo of genotype RR unless it is epidemiologically linked to a scrapie-positive RR sheep or to a scrapie type to which RR sheep are not resistant.”

We would define genetically susceptible animal as “Any goat or goat embryo, sheep or sheep embryo of a genotype other than RR or QR, or sheep or sheep embryo of undetermined genotype where Q represents any genotype other than R at codon 171.”

We would define genetically susceptible exposed animal as “Excluding low-risk exposed animals, any exposed animal or embryo that is also:

- A genetically susceptible animal; or

- A sheep or sheep embryo of genotype AV QR that is epidemiologically linked to a scrapie-positive RR or QR sheep, to a flock that the DSE has determined may be affected by valine associated scrapie (based on an evaluation of the genotypes of the scrapie-positive animals linked to the flock), or to a scrapie type to which AV QR sheep are susceptible where Q represents any genotype other than R at codon 171 and V represents any genotype other than A at codon 136; or
- A sheep or sheep embryo of genotype AA QR that is epidemiologically linked to a scrapie-positive RR or AA QR sheep or to a scrapie type to which AA QR sheep are susceptible where Q represents any genotype other than R at codon 171; or
- A sheep or sheep embryo of genotype RR that is epidemiologically linked to a scrapie-positive RR sheep or to a scrapie type to which RR sheep are susceptible.”

We also propose to add the following definition of low-risk exposed animal, identifying exposed animals that are of very low-risk of transmitting scrapie so that the program can avoid ordering the destruction of such animals. For example current science indicates that sheep and goats exposed to Nor98-like scrapie are unlikely to transmit the disease to other animals. Barring the publication of new data to the contrary, the Administrator intends to determine that animals exposed to Nor98-like scrapie are low-risk exposed animals.

We would define low-risk exposed animal as “Any exposed animal to which the DSE has determined one or more of the following applies:

- The positive animal that was the source of exposure was not born in the flock and did not lamb in the flock or in an enclosure where the exposed animal resided;

- The Administrator and State Veterinarian concur that the animal is unlikely to be infected due to factors such as, but not limited to, where the animal resided or the time period the animal resided in the flock;
- The exposed animal is male and was not born in an infected or source flock;
- The exposed animal is a castrated male;
- The exposed animal is an embryo of a genetically resistant exposed sheep or a genetically less susceptible exposed sheep unless placed in a recipient that was a genetically susceptible exposed animal; or
- The animal was exposed to a scrapie type and/or is of a genotype that the Administrator has determined poses low risk of transmission.”

We also propose to amend the definition of the term high-risk animal. The current definition includes most exposed male sheep, excluding only male sheep that have been genotyped and found to be genetically resistant (RR at codon 171). Both the current and the proposed definition include all female progeny of a scrapie-positive dam, and all exposed genetically susceptible female sheep. The current definition also automatically included all female sheep that were born into a flock during the same lambing season that a scrapie-positive female lambed in the flock or a scrapie-positive female was born into the flock. We now believe that, while many of the female sheep born in such a lambing season should be considered high risk, some of them should not, based primarily on the genetic susceptibility of the animals involved. The proposed new definition generally excludes male sheep (except suspect animals that need to be investigated, and occasional special cases identified by the Administrator) because accumulated epidemiological evidence shows little chance that a male sheep could present a high risk of transmitting scrapie.

The epidemiology and scrapie prevalence of the flock would also be considered in determining the risk level of genetically less susceptible sheep. We propose to amend the definition of high-risk animal to give the Administrator, and persons authorized to act for the Administrator (e.g., DSEs) some discretion in whether or not to classify genetically less susceptible sheep as high-risk. Specifically, we would revise the definition of high-risk animal to read “The female offspring or embryo of a scrapie-positive female animal, or any suspect animal, or a female genetically susceptible exposed animal, or any exposed animal that the Administrator determines to be a potential risk based on the scrapie type, the epidemiology of the flock or flocks with which it is epidemiologically linked, including genetics of the positive sheep, the prevalence of scrapie in the flock, any history of recurrent infection, and other animal or flock characteristics. An animal will no longer be a high-risk animal if it is redesignated in accordance with § 79.4.”

We also propose to amend the definition of suspect animal in parts 54 and 79. The new definition could apply only to an animal that is a “mature sheep or goat as evidenced by eruption of the first incisor.” This change reflects the reality that clinical signs of scrapie do not appear in very young animals. The revised definition also notes that a suspect animal might be one that was determined to be suspicious for scrapie by an accredited veterinarian or a State or APHIS representative, as the current definition states, or it might be an animal “condemned by FSIS or a State inspection authority for central nervous system signs.” This change reflects the reality that the condemnation process sometimes leads to identification of suspect animals.

Updating Other Definitions in Parts 54 and 79

To support and clarify some of the changes discussed above, we propose to make several changes to the definitions of some of the terms already in use in parts 54 and 79. In addition to

the new and revised definitions discussed above, we would also add or amend the following definitions:

Low-risk commercial sheep and low-risk goat. These defined terms are used only in part 79. We propose to replace the current definition of low-risk commercial sheep and low-risk goat with a definition of low-risk commercial flock. The current definition of low-risk commercial sheep excludes goats, and the regulations use the defined term to allow certain movements of sheep that present a low risk. We believe that it would be sensible to use definitions that apply to both sheep and goats from low-risk flocks, because such sheep and goats are both documented to present minimal risk of spreading scrapie. The proposed definition of low-risk commercial flock incorporates the standards in the current definition of low-risk commercial sheep but applies them to goats as well as sheep. This change does not significantly affect the treatment of low-risk commercial sheep under the regulations and gives equal consideration to goat owners. Note that animals that have been in contact with any female animals that do not qualify as low-risk commercial animals, or that are of unknown origin, would not be considered low-risk commercial animals. These changes, coupled with corresponding changes in § 79.3, require the official identification of many goats that were previously defined as low-risk commercial goats and exempted.

The proposed definition of low-risk exposed animal also acknowledges the concept that some animals may meet the definition of an exposed animal but present little risk of scrapie transmission; by designating these animals as low-risk exposed animals, they are not required to be destroyed and are instead identified to increase traceability.

Premises identification number (PIN). This defined term is used only in part 79. The PIN appears on premises records in the National Scrapie Database and has been used on official

identification devices and recorded on ICVIs and other documents related to the Scrapie Eradication Program. It is a unique number assigned by a State or Federal animal health authority that is associated with a physical address and/or legal land description. The current definition of premises identification number states that the form of the number must be either (1) the State's two-letter postal abbreviation followed by the premises' assigned number or (2) a seven-character alphanumeric code, with the right-most character being a check digit. The check digit number is based upon the ISO 7064 Mod 36/37 check digit algorithm.

We propose to amend this definition to provide uniformity between animal disease programs. The clarification is that all premises will have either a premises identification number created under the current definition's option (2) or a number issued by a State that is a nationally unique location identifier, which will identify that premises in the National Scrapie Database and related records. USDA and the States may also maintain secondary numbers created under option (1) to link historical premises numbers to the standardized program premises identification number in records and databases. Federal or State officials will generate a standardized program premises identification number both for existing premises in the National Scrapie Database and for any new premises.

Flock identification (ID) number and group/lot identification number. We propose adding a definition of flock identification number to part 79 to refer to a number assigned by a State or Federal animal health authority to a group of animals that are managed as a unit on one or more premises and are under the same ownership. This identifier is needed because a flock may move between multiple premises without changing ownership. The flock ID number would be nationally unique, would begin with the State postal abbreviation, would have no more than nine alphanumeric characters, and could not contain the characters "I", "O", or "Q" other than as

part of the State postal abbreviation. The flock ID number will be linked to the standardized program premises identification number(s) for the premises on which the flock resides and may serve as part of the number on an official eartag when used in conjunction with an animal number that is unique within the flock. We also propose to define a similar group/lot identification number to establish unique identification for groups of animals that are temporarily assembled from flocks for management purposes and that may or may not be under single ownership.

Slaughter channels. The first sentence of this definition currently reads “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.” We propose to change this to read “...moved either directly to or through a restricted animal sale or restricted livestock facility to a slaughter establishment that is under continuous inspection by the Food Safety and Inspection Service (FSIS) or under State inspection that FSIS has recognized as at least equal to Federal inspection or to a custom exempt slaughter establishment as defined by FSIS for immediate slaughter or to an individual for immediate slaughter for personal use or to a terminal feedlot. Any animal sold at an unrestricted sale is not in slaughter channels. Animals in slaughter channels must be accompanied by an owner/hauler statement completed in accordance with § 79.3(g) of this chapter.” This change would make the definition more consistent with definitions in other APHIS regulations that address slaughter. It would also clarify that animals are in slaughter channels whether they are moved to such a destination directly or through intermediaries, and may not be removed from slaughter channels, a requirement stated in several sections of the regulations, including current § 79.3(a) and proposed § 79.3(g). We are also

proposing to add a definition for restricted animal sale or restricted livestock facility to parts 54 and 79 to further clarify slaughter channels.

We also propose to add a new provision to the definition of terminal feedlot in part 79, and to add this definition to part 54 as well. The current definition authorizes two types of facilities as terminal feedlots. In one, either pregnant or non-pregnant animals may be maintained on a dry lot where all animals are separated by either 30 feet of distance or a solid wall. The second type of facility is limited to only non-pregnant animals (males, or ewes that have not been exposed to a ram) and is a pasture where no fence-to-fence contact is possible between animals in one flock and animals in another. The definition reflects the risk-based need for a higher level of security and less opportunity for contact where pregnant animals are involved. However, the definition does not address situations where only non-pregnant animals are kept at a dry lot, so the dry lot does not need to maintain the additional safeguards used when pregnant animals are present. We propose to add a paragraph that allows non-pregnant animals to be maintained at a dry lot under conditions similar to those used with non-pregnant animals in a pasture. Specifically, we would add language stating that one type of terminal feedlot is a dry lot “...where only animals that either are not pregnant based on the animal being male, an owner certification that any female animals have not been exposed to a male in the preceding 6 months, an ICVI issued by an accredited veterinarian stating the animals are open, or the animals are under 6 months of age at time of receipt, where only castrated males are maintained with female animals, and all animals in the terminal feedlot are separated from all other animals such that physical contact cannot occur and from which animals are moved only to another terminal feedlot or directly to slaughter.”

Changes to the Investigation of Flocks and the Designation of a Flock- and Animal's Risk for Scrapie

We propose to make several changes to the descriptions in § 79.4 regarding the investigation procedures followed by officials who are authorized to designate or redesignate exposed animals, suspect animals, high-risk animals, exposed flocks, infected flocks, and source flocks. These proposed changes are to improve the clarity and practicality of the regulations.

We also propose to remove some repetitive language concerning investigation and testing from paragraph (a) of § 79.4. This language is no longer needed due to the new proposed definition for classification or reclassification investigation.

In paragraph (b) of § 79.4, we propose to remove the detailed descriptions of the reclassification process and instead state that reclassification investigations will be conducted in accordance with procedures approved by the Administrator when evidence indicates that a previous designation can be changed.

We would provide the detailed reclassification processes to the public on the scrapie Web site at <http://www.aphis.usda.gov/animal-health/scrapie>. This will allow us to update the reclassification processes easily when necessary while providing the public with notice regarding our policies. For major changes to the reclassification processes, we would publish a notice in the Federal Register describing the proposed change and solicit public comments on the change. We would then issue a second notice discussing the comments and informing the public of our decision regarding the change. For minor changes, updates, or clarifications, we would post notice of the change prominently on the scrapie Web site. Examples of major changes might be a whole new class of live animal test that is cheap, reliable, and effective enough to make testing all animals practical, or other changes that might result in reclassification of the majority of

classified flocks or animals. We would also provide email notification to State cooperators and other stakeholders through the APHIS Stakeholder Registry. Individuals or organizations may be added to this list through GovDelivery, a free email subscription service. To subscribe to this free service go to <https://public.govdelivery.com/accounts/USDAAPHIS/subscriber/new> and select “Animal Health - Sheep and Goats” and “Federal Register Publications – Notices Regarding Animal Health.”

As part of this change, we propose to reformat the reclassification processes described in current paragraph (b) as a chart instead of text, to make it easier to understand. We would also remove some repetitive language concerning investigation and testing from the current text in paragraph (b). The proposed chart of reclassification procedures, along with other materials this rule proposes to make available through the scrapie Web site rather than in the regulations, is available by contacting the person listed under FOR FURTHER INFORMATION CONTACT, on the Regulations.gov Web site, or on the scrapie Web site at <http://www.aphis.usda.gov/animal-health/scrapie>. We invite public comment on both the current drafts of these materials and on the concept of making the materials available on the scrapie Web site rather than in the Code of Federal Regulations.

Changes to Recordkeeping and Identification Requirements

We propose to consolidate and simplify the recordkeeping requirements in the regulations. Currently, the description of these requirements is dispersed in several locations in the regulations, including the definition of terminal feedlot, in paragraphs (c) and (f) through (h) of § 54.8, Requirements for flock plans and post-exposure management and monitoring plans, and in paragraphs (b) through (d) of § 79.2, Identification of sheep and goats in interstate commerce. Some readers also found the current descriptions of recordkeeping requirements

confusing in terms of what types of people or businesses were required to keep what types of records.

To aid clarity, we propose to consolidate and replace the existing recordkeeping language with two new paragraphs addressing recordkeeping requirements in § 79.2. We also propose to add three new paragraphs dealing with removal, loss, and replacement of official identification devices, and situations where use of more than one official eartag may be allowed. This language would be added to be consistent with APHIS official identification requirements in 9 CFR part 86. We would also change the heading of § 79.2 to read Identification and records requirements for sheep and goats in interstate commerce. The two new paragraphs (f) and (g) would be titled “Records required of persons who purchase, acquire, sell, or dispose of animals” and “Records required of persons who apply official identification to animals.”

The new paragraph (f) that addresses recordkeeping requirements for people who acquire or dispose of sheep and goats would continue to require, as current § 79.2(d) does, that these persons -- whether or not the animals are required to be officially identified -- maintain business records documenting the acquisition or disposal (such as yarding receipts, sale tickets, invoices, and waybills) for 5 years. We also propose to expand on the current § 79.2(d) requirement that such persons must keep “records relating to the transfer of ownership, shipment, or handling of the sheep or goats” by specifically stating that the records must include the following information:

- The number of animals purchased or sold including animals acquired or transferred without sale;
- The date of purchase, sale, or other transfer;

- The name and address of the person from whom the animals were purchased or otherwise acquired or to whom they were sold or otherwise transferred;
- The species, breed, and class of animal, such as replacement ewe lambs, slaughter lambs or kids, cull ewes, club lambs, bred ewes, etc. If breed is unknown, for sheep the face color or in the case of goats the type (milk, fiber, or meat) must be recorded instead;
- A copy of the brand inspection certificate for animals officially identified with brands or ear notches;
- A copy of any certificate or owner/hauler statement required for movement of the animals purchased, sold, or otherwise transferred; and
- If the flock of origin or the receiving flock is under a flock plan or PEMMP, any additional records required by the plan.

New paragraph (g) that addresses recordkeeping requirements for persons who apply official identification to animals would require such persons to maintain the following records:

- The flock identification number, the name and address of the person who currently owns the animals, and the name and address of the owner of the flock of origin if different;
- The name and address of the owner of the flock of birth, if known, for animals born after January 1, 2002, in another flock and not already identified to flock of birth;
- The date the animals were officially identified;
- The number of sheep and the number of goats identified;
- The breed and class of animals such as replacement ewe lambs, slaughter lambs or kids, cull ewes, club lambs, bred ewes, etc. If breed is unknown, for sheep the face color or in the case of goats the type (milk, fiber, or meat) must be recorded instead;

- The official identification numbers applied to animals by species or the GIN applied in the case of a group lot;
- Whether the animals were identified with “Slaughter Only” or “Meat” identification devices; and
- Any GIN with which the animal was previously identified.

Each person required to keep records under either of these paragraphs would have to maintain the records for at least 5 years, or longer if the Administrator requests it by written notice to the person, for purposes of any investigation or action involving the sheep or goats identified in the records. As in the current requirements, the person would have to make the records available for inspection and copying by any authorized USDA or State representative upon that representative’s request and presentation of his or her official credentials.

New paragraph (h) in § 79.2 addresses removal or loss of official identification. The proposed requirements are consistent with parallel requirements in 9 CFR 86.4(d). Official identification is removed at slaughter, and this paragraph describes the responsibilities of slaughter plants to keep official identification correlated with carcasses through final inspection and procedures between APHIS and FSIS regarding collection of identification at the slaughter plants. This paragraph also describes procedures in the event of loss or destruction of official identification prior to slaughter.

New paragraph (i) addresses replacement of official identification devices for reasons other than loss, such as damage to the device or injury or infection of the animal that affects the device. The proposed requirements are consistent with parallel requirements in 9 CFR 86.4(e).

New paragraph (j) addresses use of more than one official eartag on a sheep or goat. The proposed requirements are consistent with parallel requirements in 9 CFR 86.4(c). We propose

to prohibit the application of additional official eartags to a single animal unless warranted by a specific situation. This is because the use of multiple official eartags with multiple official identification numbers for a single animal can cause confusion and impede efforts to track the movements of that animal. However, we do propose to allow multiple eartags in situations where they would provide herd management advantages or where allowing only a single tag is impractical. We propose to allow multiple official eartags in the following situations:

- When the additional eartag bears the same official identification number as an existing one.
- In specific cases when the need to maintain the identity of an animal is intensified (e.g., such as for export shipments, quarantined herds, field trials, experiments, or disease surveys), a State or Tribal animal health official or the Veterinary Services, Surveillance Preparedness and Response Services, Assistant Director responsible for the State involved may approve the application of a second official eartag. The person applying the second official eartag must record the following information about the event and maintain the record for 5 years: The date the second official eartag is added; the reason for the additional official eartag device; and the official identification numbers of both official eartags.
- An eartag with an animal identification number (AIN) beginning with the 840 prefix (either radio frequency identification or visual-only tag) may be applied to an animal that is already officially identified with another eartag. The person applying the AIN eartag must record the date the AIN tag is added and the official identification numbers of all official eartags on the animal and must maintain those records for 5 years.

- An official eartag that utilizes a flock identification number may be applied to a sheep or goat that is already officially identified with an official eartag if the animal has resided in the flock to which the flock identification number is assigned.

We also propose to make certain changes to the system for official animal identification in two sections, § 54.8 (retitled Requirements for flocks under investigation and flocks subject to flock plans and post-exposure management and monitoring plans) and § 79.2 (Identification and records requirements for sheep and goats in interstate commerce). Some of these changes clarify who is responsible for ensuring animal identification is applied (the owner and anyone who has control or possession of the animals) and when it must be applied. Identification must be applied no later than whenever one of the following situations applies to an animal:

- Prior to the point of first commingling with sheep or goats from any other flock of origin;
- Upon transfer of ownership of the sheep or goats;
- Upon unloading at a livestock facility or other premises that engages in interstate commerce of animals; or
- Prior to moving a sheep or goat from the premises on which it resides for any other type of movement.

We would provide an exemption from the requirement to officially identify animals before they leave their premises if they move, as part of a group lot, to a livestock facility approved in accordance with our regulations in 9 CFR 71.20 to handle the species and class of animal moved, provided that the facility has agreed to act as an agent for the owner to apply official identification. We would also exempt animals that are moved as part of a group lot to a slaughter plant listed in accordance with 9 CFR 71.21 or for managerial purposes between premises owned or leased by the same flock owner. We also propose to remove a provision in

§ 79.2(a) that expired on June 1, 2003, that allowed movement of certain animals that are not identified to their flock of birth.

Paragraph (a)(2) of § 79.2 lists approved identification methods. We are proposing to remove this list from the regulations and instead state in the regulations that sheep or goats must be identified and remain identified using a method approved by the Administrator. We would provide a list of approved identification methods on the scrapie Web site at <http://www.aphis.usda.gov/animal-health/scrapie>. For major changes to the list of approved identification methods, we would publish a notice in the Federal Register describing the proposed change and solicit public comments on the change. We would then issue a second notice discussing the comments and informing the public of our decision regarding the change. For minor changes, updates, or clarifications, we would post notice of the change prominently on the scrapie Web site. We would also provide email notification to State cooperators and other stakeholders through the APHIS Stakeholder Registry.

We are proposing this change because identification technologies are continually updated to take advantage of newly available technology and to meet industry needs. Maintaining a list of approved identification methods in the regulations requires rulemaking to update that list. Updating the list of approved identification methods without completing rulemaking will allow for more frequent and timely updates to the list, while continuing to ensure that all animal identification methods are approved by the Administrator.

As part of this rulemaking, we are also soliciting comments on changes to the current list of approved identification methods in § 79.2. Copies of the list as we would establish it on the scrapie Web site are available by contacting the person listed under FOR FURTHER INFORMATION CONTACT, on the Regulations.gov Web site, or on the scrapie Web site at

<http://www.aphis.usda.gov/animal-health/scrapie>. Some of the changes to the current approved identification methods would ensure that identification devices, in addition to providing official identification numbers, also provide information about the status of the animal when appropriate, i.e., whether the animal is scrapie-positive, permanently restricted (confined to its premises by a State or APHIS representative until it dies or is redesignated by a State or APHIS representative), or for slaughter only.

Finally, we are proposing to move the current description of the process for approving new methods of identification in § 79.2(g) into paragraph (a)(2) and amend the current text of paragraph (g) and move it to a new paragraph (k) to reflect these changes. This paragraph indicates that written requests for approval of sheep or goat identification methods not listed in paragraph (a)(2) of § 79.2 should be sent to the National Scrapie Program Coordinator, Sheep, Goat, Cervid & Equine Health Center, Surveillance, Preparedness and Response Services, VS, APHIS, 4700 River Road Unit 43, Riverdale, MD 20737–1235. If the Administrator determines that the identification method will provide a means of tracing sheep and goats in interstate commerce, notice will be published in the Federal Register adding the devices and markings to the list of approved means of sheep and goat identification.

To be consistent with the other proposed changes we have discussed, we would replace the reference to paragraph (a)(2) in current paragraph (g) with a reference to the scrapie Web site, where the approved identification methods would be listed. We would also replace the reference to publishing a notice in the Federal Register with a reference to providing public notice that the devices and markings have been added to the list of approved identification methods, to allow us flexibility to add methods without necessarily publishing a notice in the Federal Register.

With respect to responsibility for identifying animals, in § 79.2(a)(3) we propose to more clearly restate the current requirement that when an animal that is required to be identified is moved to a place where it will be put in the same enclosure with animals from a different flock of origin, the person who owns the animal, the person who transports or delivers that animal, and the person who accepts delivery of the animal are all responsible for ensuring that the animal is officially identified prior to commingling.

We are particularly seeking comment regarding the provisions in the regulations that allow some animals to be officially identified upon arrival at certain livestock facilities, rather than before leaving their premises, and that allow the identification to be applied by the livestock facility rather than the animals' owner. These provisions are found in § 79.2(a)(1)(ii) and § 79.2(a)(3) of the current regulations and appear in the regulatory text at the end of this proposed rule as § 79.2(a)(1)(ii) and § 79.3(a)(5). In both cases the livestock facility may apply the official identification if it has agreed to act as an agent for the owner to apply official identification, and has the necessary information and keeps the necessary records about the animals to correctly apply the identification, and does so before the animals are commingled with any other, unidentified animals at the facility. We seek comments on whether this provision is effective as written, or whether it should be eliminated (thereby making it a violation of the regulations to unload unidentified animals at an approved market) or amended, e.g., to require the owner of the animals to maintain the records and provide the livestock facility with the required identification tags for the market personnel to apply.

In addition to the proposed changes affecting animal identification in § 54.8, we propose to make minor changes to paragraph § 54.8(e), which requires the owner of a flock under a flock plan or PEMMP to meet requirements, including but not limited to those listed in that paragraph,

to monitor for scrapie and to prevent the recurrence or spread of scrapie in the flock. We propose to add that owners must report animals found dead and collect and submit test samples from them if an APHIS or State representative requests it. The regulations already assume owners will do this, and the requirement has appeared in the text of flock plans and PEMMPs, but we wish to add it to the regulations to ensure all owners are aware of it. We also propose to add that the owner of a flock under a flock plan or PEMMP must use genetically resistant rams if the DSE determines it is necessary to reduce the risk of the occurrence of scrapie in the flock. The use of such rams has become more common due to increased knowledge of sheep genetics, so we think it is worthwhile to add it to this paragraph as something that may be required in a flock.

We also propose to add a new paragraph (h) to § 54.8 discussing the types of animals that may be retained in a flock under a flock plan or PEMMP. This new paragraph would build on the changes discussed above that resulted from increased understanding of the genetics of scrapie resistance and the use of genetic testing as a means of assigning risk levels to animals. The result of this change would be that certain animals that previous flock plans would have removed from a flock may be allowed to remain in the flock. Proposed new paragraph (h) would read “The Administrator may allow high-risk animals that are not suspect animals to be permanently retained under restriction in the flock if they are not genetically susceptible animals or if they have tested ‘PrPsc not detected’ on a live animal scrapie test approved for this purpose by the Administrator and are maintained in a manner that the Administrator determines minimizes the risk of scrapie transmission, e.g., bred only to genetically resistant sheep, segregated for lambing, and cleaning and disinfection of the lambing area. All such animals must be tested for scrapie

when they are euthanized or die or if they are later determined to be suspect animals. These requirements will be documented in the PEMMP.”

We also propose to add a statement to § 54.8(j), which describes the requirements for flock plans. As discussed above, we added a new definition for low-risk exposed animal that applies to sheep or goats deemed to present significantly lower risks due to the nature of either the exposure or the animal. To adjust the flock plan requirement accordingly, we propose that in individual cases or for a class of cases the Administrator may waive the requirement for a flock plan or waive any of the requirements in a flock plan after determining that the flock contains only low-risk exposed animals and poses a low risk of scrapie transmission. Barring the publication of new data to the contrary, the Administrator intends to waive the requirements of a flock plan and to modify the PEMMP for flocks affected by Nor98-like scrapie.

Changes to Indemnity Provisions in Part 54

The changes discussed above that would provide for the classification of animals based on their genetic susceptibility or resistance to scrapie would likely result in fewer animals being designated as high-risk animals. Most of the animals eligible for indemnity in accordance with § 54.3 are high-risk animals.⁶ We believe it is appropriate to deny indemnity for exposed animals that have been genetically tested and found to be genetically resistant or less susceptible to scrapie. Such animals can generally be moved interstate with only minor restrictions, and sold on the open market for prices similar to those obtained for sheep that have never been exposed to scrapie. It is not appropriate to pay indemnity for animals when their owners have these options.

⁶ Section 54.3(a)(2) also allows indemnity to be paid for other types of animals when the Administrator determines that the destruction of these animals will contribute to the eradication of scrapie.

We also believe it is necessary to clarify what is meant by a statement in current § 54.3(b), “No indemnity will be paid to an owner if the owner assembled or increased his flock for the purpose of collecting or increasing indemnity.” Therefore, we propose several changes to § 54.3. First, we propose to clearly state that no indemnity will be paid for any animal, or the progeny of any animal, that has been moved or handled by the owner in violation of the requirements of 9 CFR chapter I. In line with this, we would also specifically state that no indemnity will be paid for an animal added to the premises while a flock is under investigation or while it is an infected or source flock other than for animals that are natural additions. We also propose that no indemnity will be paid for natural additions born more than 60 days after indemnity is offered in writing unless the Administrator makes a determination that the animals could not be removed within the allowed time as a result of conditions outside the control of the owner.

One current requirement of § 54.3 is that no indemnity shall be paid until the premises, including all structures, holding facilities, conveyances, and materials contaminated because of occupation or use by the depopulated animals, has been properly cleaned and disinfected. In enforcing this provision we have become aware that sometimes circumstances beyond an owner’s control delay the cleaning and disinfection, despite the owner’s best intentions. To alleviate financial hardship in such cases, we propose to amend § 54.3 to state that partial indemnity may be paid when the Administrator determines that weather or other factors outside the control of the owner make immediate disinfection impractical.

In § 54.6, paragraphs (a) and (b) set out procedures for determining what indemnity will be paid for sheep and goats that are eligible for indemnity under § 54.3. Paragraph (a) contains detailed information regarding price reports published by the Agricultural Marketing Service

(AMS) that are used to calculate indemnity for sheep. Paragraph (b) sets out the process by which these price reports are used to determine indemnity for various classes of animals, with premiums paid for certain types of animals, such as registered animals and flock sires.

We are proposing to remove this detailed information from the regulations. The price reports we use as a basis for our indemnity calculations change frequently, as do the terms used in those price reports to refer to various types of sheep and goats. The price reports listed in paragraphs (a)(1) through (a)(6) in § 54.6 are currently out of date, and it would require frequent updates of the regulations to keep them consistent with the AMS data. In addition, the process in paragraph (b) sets out numerous specific weight thresholds and sets out dollar amounts for premiums. If the sheep and goat industries change, making these weight thresholds obsolete or the premiums inadequate to provide a fair indemnity, we must update the regulations.

Rather than use scrapie program resources to continually update § 54.6(a) and (b), we propose to retain only the general statement that indemnity paid for sheep and goats in accordance with § 54.3 will be the fair market value for the animals, based on available price report data that most accurately reflect the type of animal being indemnified and the time at which the animal was indemnified. Paragraph (a) of § 54.6 would also specify that premiums would be paid for certain animals and that APHIS will use AMS price report data or other available price information and any other data necessary to establish the value of different types of sheep and goats in its calculations. We would provide a detailed description of how we calculate indemnity on the scrapie Web site.

This approach would be consistent with some other parts in 9 CFR subchapter B, which provide that indemnity will be provided based on appraisals but do not specify the details of how an appraisal is conducted. For example, 9 CFR part 56, which provides for the payment of

indemnity for poultry affected by low pathogenic avian influenza, states that indemnity will be paid based on appraisals; however, those regulations do not include the details of how appraisals are conducted, and they are typically conducted by use of spreadsheets showing data on inputs and expected prices. Similarly, the scrapie regulations provide for calculation of indemnity based on broad market data, with a few modifications; we believe it is appropriate to state in the regulations that indemnity will be based on those broad market data and provide the details on the scrapie Web site. We invite public comment on this approach.

We would also reorganize and renumber the paragraphs in § 54.6 and make other minor changes to the section to improve its comprehensibility.

As part of this change, we also propose to create a new indemnity classification for certain pregnant animals and early maturing ewes. At sales, animals in late pregnancy bring higher prices than animals that are not pregnant because of the additional value of the offspring they carry. We believe that indemnity prices should reflect this increase in value since indemnity is related to the fair market value of animals. We would also categorize early maturing ewe lambs as yearlings, which typically qualify for a higher indemnity value, because early maturing ewes can be bred at about 7 months and lamb at 12-14 months, increasing their value.

Descriptions of these classifications as we would establish them are available by contacting the person listed under FOR FURTHER INFORMATION CONTACT, on the Regulations.gov Web site, or on the scrapie Web site at <http://www.aphis.usda.gov/animal-health/scrapie>. We invite public comment on these classifications.

Sections 54.3 and 54.5 already require that to obtain indemnity owners must make available to APHIS all bills of sale, pedigree registration certificates, and other records associated with ownership or movement of the animals. We propose to amend § 54.3 to also

state that owners applying for indemnity must, within 30 days of request, make the animals in the flock available for inventory, evaluation, and testing. We propose this change because it is sometimes necessary to have physical access to the animals to confirm their eligibility for indemnity.

Current § 54.6(e) states that indemnity will be paid to an owner only for animals actually in a flock at the time indemnity is first offered. We propose to add that indemnity would be paid for offspring born to animals in that flock within 60 days after the time indemnity is first offered in writing. This change is proposed in response to indemnity situations that have occurred where owners with ewes nearly ready to give birth become eligible for indemnity. We also propose to add several other provisions intended to encourage the prompt removal of animals identified for indemnity, to minimize the risks that might result if these animals remained in a flock for long periods. We propose that if an owner declines to remove an animal within 60 days of when indemnity is first offered in writing the indemnity amount would be reevaluated using current AMS price reports. The owner would then receive the lower value of the indemnities calculated from price reports when indemnity was first offered and when the animal was actually removed. We also propose that APHIS may withdraw an indemnity offer if an owner does not make animals available for inventory, gestational assessment, and testing within 30 days or does not remove an animal within 60 days of the indemnity offer or by the date specified in a flock plan or PEMMP.

We also propose to revise the definition of flock sire in part 54 to ensure that only the appropriate animals receive the indemnity premium applied to flock sires. The current definition reads “a sexually intact male animal that has ever been used for breeding in a flock.” However, this allows a premium to be paid for animals that are too old to breed, or that were once tried as

sires but were found to produce inferior progeny. Such animals no longer have an economic value that justifies an indemnity premium. Therefore, we propose to change the definition of flock sire to read “A sexually intact male animal that has produced offspring in the preceding 12 months or that was used for breeding during the current breeding cycle.”

We believe the changes to parts 54 and 79 discussed above would improve the effectiveness of the scrapie program, reduce the risks associated with moving sheep and goats interstate, reduce some identification and recordkeeping requirements while changing others, and make the scrapie indemnity program more equitable.

Changes Concerning Tests for Scrapie and Laboratories Approved to Perform Tests

We are proposing certain changes to § 54.10, “Tests for scrapie,” and §54.11, “Approval of laboratories to run official scrapie tests and official genotype tests.” The proposed changes are intended to provide more information about APHIS procedures in these matters and to make the testing and laboratory approval processes more reliable, flexible, and market-oriented.

We propose to change the section title of § 54.10 to read “Program approval of tests for scrapie” to clarify that the section concerns how tests are approved, and is not merely a list of tests. We propose to change a sentence that states that specific guidance on the use of approved tests “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.” We would change this to read “will be made available on the scrapie Web site at <http://www.aphis.usda.gov/animal-health/scrapie>.” This change would allow APHIS to respond more quickly to advances in science and in scrapie testing specifically. For major changes to how tests are used within the scrapie program, we would publish a notice in the Federal Register describing the proposed change and solicit public comments on the change. We would then

issue a second notice discussing the comments and informing the public of our decision regarding the change. For the addition of guidance for a new test used for purposes similar to an existing test, or for minor changes, updates, or clarifications, we would post notice of the change prominently on the scrapie Web site. We would also provide email notification to State cooperators and other stakeholders through GovDelivery, a free email subscription service. To subscribe to this free service go to <https://public.govdelivery.com/accounts/USDAAPHIS/subscriber/new> and select “Animal Health - Sheep and Goats” and “Federal Register Publications – Notices Regarding Animal Health.” Proposed procedures for using tests are in the draft National Scrapie Eradication Program Standards. Copies are available by contacting the person listed under FOR FURTHER INFORMATION CONTACT, on the Regulations.gov Web site, or on the Web site at <http://www.aphis.usda.gov/animal-health/scrapie>.

We also propose to add to both § 54.10 and § 54.11 a standard paragraph stating that the Administrator may withdraw or suspend approval of an official test, or approval of a laboratory to perform tests. In both § 54.10, regarding approved tests, and § 54.11, regarding approved laboratories, there would be an opportunity for an appeal to the Administrator to resolve any questions of material fact regarding the withdrawal or suspension. The Administrator’s decision would constitute final agency action.

We propose to add ELISA testing to the definition of scrapie-positive animal as one of the test methods that may be used by NVSL when making an official diagnosis of scrapie. The current definition specifically mentions “proteinase-resistant protein analysis methods including but not limited to immunohistochemistry and/or western blotting.” APHIS is continually

evaluating scrapie test methods for sensitivity, specificity and reliability, and ELISA tests are currently one of the methods used by NVSL.

Changes Affecting Consistent State Requirements and State Surveillance Programs

Surveillance is an important component of the National Scrapie Eradication Program because it identifies infected animals, and successful traceback of these animals to their flocks of origin allows us to identify previously unrecognized infected flocks for cleanup. As the United States progresses toward eradication of scrapie, surveillance is also necessary to measure the effectiveness of control measures and to document when regions achieve freedom from disease as defined by international standards affecting trade in animals and products from the regions.

To support traceback and eradication efforts, we propose to add a requirement that States must implement effective scrapie surveillance in order to qualify as a Consistent State. This requirement would include three components: Facilitating surveillance at slaughter establishments that do not engage in interstate commerce; reporting submission information and test results electronically to the National Scrapie Database administered by APHIS; and testing an appropriate number of targeted animals annually.

The first of these three new requirements would affect surveillance at slaughter establishments. Slaughter surveillance is a major component of the ongoing scrapie surveillance conducted by APHIS. The regulations in 9 CFR 71.21 describe the collection of tissues for surveillance purposes at slaughter establishments that receive livestock in interstate commerce. To achieve the eradication of scrapie, it is important to conduct surveillance in all slaughter establishments that receive targeted animals – including State-inspected and custom establishments that do not participate in interstate commerce. Surveillance at these concentration points, along with traceability of animals, is key to program effectiveness. Therefore, we

propose to provide for scrapie surveillance in slaughter establishments that do not participate in interstate commerce (i.e., State-inspected and custom establishments). We propose to add language in § 79.6(a)(10)(i) requiring States that are Consistent States to collect and submit surveillance samples from targeted animals slaughtered in State-inspected establishments and from slaughter establishments within the State that are not covered under § 71.21. Typically, when sample collection by State personnel is necessary it could be accomplished by State personnel already assigned to such establishments. Alternatively, in places where APHIS has Federal employees or contractors available to collect samples from such plants, the State could instead elect to allow and facilitate the collection of such samples by USDA personnel or contractors. The intent of this proposed requirement is to ensure that surveillance for scrapie consistently occurs in all slaughter establishments that receive targeted animals.

The second new requirement would affect the reporting of surveillance data by States. In order to insure the integrity of surveillance data and to verify that a State is conducting adequate surveillance for scrapie, we propose to add language to § 79.6(a)(10)(ii) requiring that submission data and epidemiological information for all samples be electronically transmitted by accessing and updating a system provided by APHIS. Submission data will be electronically transmitted to an approved laboratory and the epidemiologic and testing data will be stored in the National Scrapie Database, allowing complete reports concerning scrapie surveillance to be generated for each State as well as for the entire United States. This system is currently used to submit information for over 99 percent of the scrapie samples collected for testing.

In the third new surveillance requirement, we propose to determine the appropriate sample size for surveillance within a State using one of two approaches. A State could meet annual State-level surveillance minimums established by APHIS. These minimums will be made

publicly available at <http://www.aphis.usda.gov/animal-health/scrapie>. APHIS may update the surveillance minimums once a year and will provide them to the States at least 6 months before the start of the collection period. These surveillance minimums call for a certain level of activity, including the coordination of sampling and testing of mature sheep at slaughter that have a higher than average probability of being infected with scrapie and surveillance in targeted animals from other sources such as veterinary diagnostic laboratories, public health laboratories, renderers, dead stock haulers, markets, feedlots, and farms. The State-level minimums will be based on the number of targeted animals residing in a State, the occurrence of scrapie in sheep and goats in the State, and other relevant factors such as the percentage of flocks surveyed. States may contact the Administrator within 60 days of publication of their State's surveillance minimum to appeal the surveillance minimum if they believe there was any error in the facts used to establish the minimum. Alternatively, a State could design and implement its own surveillance plan as long as the State demonstrates that the surveillance is sufficient to detect scrapie if it is present at a prevalence of 0.1 percent in the population of targeted animals originating from within the State, with a 95 percent confidence level, each year. This is the level of surveillance currently specified by Article 14.9.2 of the World Animal Health Organization (the OIE) Terrestrial Animal Health Code to determine a scrapie free country or zone. These surveillance requirements for States would be added to § 79.6(a)(10)(iii) and (iv). APHIS intends to continue to provide support to the States in meeting surveillance minimums and to set minimums in line with funds available for surveillance activities. APHIS currently supports surveillance by providing testing for scrapie samples through contracts with State veterinary diagnostic laboratories, sampling contracts, cooperative agreements to support collection activities by States, and collection of samples by APHIS personnel.

Definition of Consistent State

The definition of Consistent State in § 79.1 currently includes criteria for listing a State as a Consistent State and a list of States that meet these criteria. As the definition itself indicates when a State will be listed as a Consistent State, providing the list of Consistent States in the regulations is not necessary. We are proposing to remove the list of Consistent States from this definition and instead indicate that a list of Consistent States can be found on the scrapie Web site. (Currently, all 50 States are listed as Consistent States; we are not proposing to change the list.)

We are also proposing to provide in the regulations a process for updating the list of Consistent States. When we determine that a State should be added to or removed from the list of Consistent States, we would publish a notice in the Federal Register advising the public of our determination and providing the reasons for that determination. The notice would solicit public comments. After considering any comments we receive, we would publish a second notice either advising the public that we are adding or removing the State from the list of Consistent States or notifying the public that we are not making any changes to the list of Consistent States, depending on the information presented in the comments.

Other Changes to Parts 54 and 79

We propose to change § 54.21, “Participation,” which currently states that APHIS makes available a list of flocks participating in the SFCP and another list of flocks that are not in compliance with these regulations. We propose to make available a third list, of flocks that sold exposed animals that could not be traced, which would be of potential risk management use to persons who purchased animals from these flocks.

We propose to add several definitions to part 79 to ensure that readers understand terms used in those regulations. These include owner/hauler statement, person, restricted animal sale or restricted livestock facility, and test eligible. The only one of these terms that may not already be familiar to those affected by the regulations is owner/hauler statement. We propose to define this term, which would replace the current term owner statement, as “A signed written statement by the owner or hauler that includes:

- (1) The name, address, and phone number of the owner and, if different, the hauler;
- (2) The date the animals were moved;
- (3) The flock identification number or PIN assigned to the flock or premises of the animals;
- (4) If moving individually unidentified animals, the group/lot identification number and any information required to officially identify the animals;
- (5) The number of animals;
- (6) The species, breed, and class of animals. If breed is unknown, for sheep the face color and for goats the type (milk, fiber, or meat) must be recorded instead; and
- (7) The name and address of point of origin, if different from the owner’s address, and the destination.”

The changes discussed above, particularly the use of genetic information and testing to improve our ability to categorize animals by risk categories, would allow us to greatly simplify and shorten § 79.3, which describes the basic restrictions on the movement and commingling of regulated sheep and goats. We propose to replace the chart in § 79.3 with a simpler, less repetitive format that preserves the movement restrictions but describes them using the improved animal category definitions and terms proposed in this document.

We are also proposing to revise § 79.5 (retitled Issuance of Interstate Certificates of Veterinary Inspection (ICVI)) to replace the term “certificates” with reference to ICVIs for consistency with other areas of the regulations. Section 79.5 would also revise the information that must be contained in a certificate now termed an ICVI. In addition, we are revising the section to make the requirements and terms in it match those proposed elsewhere in this document and, to the degree appropriate, those in 9 CFR part 86 (Animal Disease Traceability) e.g., by changing "premises identification" to "flock identification number." In support of this proposal's goal of using available genetic information to better characterize risks, we would also add a statement in paragraph (a) that, if any animals covered by a ICVI are intended for breeding and have undergone an official genotype test, the name of the testing laboratory and the date and result of the test must be included.

Miscellaneous Changes

We are also proposing to make miscellaneous changes, particularly in the definitions sections of parts 54 and 79, and in the description of cleaning and disinfection of premises in § 54.7, to make terminology and citations consistent throughout the regulations. We are changing the definitions of several terms to make them consistent with the definitions in new animal disease traceability regulations in 9 CFR part 86. In § 54.7, we propose to expand the brief description of cleaning and disinfection procedures to include more information about burial and composting options for organic and/or inorganic materials. We also propose minor changes throughout the regulations to consistently use the term “identification devices” instead of referring to “devices” in some sections and “tags” in others, to correct outdated Internet addresses, and to otherwise improve accuracy and readability.

Executive Orders 12866 and 13563 and Regulatory Flexibility Act

This proposed 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.

We have prepared an economic analysis for this rule. The economic analysis provides a cost-benefit analysis, as required by Executive Orders 12866 and 13563, which direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. The economic analysis also provides an initial regulatory flexibility analysis that examines the potential economic effects of this rule on small entities, as required by the Regulatory Flexibility Act. The economic analysis is summarized below. Copies of the full analysis are available by contacting the person listed under FOR FURTHER INFORMATION CONTACT or on the Regulations.gov Web site (see ADDRESSES above for instructions for accessing Regulations.gov).

Based on the information we have, there is no reason to conclude that adoption of this proposed rule would result in any significant economic effect on a substantial number of small entities. However, we do not currently have all of the data necessary for a comprehensive analysis of the effects of this proposed rule on small entities. Therefore, we are inviting comments on potential effects. In particular, we are interested in determining the number and kind of small entities that may incur benefits or costs from the implementation of this proposed rule.

APHIS is proposing to amend the scrapie regulations to relieve certain restrictions associated with the interstate movement of sheep and goats, reduce the number of exposed sheep

and goats that are destroyed, and improve overall program effectiveness. More specifically, genetic testing would be used to identify genetically resistant or less susceptible sheep for exemption from destruction and as qualifying for interstate movement; designated scrapie epidemiologists would be given greater flexibility in determining the testing needs of flocks; the indemnity regulations would be changed to apply only to those animals that are found to be genetically susceptible to scrapie; official identification of goats produced for meat or fiber would be required; submission of tagging records by individuals who tag sheep or goats that do not originate on their premises would be required; and certain recordkeeping requirements would be reduced, changed or removed.

The primary benefits of this proposed rule for producers and the public would be more rapid progress toward scrapie eradication and the related boost to the Nation's animal health status, decreased losses for owners of exposed herds, and increased export opportunities for sheep and goats and their products. All segments and marketing channels of the sheep and goat industries would benefit from being able to operate under fewer restrictions while still complying with the scrapie eradication program. By enhancing traceability, the proposed rule would shorten the time and reduce the cost of eradication.

Costs associated with the proposed rule would be borne by APHIS and the regulated industry. APHIS would incur the costs of genotyping exposed sheep and testing genetically susceptible animals for scrapie. The total laboratory cost to APHIS for testing an average-sized exposed flock is estimated to be around \$610. This Federal cost may be largely offset by a reduction in indemnity payments; genotyping is expected to result in the destruction of fewer animals.

Producers of goats for meat or fiber would incur costs of official identification as a result of the proposed rule. However, close to one-half of the goat farms reported in the 2012 Census of Agriculture are already in compliance with the proposed identification requirements.

The proposed rule would affect sheep and goat producers, as well as marketers and dealers. Most of these entities are small. However, in that costs of genotyping, testing, and provision of eartags would be borne by the Federal Government, we do not believe this rule would pose a significant cost burden for producers.

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 2 CFR chapter IV)

Executive Order 12988

This proposed rule has been reviewed under Executive Order 12988, Civil Justice Reform. If this proposed rule is adopted: (1) All State and local laws and regulations that are in conflict with this rule will be preempted; (2) no retroactive effect will be given to this rule; and (3) administrative proceedings will not be required before parties may file suit in court challenging this rule.

Executive Order 13175

This rule has been reviewed in accordance with the requirements of Executive Order 13175, Consultation and Coordination with Indian Tribal Governments. The review reveals that this rule will not have substantial and direct effects on Tribal governments and will not have significant Tribal implications.

As part of this review, APHIS sent letters to Tribal leaders describing the proposed rule, asking the leaders to consider and inform us of any potential impacts or possible outcomes for their tribes, and offering further discussion or consultation if desired. No Tribe identified issues of concern or requested further consultation. We believe that the issue in this proposed rule that is of most potential concern to Tribes is animal identification and traceability. That issue has been addressed in a previous proposed rule concerning traceability for livestock moving interstate (Docket No. APHIS–2009–0091, 76 FR 50082, published August 11, 2011). The Tribal summary impact statement for that proposed rule is available at <http://www.regulations.gov/#!documentDetail;D=APHIS-2009-0091-0474>.

Paperwork Reduction Act

In accordance with section 3507(d) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.), the information collection or recordkeeping requirements included in this proposed rule have been submitted for approval to the Office of Management and Budget (OMB). Please send written comments to the Office of Information and Regulatory Affairs, OMB, Attention: Desk Officer for APHIS, Washington, DC 20503. Please state that your comments refer to Docket No. APHIS-2007-0127. Please send a copy of your comments to: (1) Docket No. APHIS-2007-0127, Regulatory Analysis and Development, PPD, APHIS, Station 3A-03.8, 4700 River Road Unit 118, Riverdale, MD 20737-1238, and (2) Clearance Officer, OCIO, USDA, room 404-W, 14th Street and Independence Avenue SW., Washington, DC 20250. A comment to OMB is best assured of having its full effect if OMB receives it within 30 days of publication of this proposed rule.

Implementing the requirements of the proposed rule would change information collection and recordkeeping burden for persons such as animal market operators, dealers, accredited

veterinarians, tag manufacturers, flock owners, haulers, State officials, terminal feedlot owners, laboratories, test kit manufacturers, slaughter plant/establishment owners, and other persons who apply official identification to sheep and goats. These changes will primarily affect persons who own or handle goats in interstate commerce. Some of this information would be entered in the Scrapie National Database, and persons who apply official identification for animal owners such as livestock markets would have the option of entering the information through a website into the Scrapie National Database or completing and submitting a form. These changes would also eliminate requirements to record individual identification numbers for certain classes of sheep and goats.

We are soliciting comments from the public (as well as affected agencies) concerning our proposed information collection and recordkeeping requirements. These comments will help us:

(1) Evaluate whether the proposed information collection is necessary for the proper performance of our agency's functions, including whether the information will have practical utility;

(2) Evaluate the accuracy of our estimate of the burden of the proposed information collection, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the information collection on those who are to respond (such as through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology; e.g., permitting electronic submission of responses).

Estimate of burden: Public reporting burden for this collection of information is estimated to average 0.24 hours per response.

Respondents: Market operators, dealers, accredited veterinarians, tag manufacturers, flock owners, haulers, State officials, terminal feedlot owners, laboratories, test kit manufacturers, slaughter plant/establishment owners, and other persons who apply official identification to sheep and goats.

Estimated annual number of respondents: 157,053.

Estimated annual number of responses per respondent: 2.89.

Estimated annual number of responses: 454,061.

Estimated total annual burden on respondents: 108,981 hours. (Due to averaging, the total annual burden hours may not equal the product of the annual number of responses multiplied by the reporting burden per response.)

Copies of this information collection can be obtained from Ms. Kimberly Hardy, APHIS' Information Collection Coordinator, at (301) 851-2727.

E-Government Act Compliance

The Animal and Plant Health Inspection Service is committed to compliance with the E-Government Act to promote the use of the Internet and other information technologies, to provide increased opportunities for citizen access to Government information and services, and for other purposes. For information pertinent to E-Government Act compliance related to this proposed rule, please contact Ms. Kimberly Hardy, APHIS' Information Collection Coordinator, at (301) 851-2727.

List of Subjects

9 CFR Part 54

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

9 CFR Part 79

Animal diseases, Quarantine, Sheep, Transportation.

Accordingly, we are proposing to amend 9 CFR parts 54 and 79 as follows:

PART 54--CONTROL OF SCRAPIE

1. The authority citation for part 54 continues to read as follows:

Authority: 7 U.S.C. 8301-8317; 7 CFR 2.22, 2.80, and 371.4.

2. Section 54.1 is amended as follows:

- a. Revise the heading of the definition for approved test to read program approved test and place in alphabetical order.
- b. In the definition for breed association and registries, by removing the words “listed in § 151.9 of this chapter”.
- c. Removing the definition for certificate.
- d. Adding a definition for classification or reclassification investigation.
- e. In the heading of the definition for designated scrapie epidemiologist, add the acronym “DSE” immediately after “epidemiologist”.
- f. Revising the definitions for destroyed, exposed animal, and exposed flock.
- g. In the definition for flock, paragraph (2)(v), by adding the word “Free” between the words “Scrapie” and “Flock”.
- h. In the definition for flock plan, last sentence, by removing “(f)” and by adding “(j)” in its place.
- i. Revising the definition for flock sire.

j. Adding definitions for flock under investigation, genetically less susceptible exposed sheep, genetically resistant exposed sheep, genetically resistant sheep, genetically susceptible animal, and genetically susceptible exposed animal.

k. Revising the definition for high-risk animal.

l. Adding a definition for interstate certificate of veterinary inspection (ICVI).

m. In the definition for limited contacts, last sentence, by adding the word “Free” between the words “Scrapie” and “Flock”.

n. Adding a definition for low-risk exposed animal.

o. In the definition for National Scrapie Database, by adding the word “Free” between the words “Scrapie” and “Flock”.

p. The definition for noncompliant flock is amended as follows:

i. In paragraph (1), by removing the words “source or infected flock” and adding the words “source, infected, or exposed flock or flock under investigation”;

ii. In paragraph (2), by adding the words “or flock under investigation” immediately after the words “exposed flock”; and

iii. In paragraph (3), by removing the words “owner statement” and adding the words “owner/hauler statement” in their place.

q. Revising the definition for official genotype test.

r. Adding a definition for restricted animal sale or restricted livestock facility.

s. In the heading of the definition for Scrapie Flock Certification Program (SFCP), by adding the word “Free” immediately after the word “Scrapie”.

t. In the heading of the definition for Scrapie Flock Certification Program standards, by adding the word “Free” immediately after the word “Scrapie” and, in footnote 2, by removing

the Internet address “http://www.aphis.usda.gov/vs/scrapie” and adding the Internet address “www.aphis.usda.gov/animal-health/scrapie” in its place.

u. In the definition for scrapie-positive animal, in paragraph (2), by adding the words “, and/or ELISA,” immediately after the word “immunohistochemistry” and, in paragraph (5), by removing the words “test method” and adding the words “method or combination of methods” in their place.

v. By removing the definitions for separate contemporary lambing group.

w. Revising the definition for slaughter channels and paragraph (1) in the definition of suspect animal.

x. Adding definitions for tamper-resistant sampling kit and terminal feedlot.

The additions and revisions read as follows:

§ 54.1 Definitions.

* * * * *

Classification or reclassification investigation. An epidemiological investigation conducted or directed by a DSE for the purpose of designating or redesignating the status of a flock or animal. In conducting such an investigation, the DSE will evaluate the available records for flocks and individual animals and conduct or direct any testing needed to assess the status of a flock or animal. The status of an animal or flock will be determined based on the applicable definitions in this section and, when needed to make a designation under § 79.4 of this chapter, official genotype test results, exposure risk, scrapie type involved, and/or results of official scrapie testing on live or dead animals

* * * * *

Destroyed. Euthanized and the carcass disposed of by means authorized by the Administrator that will prevent its use as feed or food, or moved to a quarantined research facility if the movement has been approved by the Administrator.

* * * * *

Exposed animal. Any animal or embryo that has been in a flock or in an enclosure off the premises of the flock with a scrapie-positive female animal; resides in a noncompliant flock; or has resided on the premises of a flock before or while it was designated an infected or source flock and before a flock plan was completed. An animal shall not be designated an exposed animal if it only resided on the premises before the date that infection was most likely introduced to the premises as determined by a Federal or State representative. If the probable date of infection cannot be determined based on the epidemiologic investigation, a date 2 years before the birth of the oldest scrapie-positive animal(s) will be used. If the actual birth date is unknown, the date of birth will be estimated based on examination of the teeth and any available records. If an age estimate cannot be made, the animal will be assumed to have been 48 months of age on the date samples were collected for scrapie diagnosis. Exposed animals will be further designated as genetically resistant exposed sheep, genetically less susceptible exposed sheep, genetically susceptible exposed animals, or low-risk exposed animals. An animal will no longer be an exposed animal if it is redesignated in accordance with § 79.4 of this chapter.

Exposed flock. (1) Any flock that was designated an infected or source flock that has completed a flock plan and that retained a female genetically susceptible exposed animal;

(2) Any flock under investigation that retains a female genetically susceptible exposed animal or a suspect animal, or whose owner declines to complete genotyping and live-animal

and/or post-mortem scrapie testing required by the APHIS or State representative investigating the flock; or

(3) Any noncompliant flock or any flock for which a PEMMP is required that is not in compliance with the conditions of the PEMMP. A flock will no longer be an exposed flock if it is redesignated in accordance with § 79.4 of this chapter.

* * * * *

Flock sire. A sexually intact male animal that has produced offspring in the preceding 12 months or that was used for breeding during the current breeding cycle.

Flock under investigation. Any flock in which an APHIS or State representative has determined that a scrapie-suspect animal, high-risk animal, or scrapie-positive animal resides or may have resided. A flock will no longer be a flock under investigation if it is redesignated in accordance with § 79.4 of this chapter.

Genetically less susceptible exposed sheep. Any sheep or sheep embryo that is:

(1) An exposed sheep or sheep embryo of genotype AA QR, unless it is epidemiologically linked to a scrapie-positive RR or AA QR sheep or to a scrapie type to which AA QR sheep are not less susceptible where Q represents any genotype other than R at codon 171; or

(2) An exposed sheep or sheep embryo of genotype AV QR, unless it is epidemiologically linked to a scrapie-positive RR or QR sheep, to a flock that the DSE has determined may be affected by valine associated scrapie (based on an evaluation of the genotypes of the scrapie-positive animals linked to the flock), or to another scrapie type to which AV QR sheep are not less susceptible where Q represents any genotype other than R at codon 171 and V represents any genotype other than A at codon 136; or

(3) An exposed sheep or sheep embryo of a genotype that has been exposed to a scrapie type to which the Administrator has determined that genotype is less susceptible.

Genetically resistant exposed sheep. Any exposed sheep or sheep embryo of genotype RR unless it is epidemiologically linked to a scrapie-positive RR sheep or to a scrapie type to which RR sheep are not resistant.

Genetically resistant sheep. Any sheep or sheep embryo of genotype RR unless it is epidemiologically linked to a scrapie-positive RR sheep or to a scrapie type that affects RR sheep.

Genetically susceptible animal. Any goat or goat embryo, sheep or sheep embryo of a genotype other than RR or QR, or sheep or sheep embryo of undetermined genotype where Q represents any genotype other than R at codon 171.

Genetically susceptible exposed animal. Excluding low-risk exposed animals, any exposed animal or embryo that is also:

- (1) A genetically susceptible animal; or
- (2) A sheep or sheep embryo of genotype AV QR that is epidemiologically linked to a scrapie-positive RR or QR sheep, to a flock that the DSE has determined may be affected by valine associated scrapie (based on an evaluation of the genotypes of the scrapie-positive animals linked to the flock), or to a scrapie type to which AV QR sheep are susceptible where Q represents any genotype other than R at codon 171 and V represents any genotype other than A at codon 136; or
- (3) A sheep or sheep embryo of genotype AA QR that is epidemiologically linked to a scrapie-positive RR or AA QR sheep or to a scrapie type to which AA QR sheep are susceptible where Q represents any genotype other than R at codon 171; or

(4) A sheep or sheep embryo of genotype RR that is epidemiologically linked to a scrapie-positive RR sheep or to a scrapie type to which RR sheep are susceptible.

High-risk animal. The female offspring or embryo of a scrapie-positive female animal, or any suspect animal, or a female genetically susceptible exposed animal, or any exposed animal that the Administrator determines to be a potential risk based on the scrapie type, the epidemiology of the flock or flocks with which it is epidemiologically linked, including genetics of the positive sheep, the prevalence of scrapie in the flock, any history of recurrent infection, and other flock characteristics. An animal will no longer be a high-risk animal if it is redesignated in accordance with § 79.4 of this chapter.

* * * * *

Interstate certificate of veterinary inspection (ICVI). An official document issued by a Federal, State, Tribal, or accredited veterinarian certifying the inspection of animals in preparation for interstate movement or other uses as described in this part and in accordance with § 79.5 of this chapter.

* * * * *

Low-risk exposed animal. Any exposed animal to which the DSE has determined one or more of the following applies:

(1) The positive animal that was the source of exposure was not born in the flock and did not lamb in the flock or in an enclosure where the exposed animal resided;

(2) The Administrator and State representative concur that the animal is unlikely to be infected due to factors such as, but not limited to, where the animal resided or the time period the animal resided in the flock;

(3) The exposed animal is male and was not born in an infected or source flock;

(4) The exposed animal is a castrated male;

(5) The exposed animal is an embryo of a genetically resistant exposed sheep or a genetically less susceptible exposed sheep unless placed in a recipient that was a genetically susceptible exposed animal; or

(6) The animal was exposed to a scrapie type and/or is of a genotype that the Administrator has determined poses low risk of scrapie transmission.

* * * * *

Official genotype test. A test to determine the genotype of a live or dead animal conducted at either the National Veterinary Services Laboratories or at an approved laboratory. The test subject must be an animal that is officially identified and the test accurately recorded on an official form supplied or approved by APHIS, with the samples collected and shipped to the laboratory using a shipping method specified by the laboratory by:

(1) An accredited veterinarian;

(2) A State or APHIS representative; or

(3) The animal's owner or owner's agent, using a tamper-resistant sampling kit approved by APHIS for this purpose.

* * * * *

Restricted animal sale or restricted livestock facility. A sale where any animals in slaughter channels are maintained separate from other animals not in slaughter channels and are sold in lots that consist entirely of animals sold for slaughter only or a livestock facility at which all animals are in slaughter channels and where the sale or facility manager maintains a copy of, or maintains a record of, the information from, the owner/hauler statement for all animals

entering and leaving the sale or facility. A restricted animal sale may be held at a livestock facility that is not restricted.

* * * * *

Slaughter channels. Animals in slaughter channels include any animal that is sold, transferred, or moved either directly to or through a restricted animal sale or restricted livestock facility to a slaughter establishment that is under continuous inspection by the Food Safety and Inspection Service (FSIS) or under State inspection that FSIS has recognized as at least equal to Federal inspection or to a custom exempt slaughter establishment as defined by FSIS for immediate slaughter or to an individual for immediate slaughter for personal use or to a terminal feedlot. Any animal sold at an unrestricted sale is not in slaughter channels. Animals in slaughter channels must be accompanied by an owner/hauler statement completed in accordance with § 79.3(g) of this chapter. Animals in slaughter channels may not be held in the same enclosure with sexually intact animals from another flock of origin that are not in slaughter channels. When selling animals that do not meet the requirements to move as breeding animals, owners must note on the bill of sale that the animals are sold only for slaughter.

* * * * *

Suspect animal. * * *

(1) A mature sheep or goat as evidenced by eruption of the first incisor that has been condemned by FSIS or a State inspection authority for central nervous system (CNS) signs, or that exhibits any of the following clinical signs of scrapie and has been determined to be suspicious for scrapie by an accredited veterinarian or a State or USDA representative, based on one or more of the following signs and the severity of the signs: Weakness of any kind including, but not limited to, stumbling, falling down, or having difficulty rising, not including those with

visible traumatic injuries and no other signs of scrapie; behavioral abnormalities; significant weight loss despite retention of appetite or in an animal with adequate dentition; increased sensitivity to noise and sudden movement; tremors; star gazing; head pressing; bilateral gait abnormalities such as but not limited to incoordination, ataxia, high stepping gait of forelimbs, bunny-hop movement of rear legs, or swaying of back end, but not including abnormalities involving only one leg or one front and one back leg; repeated intense rubbing with bare areas or damaged wool in similar locations on both sides of the animal's body or, if on the head, both sides of the poll; abraded, rough, thickened, or hyperpigmented areas of skin in areas of wool/hair loss in similar locations on both sides of the animal's body or, if on the head, both sides of the poll; or other signs of CNS disease. An animal will no longer be a suspect animal if it is redesignated in accordance with § 79.4 of this chapter.

* * * * *

Tamper-resistant sampling kit. A device or method for collecting DNA samples from sheep or goats that is approved by the Administrator and that identifies both the sample and the animal at the time the sample is collected. These devices or methods must ensure that the sample, its corresponding label, and the official ID device or method applied to the animal meets the requirements of § 79.2(k) of this chapter and that the sample is from the same animal to which the official ID device or method was applied. The kit must include an APHIS-approved official form or another form, device, or method acceptable to APHIS for transmitting the information required to APHIS and the approved laboratory.

Terminal feedlot. (1) A dry lot approved by a State or APHIS representative or an accredited veterinarian who is authorized to perform this function where animals in the terminal feedlot 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 must be cleaned of all organic material prior to being used to contain sheep or goats that are not in slaughter channels, where only castrated males are maintained with female animals and from which animals are moved only to another terminal feedlot or directly to slaughter; or

(2) A dry lot approved by a State or APHIS representative or an accredited veterinarian authorized to perform this function where only animals that either are not pregnant based on the animal being male, an owner certification that any female animals have not been exposed to a male in the preceding 6 months, an ICVI issued by an accredited veterinarian stating the animals are open, or the animals are under 6 months of age at time of receipt, where only castrated males are maintained with female animals, and all animals in the terminal feedlot are separated from all other animals such that physical contact cannot occur and from which animals are moved only to another terminal feedlot or directly to slaughter; or

(3) A pasture when approved by and maintained under the supervision of the State and in which only nonpregnant animals are permitted based on the animal being male, an owner certification that any female animals have not been exposed to a male in the preceding 6 months, or an ICVI issued by an accredited veterinarian stating the animals are open, or the animals are under 6 months of age at time of receipt, where only castrated males are maintained with female animals, 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.

(4) Records of all animals entering and leaving a terminal feedlot must be maintained for 5 years after the animal leaves the feedlot and must meet the requirements of § 79.2 of this chapter, including either a copy of the required owner/hauler statements for animals entering and

leaving the facility or the information required to be on the statements. Records must be made available for inspection and copying by an APHIS or State representative upon request.

* * * * *

§ 54.2 [Amended]

3. Section 54.2 is amended by adding the word “Free” between the words “Scrapie” and “Flock” each time they appear.

4. In § 54.3, paragraph (b) is revised to read as follows:

§ 54.3 Animals eligible for indemnity payments.

* * * * *

(b) USDA may withdraw an offer of indemnity if the owner of the animal fails to, within 30 days of request, make the animals in the flock available for inventory, evaluation, and testing or to provide APHIS animal registration certificates, sale and movement records, or other records requested in accordance with § 54.5. No indemnity will be paid for any animal, or the progeny of any animal, that has been moved or handled by the owner in violation of the requirements of the Animal Health Protection Act or the regulations promulgated thereunder. No indemnity will be paid for an animal added to the premises while a flock is under investigation or while it is an infected or source flock other than natural additions. No indemnity will be paid for natural additions born more than 60 days after the owner is notified they are eligible for indemnity unless the Administrator makes a determination that the dam could not be removed within the allowed time as a result of conditions outside the control of the owner. No indemnity will be paid unless the owner has signed and is in compliance with the requirements of a flock plan or post-exposure management and monitoring plan (PEMMP) as described in § 54.8. 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); Except that, partial indemnity may be paid when the Administrator determines that weather or other factors outside the control of the owner make immediate disinfection impractical. 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 established or increased his flock for the purpose of collecting or increasing indemnity.

5. In § 54.4, paragraph (a)(5) is revised to read as follows:

§ 54.4 Application by owners for indemnity payments.

(a) * * *

(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); and

* * * * *

§ 54.5 [Amended]

6. In § 54.5, paragraph (d) is amended by removing the word “slaughtered,”.

7. Section 54.6 is revised to read as follows:

§ 54.6 Amount of indemnity payments.

(a) Indemnity. Indemnity paid for sheep and goats in accordance with § 54.3 will be the fair market value of the animals. APHIS' determination of fair market value will be based on available price report data that most accurately reflect the type of animal being indemnified and the time at which the animal was indemnified. Premiums will be paid for certain types of sheep and goats, including, but not limited to: Registered animals, flock sires, pregnant animals and early-maturing ewes; Except that, no premium will be added for animals of any age that were in slaughter channels when indemnity was offered. To calculate indemnity, APHIS will use price information provided by the Agricultural Marketing Service (AMS) or other available price information and any other data necessary to establish the value of different types of sheep and goats. A detailed description of the methods APHIS uses to calculate indemnity for sheep and goats is available at <http://www.aphis.usda.gov/animal-health/scrapie>.

(b) Age and number of animals. 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.

(c) Animal weights. If the owner disagrees with the average weight estimate, he may have the animals weighed at a public scale at his own expense, provided that the animals 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 price per pound for the class of animal as reported in the appropriate price report or other available price information.

(d) Eligibility for indemnity. Indemnity will be paid to an owner only for animals actually in a flock at the time indemnity is first offered in writing, and for offspring born to animals in that flock within 60 days after the time indemnity is first offered in writing. Animals removed from the flock as part of an investigation or a post-exposure management and monitoring plan (PEMMP) will be paid indemnity based on the calculated prices at the time an APHIS representative designates, in writing, the animals for removal. If an owner declines to remove an animal within 60 days of when indemnity is first offered the owner will receive the lower value of when indemnity was first offered in writing or when the animal was actually removed. APHIS may withdraw an indemnity offer if an owner does not make animals available for inventory, gestational assessment, and testing within 30 days or does not remove an animal within 60 days of the written indemnity offer or by the date specified in a flock plan or PEMMP.

8. Section 54.7 is amended as follows:

a. By revising paragraphs (a) and (d).

b. In paragraph (e) introductory text, by removing the words “Scrapie Flock Certification Program standards and the Scrapie Eradication Uniform Methods and Rules” and adding in their place “Scrapie Program Standards Volume 1: National Scrapie Eradication Program and Scrapie Program Standards Volume 2: Scrapie Free Flock Certification Program (SFCP)”.

c. In paragraph (e)(1), by removing the words “animals or wildlife” and adding in their place the words “or wild ruminants”.

d. By revising paragraph (e)(2) introductory text.

e. By removing paragraph (e)(2)(i), redesignating paragraphs (e)(2)(ii) and (iii) as paragraphs (e)(2)(i) and (ii), respectively, and by adding new paragraphs (e)(2)(iii) and (iv).

The additions and revisions read as follows:

§ 54.7 Procedures for destruction of animals.

(a) 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.

* * * * *

(d) APHIS may pay the reasonable costs of disposal for 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. For reimbursement to be made, the owner of the animals must present the Veterinary Services, Surveillance Preparedness and Response Services, Assistant Director responsible for the State involved 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) * * *

(2) Cement, wood, metal and other non-earth surfaces, tools, equipment, instruments, feed, hay, bedding, and other materials. Organic and/or inorganic materials may be disposed of by incineration or burial. Inorganic material and wood structures may be cleaned and disinfected. To disinfect, remove all organic material and incinerate, bury, till under, or compost the removed organic material in areas not accessed by domestic or wild ruminants until it can be

incinerated, buried, or tilled under. 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 one of the following methods:

* * * * *

(iii) Use a product registered by the U.S. Environmental Protection Agency (EPA) specifically for reduction of prion infectivity at these sites in accordance with the label.

(iv) Use a product in accordance with an emergency exemption issued by the EPA for reduction of prion infectivity at these sites.

9. Section 54.8 is revised to read as follows:

§ 54.8 Requirements for flocks under investigation and flocks subject to flock plans and post-exposure management and monitoring plans.

(a) Identification of animals in a flock under investigation, flock plan, or post-exposure management and monitoring plan (PEMMP). 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. APHIS may specify the type of official identification that may be used in order to maximize retention of the means of identification, identify restricted or test positive animals or to facilitate the testing or inventory of the animals.

The owner of the flock or his or her agent must officially identify and maintain the identity of:

(1) All animals in the flock while it is subject to a flock plan or PEMMP;

(2) Any high-risk or genetically susceptible exposed animals in the flock and any other restricted animals;

(3) Any animals designated for testing by an APHIS representative or State representative until testing is completed, results reported, and animals classified, and

(4) All sexually intact animals, all exposed animals, and animals 18 months of age and older (as evidenced by the eruption of the second incisor) prior to a change in ownership and before they are moved off the premises of the flock.

(b) Records for flocks under a flock plan or PEMMP. The flock owner must maintain the following records for 5 years or until the flock plan and/or PEMMP is completed, whichever is longer.

(1) For acquired animals, the date of acquisition, name and address of the person from whom the animal was acquired, any identifying marks, or identification devices present on the animal including but not limited to the animal's individual official identification number(s) from its electronic implant, flank tattoo, ear tattoo, tamper-resistant eartag, or, in the case of goats, tail fold tattoo, and any secondary form of identification the owner of the flock may choose to maintain and the records required by § 79.2 of this chapter.

(2) For animals leaving the premises of the flock, the disposition of the animal, including, any identifying marks or identification devices present on the animal, including but not limited to the animal's individual official identification number from its electronic implant, flank tattoo, ear tattoo, tamper-resistant eartag, 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 and the records required by § 79.2 of this chapter.

(c) Upon request by a State or APHIS representative or as required in a PEMMP, 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 or collect and submit samples by another method acceptable to APHIS.

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

(e) The owner of the flock or his or her agent must meet requirements found necessary by a DSE 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; reporting animals found dead and collecting and submitting test samples from them; restrictions on the animals that may be moved from the flock; use of genetically resistant rams; 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.

(f) 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; ensure that samples are properly collected for testing if the animal dies; allow the animals to be tested, 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; wool loss; 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; rubbing, 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.

(g) 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 except as provided in paragraph (h) of this section. The animals must be removed either by movement to an approved research facility or by euthanasia and disposal of the carcasses by burial, incineration, or other methods approved by the Administrator and in accordance with local, State, and Federal laws, or upon request in individual cases by another means determined by the Administrator to be sufficient to prevent the spread of scrapie;

(h) The Administrator may allow high-risk animals that are not suspect animals to be retained under restriction if they are not genetically susceptible animals or if they have tested “PrPsc not detected” on a live animal scrapie test approved for this purpose by the Administrator and are maintained in a manner that the Administrator determines minimizes the risk of scrapie transmission, e.g., bred only to genetically resistant sheep, segregated for lambing, and cleaning and disinfection of the lambing area. All such animals must be tested for scrapie when they are euthanized or die or if they are later determined to be suspect animals. These requirements will be documented in the PEMMP.

(i) The owner of the flock, or his or her agent, must request breed associations and registries, livestock facilities, 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;

(j) Requirement for flock plans only. The flock plan will include a description of the types of animals that must be removed from a flock, the timeframes in which they must be

removed and any other actions that must be accomplished in order for the flock plan to be completed. Flock plans shall require an owner to agree to:

(1) Clean and disinfect the premises in accordance with § 54.7(e). Premises or portions of premises may be exempted from the cleaning and disinfecting requirements if a designated scrapie epidemiologist determines, based on an 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 confined area where a scrapie-positive animal was born, lambled or aborted may be exempted;

(2) Agree to conduct a post-exposure management and monitoring plan (PEMMP); and

(3) Comply with any other conditions in the flock plan; Provided that, the Administrator may waive the requirement for a flock plan or PEMMP or waive any of the requirements in a flock plan or PEMMP after determining that the flock poses a low risk of scrapie transmission.

(k) Post-exposure management and monitoring plans for exposed flocks and flocks under investigation that were not source or infected flocks. A PEMMP will be required for exposed flocks and may be required for flocks under investigation. A PEMMP may also be required for flocks that formerly were exposed flocks or flocks under investigation as a condition for being redesignated. A designated scrapie epidemiologist shall determine when to require a PEMMP and the monitoring requirements for these flocks based on the findings of the classification or reclassification investigation.

10. Section 54.10 is revised to read as follows:

§ 54.10 Program approval of tests for scrapie.

(a) The Administrator may approve new tests or test methods for the diagnosis of scrapie conducted on live or dead animals for use in the Scrapie Eradication Program and/or the Scrapie Free Flock Certification 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 repeatability, that is, the ability to reproduce the same result repeatedly on a given sample;

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

(4) Data to support the diagnostic and in the case of assays the analytical sensitivity and specificity of the test; and

(5) Any other data or information requested by the Administrator to determine the suitability of the test for program use. This may include but is not limited to past performance, cost of test materials and equipment, ease of test performance, generation of waste, and potential use of existing equipment.

(b) To be approved for program use, a scrapie test must be able to be readily and successfully performed at the National Veterinary Services Laboratories.

(c) The test must have a reliable, timely, and cost effective method of proficiency testing.

(d) The Administrator may decline to evaluate any test kit for program approval that has not been licensed for the intended use and may decline to evaluate any test or test method for

program use unless the requester can demonstrate that the new method offers a significant advantage over currently approved methods.

(e) A test or combination of tests may be approved for the identification of suspect animals, or 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 demonstrate a diagnostic specificity comparable to that of current program-approved tests, and the sensitivity of the test will also be considered in determining the approved uses of the test within the program. For a test to be approved for the removal of high-risk, exposed, or suspect animal designations the test must have a diagnostic sensitivity at least comparable to that of current program-approved tests used for this purpose. Since the purpose of a screening test is usually to identify a subset of animals for further testing, for a test to be approved as a screening test for the identification of suspect animals, the test must be usually reliable but need not be definitive for diagnosing scrapie.

(f) Specific guidelines for use of program-approved tests within the Scrapie Eradication Program or Scrapie Free Flock Certification Program will be made available on the scrapie Web site at <http://www.aphis.usda.gov/animal-health/scrapie>. Guidelines will be based on the characteristics of the test, including specificity, sensitivity, and predictive value in defined groups of animals.

(g) 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 the test is conducted as part of a research protocol and the protocol includes appropriate measures to prevent the spread of scrapie.

(h) The Administrator may withdraw or suspend approval of any test or test method if the test or method does not perform at an acceptable level following approval or if a more effective test or test method is subsequently approved. The Administrator shall give written notice of the suspension or proposed withdrawal to the director of the laboratories using the test or method or in the case of test kits to the manufacturer and shall give the director or manufacturer an opportunity to respond. Such action shall become effective upon oral or written notification, whichever is earlier, to the laboratory or manufacturer. If there are conflicts as to any material fact concerning the reason for withdrawal, a hearing may be requested in accordance with the procedure in § 79.4(c)(3) of this chapter. The action under appeal shall continue in effect pending the final determination of the Administrator, unless otherwise ordered by the Administrator. The Administrator's decision constitutes final agency action.

11. Section 54.11 is revised to read as follows:

§ 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 and conduct 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 that are approved or provided by NVSL;

(4) Meets check test proficiency requirements and consistently produces accurate test results as determined by NVSL review;

(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 and DNA from all genotype tests for at least 5 years and will forward copies of records and any of these materials to NVSL within 5 business days of request; Except that, NVSL may authorize a shorter retention time in a standard operating procedure or contract.

(7) Will allow APHIS to inspect the laboratory without notice during normal business hours. An inspection may include, but is not limited to, review and copying of records, examination of slides, review of quality control procedures, observation of sample handling/tracking procedures, observation of the test being conducted, and interviewing of personnel;

(8) Will report all test results to State and Federal animal health officials and record them in the National Scrapie Database within timeframes and in the manner and format specified by the Administrator; and

(9) Complies with any other written guidance provided to the laboratory by the Administrator.

(b) A laboratory may request approval to conduct one or more types of program-approved 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 suspend or 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 suspension or the proposed withdrawal to the director of the laboratory and shall give the director an opportunity to respond. Such action shall become effective upon oral or written notification, whichever is earlier, to the laboratory or manufacturer. If there are conflicts as to any material fact concerning the reason for withdrawal, a hearing may be requested in accordance with the procedure in § 79.4(c)(3) of this chapter. The action under appeal shall continue in effect pending the final determination of the Administrator, unless otherwise ordered by the Administrator. The Administrator's decision constitutes final agency action

(d) The Administrator may require approved laboratories to reimburse APHIS for part or all of the costs associated with the approval and monitoring of the laboratory.

Subpart B—Scrapie Free Flock Certification Program

12. In part 54, the heading for subpart B is revised to read as set forth above.

13. Section 54.21 is revised to read as follows:

§ 54.21 Participation.

Any owner of a sheep or goat flock may apply to enter the Scrapie Free Flock Certification Program by sending a written request to a State scrapie certification board or to the Veterinary Services, Surveillance Preparedness and Response Services, Assistant Director responsible for the State involved. A notice containing a current list of flocks participating in the Scrapie Free Flock Certification Program, and the certification status of each flock, may be obtained from the APHIS web site at <http://www.aphis.usda.gov/animal-health/scrapie>. A list of noncompliant flocks and a list of flocks that sold exposed animals that could not be traced may

also be obtained from this site, and these lists may be obtained by writing to the National Scrapie Program Coordinator, Surveillance Preparedness and Response Services, VS, APHIS, 4700 River Road Unit 43, Riverdale, MD 20737-1235.

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

PART 79--SCRAPIE IN SHEEP AND GOATS

14. The authority citation for part 79 continues to read as follows:

Authority: 7 U.S.C. 8301-8317; 7 CFR 2.22, 2.80, and 371.4.

15. Section 79.1 is amended as follows:

- a. Revise the definition for animal identification number (AIN).
- b. In the definition for breed association and registries, by removing the words “listed in § 151.9 of this chapter”.
- c. By removing the definition for certificate.
- d. Add a definition for classification or reclassification investigation.
- e. Revise the definitions for consistent State, exposed animal, and exposed flock.
- f. Add a definition for flock identification (ID) number.
- g. In the definition for flock plan, by removing the citation “§ 54.8(a)(f)” and by adding the words “§ 54.8(a) through (j)” in its place.
- h. Add definitions for flock under investigation, genetically less susceptible exposed sheep, genetically resistant exposed sheep, genetically resistant sheep, genetically susceptible animal, genetically susceptible exposed animal, group/lot identification number (GIN).
- i. Revise the definition for high-risk animal.
- j. Add definitions for interstate certificate of veterinary inspection (ICVI) and low-risk commercial flock.

- k. Remove the definition for low-risk commercial sheep.
- l. Add a definition for low-risk exposed animal.
- m. Remove the definition for low-risk goat.
- n. Add a definition for National Uniform Eartagging System (NUES).
- o. In the definition for noncompliant flock, in paragraph (3), by removing the words “owner statement” and adding the words “owner/hauler statement” in their place.
- p. Revise the definitions for official eartag, official genotype test, and official identification device or method.
- q. Add definitions for official identification number, officially identified, and owner/hauler statement.
- r. Remove the definition for owner statement.
- s. Add a definition for person.
- t. Revise the definition for premises identification number (PIN).
- u. Add a definition for restricted animal sale or restricted livestock facility.
- v. In the heading of the definition for Scrapie Flock Certification Program (SFCP), by adding the word “Free” immediately after the word “Scrapie”.
- w. In the heading of the definition for Scrapie Flock Certification Program standards, by adding the word “Free” immediately following the word “Scrapie” and, in footnote 2, by removing the Internet address “<http://www.aphis.usda.gov/vs>” and adding the Internet address “<http://www.aphis.usda.gov/animal-health/scrapie>” in its place.
- x. In the definition for scrapie-positive animal, in paragraph (2) by adding the words “, and/or ELISA,” immediately after the word “immunohistochemistry” and in paragraph (5) by

removing the words “test method” and adding the words “method or combination of methods” in their place.

y. By removing the definition for separate contemporary lambing groups.

z. Revise the definition for slaughter channels, paragraph (1) of the definition for suspect animal, and the definition for terminal feedlot.

aa. Add a definition for test eligible.

The additions and revisions read as follows:

§ 79.1 Definitions.

* * * * *

Animal identification number (AIN). This term has the meaning set forth in § 86.1 of this subchapter, except that only AIN devices approved and distributed in accordance with § 79.2 (k) and methods approved for use in sheep and goats in accordance with § 79.2(a)(2) are included.

* * * * *

Classification or reclassification investigation. An epidemiological investigation conducted or directed by a DSE for the purpose of designating or redesignating the status of a flock or animal. In conducting such an investigation, the DSE will evaluate the available records for flocks and individual animals and conduct or direct any testing needed to assess the status of a flock or animal. The status of an animal or flock will be determined based on the applicable definitions in this section and, when needed to make a designation under § 79.4, official genotype test results, exposure risk, scrapie type involved, and/or results of official scrapie testing on live or dead animals.

* * * * *

Consistent State. (1) A State that the Administrator has determined conducts an active State scrapie control program that meets the requirements of §79.6 or 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) A list of Consistent States can be found on the Internet at <http://www.aphis.usda.gov/animal-health/scrapie>.

(3) When the Administrator determines that a State should be added to or removed from the list of Consistent States, APHIS will publish a notice in the Federal Register advising the public of the Administrator's determination, providing the reasons for that determination, and soliciting public comments. After considering any comments we receive, APHIS will publish a second notice either advising the public that the Administrator has decided to add or remove the State from the list of Consistent States or notifying the public that the Administrator has decided not to make any changes to the list of Consistent States, depending on the information presented in the comments.

* * * * *

Exposed animal. Any animal or embryo that has been in a flock or in an enclosure off the premises of the flock with a scrapie-positive female animal; resides in a noncompliant flock; or has resided on the premises of a flock before or while it was designated an infected or source flock and before a flock plan was completed. An animal shall not be designated an exposed animal if it only resided on the premises before the date that infection was most likely introduced to the premises as determined by a Federal or State representative. If the probable date of infection cannot be determined based on the epidemiologic investigation, a date 2 years before the birth of the oldest scrapie-positive animal(s) will be used. If the actual birth date is unknown,

the date of birth will be estimated based on examination of the teeth and any available records. If an age estimate cannot be made, the animal will be assumed to have been 48 months of age on the date samples were collected for scrapie diagnosis. Exposed animals will be further designated as genetically resistant exposed sheep, genetically less susceptible exposed sheep, genetically susceptible exposed animals, or low-risk exposed animals. An animal will no longer be an exposed animal if it is redesignated in accordance with § 79.4.

Exposed flock. (1) Any flock that was designated an infected or source flock that has completed a flock plan and that retained a female genetically susceptible exposed animal;

(2) Any flock under investigation that retains a female genetically susceptible exposed animal or a suspect animal, or whose owner declines to complete genotyping and live-animal and/or post-mortem scrapie testing required by the APHIS or State representative investigating the flock; or

(3) Any noncompliant flock or any flock for which a PEMMP is required that is not in compliance with the conditions of the PEMMP. A flock will no longer be an exposed flock if it is redesignated in accordance with § 79.4.

* * * * *

Flock identification (ID) number. A nationally unique number assigned by a State or Federal animal health authority to a group of animals that are managed as a unit on one or more premises and are under the same ownership. The flock ID number must begin with the State postal abbreviation, must have no more than nine alphanumeric characters, and must not contain the characters "I", "O", or "Q" other than as part of the State postal abbreviation or another standardized format authorized by the administrator and issued through the National Scrapie Database. Flock identification numbers will be linked in the National Scrapie Database to one or

more PINs and may be used in conjunction with an animal number unique within the flock to provide a unique official identification number for an animal, or may be used in conjunction with the date and a sequence number to provide a GIN for a group of animals when group identification is permitted.

* * * * *

Flock under investigation. Any flock in which an APHIS or State representative has determined that a scrapie suspect animal, high-risk animal, or scrapie-positive animal resides or may have resided. A flock will no longer be a flock under investigation if it is redesignated in accordance with § 79.4.

Genetically less susceptible exposed sheep. Any sheep or sheep embryo that is:

(1) An exposed sheep or sheep embryo of genotype AA QR, unless it is epidemiologically linked to a scrapie-positive RR or AA QR sheep or to a scrapie type to which AA QR sheep are not less susceptible where Q represents any genotype other than R at codon 171; or

(2) An exposed sheep or sheep embryo of genotype AV QR, unless it is epidemiologically linked to a scrapie-positive RR or QR sheep, to a flock that the DSE has determined may be affected by valine associated scrapie, or to another scrapie type to which AV QR sheep are not less susceptible where Q represents any genotype other than R at codon 171 and V represents any genotype other than A at codon 136; or

(3) An exposed sheep or sheep embryo of a genotype that has been exposed to a scrapie type to which the Administrator has determined that genotype is less susceptible.

Genetically resistant exposed sheep. Any exposed sheep or sheep embryo of genotype RR unless it is epidemiologically linked to a scrapie-positive RR sheep or to a scrapie type to which RR sheep are not resistant.

Genetically resistant sheep. Any sheep or sheep embryo of genotype RR unless it is epidemiologically linked to a scrapie-positive RR sheep or to a scrapie type that affects RR sheep.

Genetically susceptible animal. Any goat or goat embryo, sheep or sheep embryo of a genotype other than RR or QR, or sheep or sheep embryo of undetermined genotype where Q represents any genotype other than R at codon 171.

Genetically susceptible exposed animal. Excluding low-risk exposed animals, any exposed animal or embryo that is also:

- (1) A genetically susceptible animal; or
- (2) A sheep or sheep embryo of genotype AV QR that is epidemiologically linked to a scrapie-positive RR or QR sheep, to a flock that the DSE has determined may be affected by valine associated scrapie (based on an evaluation of the genotypes of the scrapie-positive animals linked to the flock), or to a scrapie type to which AV QR sheep are susceptible where Q represents any genotype other than R at codon 171 and V represents any genotype other than A at codon 136; or
- (3) A sheep or sheep embryo of genotype AA QR that is epidemiologically linked to a scrapie-positive RR or AA QR sheep or to a scrapie type to which AA QR sheep are susceptible where Q represents any genotype other than R at codon 171; or
- (4) A sheep or sheep embryo of genotype RR that is epidemiologically linked to a scrapie-positive RR sheep or to a scrapie type to which RR sheep are susceptible.

Group/lot identification number (GIN). The identification number used to uniquely identify a unit of animals that is managed together as one group. The format of the GIN may be either as defined in § 71.1 of this chapter, or the flock identification number followed by a six-digit representation of the date on which the group or lot of animals was assembled (MM/DD/YY). If more than one group is created on the same date a sequential number will be added to the end of the GIN. If a flock identification number is used, the flock identification number, date, and sequential number will be separated by hyphens.

High-risk animal. The female offspring or embryo of a scrapie-positive female animal, or any suspect animal, or a female genetically susceptible exposed animal, or any exposed animal that the Administrator determines to be a potential risk based on the scrapie type, the epidemiology of the flock or flocks with which it is epidemiologically linked, including genetics of the positive sheep, the prevalence of scrapie in the flock, any history of recurrent infection, and other animal or flock characteristics. An animal will no longer be a high-risk animal if it is redesignated in accordance with § 79.4.

* * * * *

Interstate certificate of veterinary inspection (ICVI). An official document issued by a Federal, State, Tribal, or accredited veterinarian certifying the inspection of animals in preparation for interstate movement or other uses as described in this part and in accordance with § 79.5.

* * * * *

Low-risk commercial flock. A flock composed of commercial whitefaced, whitefaced cross, or commercial hair sheep or commercial goats that were born in, and have resided throughout their lives in, flocks with no known risk factors for scrapie, including any exposure to

female blackfaced sheep other than whiteface crosses born on the premises; that has never contained a scrapie-positive female, suspect female, or high-risk animal; and that has never been an infected, exposed, or source flock or a flock under investigation. The animals are identified with a legible permanent brand or ear notch pattern registered with an official brand registry or with an official flock identification eartag. The term “brand” includes official brand registry brands on eartags in those States whose brand law or regulation recognizes brands placed on eartags as official brands. Low-risk commercial flocks may exist only in a State where in the previous 10 years no flock that had met the definition of a low-risk commercial flock prior to a classification investigation was designated a source or infected flock.

Low-risk exposed animal. Any exposed animal to which the DSE has determined one or more of the following applies:

(1) The positive animal that was the source of exposure was not born in the flock and did not lamb in the flock or in an enclosure where the exposed animal resided;

(2) The Administrator and State representative concur that the animal is unlikely to be infected due to factors such as, but not limited to, where the animal resided or the time period the animal resided in the flock;

(3) The exposed animal is male and was not born in an infected or source flock;

(4) The exposed animal is a castrated male;

(5) The exposed animal is an embryo of a genetically resistant exposed sheep or a genetically less susceptible exposed sheep unless placed in a recipient that was a genetically susceptible exposed animal; or

(6) The animal was exposed to a scrapie type and/or is of a genotype that the Administrator has determined poses low risk of transmission.

* * * * *

National Uniform Eartagging System (NUES). This term has the meaning set forth in § 86.1 of this subchapter.

* * * * *

Official eartag. This term has the meaning set forth in § 86.1 of this subchapter, except that only eartags approved and distributed in accordance with § 79.2(k) are included.

Official genotype test. A test to determine the genotype of a live or dead animal conducted at either the National Veterinary Services Laboratories or at an approved laboratory. The test subject must be an animal that is officially identified and the test accurately recorded on an official form supplied or approved by APHIS, with the samples collected and shipped to the laboratory using a shipping method specified by the laboratory by:

- (1) An accredited veterinarian;
- (2) A State or APHIS representative; or
- (3) The animal's owner or owner's agent, using a tamper-resistant sampling kit approved by APHIS for this purpose.

* * * * *

Official identification device or method. This term has the meaning set forth in § 86.1 of this subchapter, except that only devices approved and distributed in accordance with § 79.2(k) are included.

Official identification number. This term has the meaning set forth in § 86.1 of this subchapter.

Officially identified. Identified by means of an official identification device or method approved by the Administrator for use in sheep and goats in accordance with this part.

* * * * *

Owner/hauler statement. A signed written statement by the owner or hauler that includes:

- (1) The name, address, and phone number of the owner and, if different, the hauler;
- (2) The date the animals were moved;
- (3) The flock identification number or PIN assigned to the flock or premises of the animals;
- (4) If moving individually unidentified animals, the group/lot identification number and any information required to officially identify the animals;
- (5) The number of animals;
- (6) The species, breed, and class of animals. If breed is unknown, for sheep the face color and for goats the type (milk, fiber, or meat) must be recorded instead; and
- (7) The name and address of point of origin, if different from the owner's address, and the destination.

* * * * *

Person. An individual, partnership, company, corporation, or any other legal entity.

* * * * *

Premises identification number (PIN). This term has the meaning set forth in § 86.1 of this subchapter. APHIS may also maintain historical and/or State premises numbers and link them to the premises identification number in records and databases. Such secondary or historical numbers are typically the State's two-letter postal abbreviation followed by a number assigned by the State.

Restricted animal sale or restricted livestock facility. A sale where any animals in slaughter channels are maintained separate from other animals not in slaughter channels and are

sold in lots that consist entirely of animals sold for slaughter only or a livestock facility at which all animals are in slaughter channels and where the sale or facility manager maintains a copy of, or maintains a record of, the information from, the owner/hauler statement for all animals entering and leaving the sale or facility. A restricted animal sale may be held at a livestock facility that is not restricted.

* * * * *

Slaughter channels. Animals in slaughter channels include any animal that is sold, transferred, or moved either directly to or through a restricted animal sale or restricted livestock facility to a slaughter establishment that is under continuous inspection by the Food Safety and Inspection Service (FSIS) or under State inspection that FSIS has recognized as at least equal to Federal inspection or to a custom exempt slaughter establishment as defined by FSIS for immediate slaughter or to an individual for immediate slaughter for personal use or to a terminal feedlot. Any animal sold at an unrestricted sale is not in slaughter channels. Animals in slaughter channels must be accompanied by an owner/hauler statement completed in accordance with § 79.3(g). Animals in slaughter channels may not be held in the same enclosure with sexually intact animals from another flock of origin that are not in slaughter channels. When selling animals that do not meet the requirements to move as breeding animals, owners must note on the bill of sale that the animals are sold only for slaughter.

* * * * *

Suspect animal. * * *

(1) A mature sheep or goat as evidenced by eruption of the first incisor that has been condemned by FSIS or a State inspection authority for central nervous system (CNS) signs, or that exhibits any of the following clinical signs of scrapie and has been determined to be

suspicious for scrapie by an accredited veterinarian or a State or USDA representative, based on one or more of the following signs and the severity of the signs: Weakness of any kind including, but not limited to, stumbling, falling down, or having difficulty rising, not including those with visible traumatic injuries and no other signs of scrapie; behavioral abnormalities; significant weight loss despite retention of appetite or in an animal with adequate dentition; increased sensitivity to noise and sudden movement; tremors; star gazing; head pressing; bilateral gait abnormalities such as but not limited to incoordination, ataxia, high stepping gait of forelimbs, bunny-hop movement of rear legs, or swaying of back end, but not including abnormalities involving only one leg or one front and one back leg; repeated intense rubbing with bare areas or damaged wool in similar locations on both sides of the animal's body or, if on the head, both sides of the poll; abraded, rough, thickened, or hyperpigmented areas of skin in areas of wool/hair loss in similar locations on both sides of the animal's body or, if on the head, both sides of the poll; or other signs of CNS disease. An animal will no longer be a suspect animal if it is redesignated in accordance with § 79.4 of this part.

* * * * *

Terminal feedlot. (1) A dry lot approved by a State or APHIS representative or an accredited veterinarian who is authorized to perform this function where animals in the terminal feedlot 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 must be cleaned of all organic material prior to being used to contain sheep or goats that are not in slaughter channels, where only castrated males are maintained with female animals and from which animals are moved only to another terminal feedlot or directly to slaughter; or

(2) A dry lot approved by a State or APHIS representative or an accredited veterinarian authorized to perform this function where only animals that either are not pregnant based on the animal being male, an owner certification that any female animals have not been exposed to a male in the preceding 6 months, an ICVI issued by an accredited veterinarian stating the animals are open, or the animals are under 6 months of age at time of receipt, where only castrated males are maintained with female animals, and all animals in the terminal feedlot are separated from all other animals such that physical contact cannot occur and from which animals are moved only to another terminal feedlot or directly to slaughter; or

(3) A pasture when approved by and maintained under the supervision of the State and in which only nonpregnant animals are permitted based on the animal being male, an owner certification that any female animals have not been exposed to a male in the preceding 6 months, or an ICVI issued by an accredited veterinarian stating the animals are open, or the animals are under 6 months of age at time of receipt, where only castrated males are maintained with female animals, 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.

(4) Records of all animals entering and leaving a terminal feedlot must be maintained for 5 years after the animal leaves the feedlot and must meet the requirements of § 79.2, including either a copy of the required owner/hauler statements for animals entering and leaving the facility or the information required to be on the statements. Records must be made available for inspection and copying by an APHIS or State representative upon request.

Test eligible. An animal that meets a test protocol's age and post-exposure elapsed time requirements for the test to be meaningfully applied.

* * * * *

16. Section 79.2 is revised to read as follows:

§ 79.2 Identification and records requirements for sheep and goats in interstate commerce.

(a) No sheep or goat that is required to be individually identified or group identified by § 79.3 may be sold, disposed of, acquired, exhibited, transported, received for transportation, offered for sale or transportation, loaded, unloaded, or otherwise handled in interstate commerce or commingled with such animals or be loaded or unloaded at a premises or animal concentration point (including premises that exhibit animals) that engages in interstate commerce of animals unless each sheep or goat has been 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 birth⁴ by the owner of the animal or his or her agent, at whichever of the following points in interstate commerce comes first:

(i) Prior to the point of first commingling of the sheep or goats with sheep or goats from any other flock of origin;

⁴ You need not identify an animal to its flock of birth or its flock of origin if this information is unknown because the animal changed ownership while it was exempted from flock of origin identification requirements in accordance with § 79.6(a)(10)(i). Such animals may be moved interstate with individual animal identification that is only traceable to the State of origin and to the owner of the animals at the time they were so identified. To use this exemption the person applying the identification must have supporting documentation indicating that the animals were born and had resided throughout their life in the State. Likewise, animals born before January 1, 2002, need only be identified to their flock of origin and, for animals not required to be identified prior to [effective date of final rule] may, be identified to the owner of the animals and the flock of residence as of [effective date of final rule].

(ii) Upon unloading of the sheep or goats at an approved livestock facility that is approved to handle that species and class of animals as described in § 71.20 of this subchapter that has agreed to act as an agent for the owner to apply official identification and prior to commingling with animals from another flock of origin. Such animals must be accompanied by an owner/hauler statement that contains the information needed for the livestock facility to officially identify the animals to their flock of origin and, when required, their flock of birth;

(iii) Upon transfer of ownership of the sheep or goats;

(iv) Prior to moving a sheep or goat from the premises on which it resides if the owner of the premises engages in the interstate commerce of animals unless the animals are moving to a livestock facility approved to handle the species and class of animal to be moved as described in § 71.20 of this subchapter that has agreed to act as an agent for the owner to apply official identification and in accordance with paragraph (a)(1)(ii) of this section or to a slaughter plant listed in accordance with § 71.21 of this subchapter as part of a group lot.

(v) In the case of animals that have only resided on premises and in flocks owned by persons that do not engage in interstate commerce, upon unloading a sheep or goat at a livestock facility or other premises that engages in interstate commerce of animals and prior to commingling with animals from another flock of origin. Such animals must be accompanied by an owner/hauler statement that contains the information needed to officially identify the animals to their flock of origin and, when required, their flock of birth;

(2) The sheep or goats must be identified and remain identified using a device or method approved by the Administrator. All animals required to be individually identified by § 79.3 shall be identified with official identification devices or methods. A list of approved identification devices and methods, including restrictions on their use, is available at

<http://www.aphis.usda.gov/animal-health/scrapie>. Written requests for approval of sheep or goat identification device types or methods not listed at <http://www.aphis.usda.gov/animal-health/scrapie> should be sent to the National Scrapie Program Coordinator, Surveillance Preparedness and Response Services, VS, APHIS, 4700 River Road Unit 43, Riverdale, MD 20737-1235. If the Administrator determines that an identification device or method will provide an effective means of tracing sheep and goats in interstate commerce, APHIS will provide public notice that the device type or method, along with any restrictions on its use, has been added to the list of approved devices and methods of official sheep and goat identification.

(3) No person shall buy or sell, for his or her own account or as the agent of the buyer or seller, transport, receive for transportation, offer for sale or transportation, load, unload, or otherwise handle any animal that is in or has been in interstate commerce that has not been identified as required by this section including loading or unloading at a premises (including premises that exhibit animals) that engages in interstate commerce of animals. No person shall commingle animals with any animal that is in or has been in interstate commerce that has not been identified as required by this section. If the person transporting animals is aware of any animal in the shipment that loses its identification to its flock of origin while in interstate commerce, the person transporting the animal is required to inform the receiving party of this fact, and it is the responsibility of the person who has control or possession of the animal upon unloading/delivery to identify the animal or have the animal identified 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 on the waybill or other shipping document. If the flock of origin cannot be determined, all possible flocks of origin shall be listed on the

record, or if this cannot be done, the animal must be identified with a slaughter only eartag and may only move in slaughter channels or in the case of sheep may move for other purposes if the animal is inspected by an accredited veterinarian, found free of evidence of infectious or contagious disease and officially genotyped as AA QR or AA RR.

(b) Individual identification numbers. The State animal health official or Veterinary Services, Surveillance Preparedness and Response Services, Assistant Director responsible for the State involved, whoever is responsible for issuing official identification devices or numbers in that State and for assigning flock identification numbers and premises identification numbers in that State in the National Scrapie Database, may issue sets of unique serial numbers or flock identification/production numbers for use on official individual identification devices (such as eartags or tattoos). Flock identification/production numbers may only be assigned to owners of breeding flocks.

(1) Official identification numbers for use on animals not in slaughter channels may only be assigned either directly to the owner of a breeding flock or, in the case of official serial numbers or serial number devices, to APHIS or State representatives or accredited veterinarians or other responsible individuals as described in paragraphs (b)(2) and (3) of this section for reassignment to owners of breeding flocks. APHIS or State representatives or accredited veterinarians that reissue official serial numbers or devices must provide, in a manner acceptable to APHIS, assignment data associating assigned serial sequences to the flock of origin and, when required, the flock of birth. One such method would be to enter the data into the AIN module of the National Scrapie Database.

(2) The official responsible for issuing eartags in a State may also assign serial numbers of official eartags to other responsible persons, such as 4-H leaders, if the State animal health

official and Veterinary Services, Surveillance Preparedness and Response Services, Assistant Director responsible for the State involved agree that such assignments will improve scrapie control and eradication within the State. Such persons assigned serial numbers may either directly apply eartags to animals, or may reassign eartag numbers to producers. Such persons must maintain appropriate records in accordance with paragraph (g) of this section that permit traceback of animals to their flock of origin, or flock of birth when required, and must either reassign the tags in the National Scrapie Database or, if permitted by the Veterinary Services, Surveillance Preparedness and Response Services Field Office for the State involved, provide a written record of the reassignment to the Field Office or the State Office for entry into the National Scrapie Database.

(3) Persons handling sheep and goats in commerce. Sets of unique individual identification serial numbers may be assigned to persons who handle sheep and goats, but who do not own breeding flocks, if they apply to and are approved by the State animal health official or the Veterinary Services, Surveillance Preparedness and Response Services, Assistant Director responsible for the State in which the person maintains his or her business location, whichever is responsible for issuing official identification devices or numbers in that State and for assigning flock identification numbers and premises identification numbers in that State in the National Scrapie Database. Such persons must provide, in a manner acceptable to APHIS, assignment data associating assigned serial sequences to the flock of origin and, when required, the flock of birth. One such method would be to enter the data into the online animal identification number (AIN) management system module of the National Scrapie Database.

(4) Breed registries. Sets of unique individual identification numbers may also be assigned by the Administrator to breed registries that agree to reassign the sequences to the flock

of origin and, and when required, the flock of birth and to provide associated registry identifiers such as registry tattoo numbers to APHIS in the online animal identification number (AIN) management system module of the National Scrapie Database.

(5) Noncompliance. In addition to any applicable criminal or civil penalties any person who fails to comply with the requirements of this section or that makes false statements in order to acquire official identification numbers or devices shall not be assigned official identification numbers or official identification devices for a period of at least 1 year. If a person who is not in compliance with these requirements has already been assigned such numbers, the Administrator may withdraw the assignment by giving notice to such person. Such withdrawal or failure to assign official identification numbers may be appealed in accordance with § 79.4(c)(3). A person shall be subject to criminal and civil penalties if he or she continues to use assigned numbers that have been withdrawn from his or her use.

(c) No person shall apply a premises or flock identification number or a brand or ear-notch pattern to an animal that did not originate on the premises or flock 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 eartags that have been assigned to a premises or flock and registration tattoos that contain prefixes that have been assigned to a premises or flock for use as premises or flock identification. Unless the number sequence was issued specifically for use on animals born in a flock, this would not preclude the owner of a flock from using an official premises or flock identification number tag assigned to that flock on an animal owned by him or her that resides in that flock but that was born or previously resided on a different premises as long as the records required in paragraph (g) of this section are maintained.

(d) No person shall sell or transfer an official identification device or number assigned to his or her premises or flock except when it is transferred with a sheep or goat to which it has been applied as official identification or as directed in writing by an APHIS or State representative.

(e) No person shall use an official identification device or number provided for the identification of sheep and goats other than for the identification of a sheep or goat.

(f) Records required of persons who purchase, acquire, sell, or dispose of animals.

Persons who engage in the interstate commerce of animals including persons that handle or own animals that have been in interstate commerce or that purchase, acquire, sell, or dispose of sheep and/or goats to persons who engage in the interstate commerce of animals, whether or not the animals are required to be officially identified, must maintain business records (such as yarding receipts, sale tickets, invoices, and waybills) for 5 years. These persons must make the records available for inspection and copying by any authorized USDA or State representative upon that representative's request and presentation of his or her official credentials. The records must include the following information:

- (1) The number of animals purchased or sold (or transferred without sale);
- (2) The date of purchase, sale, or other transfer;
- (3) The name and address of the person from whom the animals were purchased or otherwise acquired or to whom they were sold or otherwise transferred;
- (4) The species, breed, and class of animal. If breed is unknown, for sheep the face color and for goats the type (milk, fiber, or meat) must be recorded instead;
- (5) A copy of the brand inspection certificate for animals officially identified with brands or ear notches;

(6) A copy of any certificate or owner/hauler statement required for movement of the animals purchased, sold, or otherwise transferred; and

(7) If the flock of origin or the receiving flock is under a flock plan or post-exposure management and monitoring plan, any additional records required by the plan.

(g) Records required of persons who apply official identification to animals. Persons who apply official individual or group/lot identification to animals must maintain records for 5 years. These persons must make the records available for inspection and copying by any authorized USDA or State representative upon that representative's request and presentation of his or her official credentials. The records must include the following information:

(1) The flock identification number of the flock of origin, the name and address of the person who currently owns the animals, and the name and address of the owner of the flock of origin if different;

(2) The name and address of the owner of the flock of birth, if known, for animals born after January 1, 2002, in another flock and not already identified to flock of birth;

(3) The date the animals were officially identified;

(4) The number of sheep and the number of goats identified;

(5) The breed and class of the animals. If breed is unknown, for sheep the face color and for goats the type (milk, fiber, or meat) must be recorded instead;

(6) The official identification numbers applied to animals by species or the GIN applied in the case of a group lot;

(7) Whether the animals were identified with "Slaughter Only" or "Meat" identification devices; and

(8) Any GIN with which the animal was previously identified.

(h) Removal or loss of official identification devices. Official identification devices are intended to provide permanent identification of livestock and to ensure the ability to find the source of animal disease outbreaks. Removal of these devices, including devices applied to imported animals in their countries of origin and recognized by the Administrator as official, is prohibited except at the time of slaughter, at any other location upon the death of the animal, or as otherwise approved by the State or Tribal animal health official or the Veterinary Services, Surveillance Preparedness and Response Services, Assistant Director responsible for the State involved when a device needs to be replaced.

(1) All man-made identification devices affixed to sheep or goats moved interstate must be removed at slaughter and correlated with the carcasses through final inspection by means approved by the Food Safety and Inspection Service (FSIS). If diagnostic samples, including whole heads, are taken, the identification devices must be packaged with the samples and must be left attached to approximately 1 inch of tissue or to the whole head to allow for identity testing and be correlated with the carcasses through final inspection by means approved by FSIS. Devices collected at slaughter must be made available to APHIS and FSIS.

(2) All official identification devices affixed to sheep or goat carcasses moved interstate for rendering must be removed at the rendering facility and made available to APHIS. If diagnostic samples, including whole heads, are taken, the identification devices must be packaged with the samples and must be left attached to approximately 1 inch of tissue or to the whole head to allow for identity testing.

(3) If a sheep or goat loses an official identification device except while in interstate commerce as described in paragraph (a)(3) of this section and needs a new one, the person applying the new official identification device must record the official identification number on

the old device if known in addition to the information required to be recorded in accordance with paragraph (g) of this section.

(i) Replacement of official identification devices for reasons other than loss.

(1) Circumstances under which a State or Tribal animal health official or the Veterinary Services, Surveillance Preparedness and Response Services, Assistant Director responsible for the State involved may authorize replacement of an official identification device include, but are not limited to:

(i) Deterioration of the device such that loss of the device appears likely or the number can no longer be read;

(ii) Infection at the site where the device is attached, necessitating application of a device at another location (e.g., a slightly different location of an eartag in the ear);

(iii) Malfunction of the electronic component of a radio frequency identification (RFID) device; or

(iv) Incompatibility or inoperability of the electronic component of an RFID device with the management system or unacceptable functionality of the management system due to use of an RFID device.

(2) Any time an official identification device is replaced, as authorized by the State or Tribal animal health official or the Veterinary Services, Surveillance Preparedness and Response Services, Assistant Director responsible for the State involved, the person replacing the device must record the following information about the event and maintain the record for 5 years:

(i) The date on which the device was removed;

(ii) Contact information for the location where the device was removed;

(iii) The official identification number (to the extent possible) on the device removed;

- (iv) The type of device removed (e.g., metal eartag, RFID eartag);
- (v) The reason for the removal of the device;
- (vi) The new official identification number on the replacement device; and
- (vii) The type of replacement device applied.

(j) Use of more than one official eartag. Beginning on [effective date of final rule], no more than one official eartag may be applied to an animal; except that:

(1) Another official eartag may be applied providing it bears the same official identification number as an existing one.

(2) In specific cases when the need to maintain the identity of an animal is intensified (e.g., such as for export shipments, quarantined herds, field trials, experiments, or disease surveys), a State or Tribal animal health official or the Veterinary Services, Surveillance Preparedness and Response Services, Assistant Director responsible for the State involved may approve the application of a second official eartag. The person applying the second official eartag must record the following information about the event and maintain the record for 5 years: The date the second official eartag is added; the reason for the additional official eartag device; and the official identification numbers of both official eartags.

(3) An eartag with an animal identification number (AIN) beginning with the 840 prefix (either radio frequency identification or visual-only tag) may be applied to an animal that is already officially identified with another eartag. The person applying the AIN eartag must record the date the AIN tag is added and the official identification numbers of all official eartags on the animal and must maintain those records for 5 years.

(4) An official eartag that utilizes a flock identification number may be applied to a sheep or goat that is already officially identified with an official eartag if the animal has resided in the flock to which the flock identification number is assigned.

(k) Requirements for approval of official identification devices. (1) The Administrator may approve companies to produce official identification devices for use on sheep or goats. Devices may be plastic, metal, or other suitable materials and must be an appropriate size for use in sheep and goats. Devices must be able to legibly accommodate the required alphanumeric sequences. Devices must resist removal and be difficult to place on another animal once removed unless the construction of the device makes such tampering evident, but need not be tamper-proof. Devices must be readily distinguishable as USDA official sheep and goat identification devices; must carry the alphanumeric sequences, symbols, or logos specified by APHIS; must be an allowed color for the intended use, and must have a means of discouraging counterfeiting, such as use of a unique copyrighted logo or trade mark. Devices for use only on animals in slaughter channels must be medium blue and marked with the words “Meat” or “Slaughter Only”. Devices that use RFID must conform to ISO 11784 and ISO 11785 standards unless otherwise approved. The Administrator may specify the color, shape or size of a device for an intended use to make them readily identifiable.

(2) Written requests for approval of official identification devices for sheep and goats should be sent to the National Scrapie Program Coordinator, Surveillance Preparedness and Response Services, VS, APHIS, 4700 River Road Unit 43, Riverdale, MD 20737-1235. The request must include:

(i) The materials used in the device and in the case of RFID the transponder type and data regarding the lifespan and read range.

(ii) Any available data regarding the durability of the device, durability and legibility of the identification numbers, rate of adverse reactions such as ear infections, and retention rates of the devices in animals, preferably sheep and/or goats.

(iii) A signed statement agreeing to:

(A) Send official identification devices only to a State or APHIS representative, to the owner of a premises or to the contact person for a premises at the address listed in the National Scrapie Database, or as directed by APHIS;

(B) When requested by APHIS, provide a report by State of all tags produced, including the tag sequences produced and the name and address of the person to whom the tags were shipped, and provide supplemental reports of this information when requested by APHIS;

(C) Maintain the security and confidentiality of all tag recipient information acquired as a result of being an approved tag manufacturer and utilize the information only to provide official identification tags; and

(D) Enter the sequences of tags shipped into the online animal identification number (AIN) management system module of the National Scrapie Database through an Internet Web page interface or other means specified by APHIS prior to shipping the identification device.

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

(3) Approval will only be given for devices for which data have been provided supporting high legibility, readability (visual and RFID), and retention rates in sheep and goats that minimize injury throughout their lifespan, or for which there is a reasonable expectation of such performance. Approval to produce official identification devices will be valid for 1 year and must be renewed annually. The Administrator may grant provisional approval to produce

devices for periods of less than 1 year in cases where there is limited or incomplete data. The Administrator may decline to renew a company's approval or suspend or withdraw approval if the devices do not show adequate retention and durability or cause injury in field use or if any of the requirements of this section are not met by the tag company. Companies shall be given 60 days' written notice of intent to withdraw approval. Any person who is approved to produce official 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, 7 U.S.C. 8313, or other applicable Federal statutes. Such action may be in addition to, or in lieu of, withdrawal of approval to produce tags.

17. Section 79.3 is revised to read as follows:

§ 79.3 General restrictions.

The following prohibitions and movement conditions apply to the movement of or commingling with sheep and goats in interstate commerce, and no sheep or goat may be sold, disposed of, acquired, exhibited, transported, received for transportation, offered for sale or transportation, loaded, unloaded, or otherwise handled in interstate commerce, or commingled with such animals, or be loaded or unloaded at a premises or animal concentration point (including premises that exhibit animals) that engages in interstate commerce of animals except in compliance with this part.

(a) No sexually intact animal of any age or castrated animal 18 months of age and older (as evidenced by the eruption of the second incisor) may be moved or commingled with animals

in interstate commerce unless it is individually identified to its flock of birth⁵ and is accompanied by an ICVI, except that an ICVI is not required unless the animal is moved across a state line, and except for the following, which may move with group lot identification and an owner/hauler statement:

(1) Animals in slaughter channels that are under 18 months of age;

(2) Animals in slaughter channels at 18 months and older (as evidenced by the eruption of the second incisor) if the animals were kept as a group on the same premises on which they were born and have not been maintained in the same enclosure with unidentified animals from another flock at any time, including throughout the feeding, marketing, and slaughter process;

(3) Animals in slaughter channels 18 months of age and older (as evidenced by the eruption of the second incisor) that are identified with official individual identification or in the case of animals from flocks that are low-risk commercial flocks that are identified using identification methods or devices approved for this purpose;

(4) Animals moving for grazing or other management purposes between two premises both owned or leased by the flock owner and recorded in the National Scrapie Database as additional flock premises and where commingling will not occur with unidentified animals that were born in another flock or any animal that is not part of the flock; and

⁵ You need not identify an animal to its flock of birth or its flock of origin if this information is unknown because the animal changed ownership while it was exempted from flock of origin identification requirements in accordance with § 79.6(a)(10)(i). Such animals may be moved interstate with individual animal identification that is only traceable to the State of origin and to the owner of the animals at the time they were so identified. To use this exemption the person applying the identification must have supporting documentation indicating that the animals were born and had resided throughout their life in the State. Likewise, animals born before January 1, 2002, need only be identified to their flock of origin and, for animals not required to be identified prior to [Effective date of final rule] may, be identified to the owner of the animals and the flock of residence as of [Effective date of final rule].

(5) Animals moving to a livestock facility approved in accordance with § 71.20 of this subchapter and that has agreed to act as an agent for the owner to apply official identification if the animals have been in the same flock in which they were born and have not been maintained in the same enclosure with unidentified animals born in another flock at any time.

(b) No scrapie-positive or suspect animal may be moved other than by permit to an APHIS approved research or quarantine facility or for destruction under APHIS or State supervision. Such animals must be individually identified and listed on the permit.

(c) No indemnified high-risk animal or indemnified sexually intact genetically susceptible exposed animal may be moved other than by permit to an APHIS approved research or quarantine facility or for destruction at another site. Such animals that are not indemnified may be moved to slaughter under permit. Animals moved in accordance with this paragraph must be individually identified and listed on the permit.

(d) No exposed animal may be moved unless it is officially individually identified.

(e) No animal may be moved from an infected flock or source flock except as allowed by an approved flock plan.

(f) No animal may be moved from an exposed flock, a flock under investigation or a flock subject to a PEMMP except as allowed in a PEMMP or where a PEMMP is not required, as allowed by written instructions from an APHIS or State representative.

(g) Animals moved to slaughter. Once an animal enters slaughter channels the animal may not be removed from slaughter channels. An animal is in slaughter channels if it was sold through a restricted animal sale, resided in a terminal feedlot, was sold with a bill of sale marked for slaughter only, was identified with an identification device or tattoo marked “slaughter only” or “MEAT” or was moved in a manner not permitted for other classes of animals. Animals in

slaughter channels may move either directly to a slaughter establishment that is under continuous inspection by the Food Safety and Inspection Service (FSIS) or under State inspection that FSIS has recognized as at least equal to Federal inspection or to a custom exempt slaughter establishment as defined by FSIS for immediate slaughter or to an individual for immediate slaughter for personal use, to a terminal feedlot, or may move indirectly to such a destination through a restricted animal sale or restricted livestock facility. Once an animal has entered slaughter channels it may only be officially identified with an official blue eartag marked with the words "Meat" or "Slaughter Only" or an ear tattoo reading "Meat." Animals in slaughter channels must be accompanied by an owner/hauler statement indicating the owner's name and address; the name and address of the person or livestock facility from which and where they were acquired, if different from the owner; the slaughter establishment, restricted animal sale, restricted livestock facility or terminal feedlot to which they are being moved, and a statement that the animals are in slaughter channels. A copy of the owner/hauler statement must be provided to the slaughter establishment, restricted animal sale, restricted livestock facility or terminal feedlot to which the animals are moved. Any bill of sale regarding the animals must indicate that the animals were sold for slaughter only.

(h) No animals designated for testing as part of a classification or reclassification investigation may be moved until testing is completed and results reported, except for movement by permit for testing, slaughter, research, or destruction. Such animals must be individually identified and listed on the permit.

(i) The following animals, if not restricted as part of a flock plan or PEMMP, may be moved to any destination without further restriction after being officially identified and designated or redesignated by a DSE to be:

- (1) Genetically resistant exposed sheep;
- (2) Genetically less susceptible exposed sheep; or
- (3) Low-risk exposed animals.

(j) Additional requirements for animals moved from Inconsistent States. Such animals must meet the following requirements in addition to other requirements of this section.

(1) Sheep and goats not in slaughter channels must be enrolled in the Scrapie Free Flock Certification Program or an equivalent APHIS recognized program or be sheep that are officially genotyped and determined to be AA QR or AA RR, be officially identified, and be accompanied by an ICVI that also states the individual animal identification numbers, the flock of origin and, for any animal born after January 1, 2002, the flock of birth, if different.

(2) Animals in slaughter channels must be officially identified with an official blue eartag marked with the words "Meat" or "Slaughter Only" and may move only directly to slaughter or to a terminal feedlot. Animals 18 months of age and older (as evidenced by the eruption of the second incisor) in slaughter channels must also be accompanied by an ICVI that states the individual animal identification numbers and, for any animal born after January 1, 2002, the flock of birth (and the flock of origin, if different).

(k) APHIS may enter into compliance agreements with persons such as dealers and owners of slaughter establishments and markets whereby animals may be received unidentified even if they cannot be identified to their flock of birth or origin because they were moved or commingled while unidentified, in violation of this regulation or an intrastate regulation as provided by § 79.6, if the violation is reported to the Veterinary Services, Surveillance Preparedness and Response Services, Assistant Director responsible for the State involved so that corrective action can be taken against the principal violator. In such cases the animal must

be identified with a slaughter only tag, and is moved only in slaughter channels or, in the case of sheep, moved for other purposes if the animal is inspected by an accredited veterinarian, found free of evidence of infectious or contagious disease, and officially genotyped as AA QR or AA RR.

18. Section 79.4 is revised to read as follows:

§ 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. Based on a classification investigation as defined in § 79.1, including testing of animals, if needed, a designated scrapie epidemiologist will designate a flock to be an exposed flock, an infected flock, a source flock, a flock under investigation, and/or a non-compliant flock, or designate an animal to be a scrapie-positive animal, high-risk animal, exposed animal, genetically susceptible exposed animal, genetically resistant exposed sheep, genetically less susceptible exposed sheep, low-risk exposed animal, and/or a suspect animal after determining that the flock or animal meets the criteria of the relevant definition in § 79.1.

(b) Redesignation. A reclassification investigation as defined in § 79.1 may be conducted to determine whether the current designated status of a flock or animal may be changed or removed. Reclassification investigations will be initiated and conducted, and redesignation decisions will be made in accordance with procedures approved by the Administrator. These procedures are available at <http://www.aphis.usda.gov/animal-health/scrapie>.

(c) Testing and notification procedures. Any animal that may be a high-risk animal, any animal that may have been exposed to the lambing of a high-risk animal, any suspect animal, and

any animal that was born in the flock after a high-risk animal may have lambed may be selected for testing. Which animals are selected and the method of testing selected will be based on the risk associated with the flock and the type and number of animals available for test. When flock records are adequate to determine that all high-risk animals that lambed in the flock are available for testing, the testing may be limited to postmortem testing of all high-risk and suspect animals. Testing may include an official genotype test, live-animal testing using a live-animal official test, the postmortem examination and testing of genetically susceptible animals in the flock that cannot be evaluated by a live animal test, postmortem examination of other animals, and postmortem examination and testing of animals found dead or cull animals at slaughter. Animals may not be tested for scrapie to establish the designation of the flock until they are test eligible. Animals are generally considered test eligible when the animals are over 14 months of age if born after the exposure or are 18 months post exposure. If testing these animals is necessary to establish the status of a flock they must be held for later testing unless sent directly to slaughter or a terminal feedlot.

(1) Noncooperation. If an owner does not make his or her animals available for testing within 60 days of notification, within 60 days of becoming test eligible, 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 and a noncompliant flock.

(2) Notice to owner. As soon as possible after making a designation or redesignation determination, a State or APHIS representative will attempt to notify the owner(s) of the flock(s) or animal(s) in writing of the designation.

(3) Appeal. The owner of an animal may appeal the designation of an animal as a scrapie-positive animal, high-risk animal, exposed animal, genetically susceptible exposed

animal, genetically resistant exposed sheep, genetically less susceptible exposed sheep, low-risk exposed animal, or a suspect animal. The owner of a flock may appeal the designation of the flock as an exposed flock, an infected flock, a source flock, a flock under investigation, or a non-compliant flock. The owner of a laboratory or test manufacturing facility may appeal the suspension or withdrawal of approval for a laboratory or a test. To do so, the owner must appeal by writing to the Administrator within 10 days after being informed of the reasons for the proposed action. The appeal must include all of the facts and reasons upon which the owner relies to show that the reasons for the proposed action are incorrect or do not support the action. The Administrator will grant or deny the appeal in writing as promptly as circumstances permit, stating the reason for his or her decision. If there is a conflict as to any material fact, a hearing will be held to resolve the conflict. Rules of practice concerning the hearing will be adopted by the Administrator. The action under appeal shall continue in effect pending the final determination of the Administrator, unless otherwise ordered by the Administrator. Such action shall become effective upon oral or written notification, whichever is earlier, to the owner. In the event of oral notification, written confirmation shall be given as promptly as circumstances allow. The Administrator's decision constitutes final agency action.

19. Section 79.5 is revised as follows:

§ 79.5 Issuance of Interstate Certificates of Veterinary Inspection (ICVI).

(a) ICVIs are required as specified by § 79.3 for certain interstate movements of sheep or goats and may be used to meet the requirements for entry into terminal feedlots. An ICVI must show the following information, except when § 79.3 states that the information is not required for the specific type of interstate movement:

(1) The ICVI must show the species, breed or, if breed is unknown, the face color of sheep or the type of goats (milk, fiber, or meat), and class of animal, such as replacement ewe lambs, slaughter lambs or kids, cull ewes, club lambs, bred ewes, etc.; the number of animals covered by the ICVI; the purpose for which the animals are to be moved; the address at which the animals were loaded for interstate movement or for movement to a terminal feedlot when an ICVI is required; the address to which the animals are destined; and the names of the consignor and the consignee and their addresses if different from the address at which the animals were loaded or the address to which the animals are destined; and if different the current owner;

(2) Each animal's official individual identification numbers: Provided, that, in the case of animals identified with flock identification that is assigned to the flock of origin and that meets the requirements for individual animal identification, the flock identification number may be recorded instead of the individual identification numbers, and for animals allowed by § 79.3 to move with group lot identification, the group lot number may be recorded instead of the individual identification numbers. An ICVI may not be issued for any animal that is not officially identified if official identification is required. If the animals are not required by the regulations to be officially identified, the ICVI must state the exemption that applies (e.g., sheep and goats moving for grazing without change of ownership). If the animals are required to be officially identified but the identification number is not required to be recorded on the ICVI, the ICVI must state that all animals to be moved under the ICVI are officially identified and state the exemption that applies (e.g. the ewes are identified with flock of origin tags so only the flock ID must be recorded on the ICVI);

(3) If any animals intended for breeding have undergone an official genotype test, the name of the testing laboratory, date the sample was taken, and result of the test; and

(4) A statement by the issuing accredited, State, or Federal veterinarian to the effect that on the date of issuance the animals were free of evidence of infectious or contagious disease and insofar as can be determined exposure thereto. This statement may be made with respect to scrapie for animals exposed to scrapie that's movement is not restricted that have been designated genetically resistant or less susceptible sheep or low-risk exposed animals. Except as provided in paragraphs (b) and (c) of this section, all information required by this paragraph must be typed or legibly written on the ICVI. Note that in accordance with paragraphs (a), (b), and (e) of § 79.3, scrapie-positive, suspect, and high-risk animals, some exposed animals, and some animals that originated in an infected or source flock require permits rather than ICVIs.

(b) As an alternative to typing or writing individual animal identification on an ICVI, if agreed to by the receiving State or Tribe, 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 or a printout of official identification numbers generated by computer or other means;

(2) A legible copy of the document must be stapled to the original and each copy of the ICVI;

(3) Each copy of the document must identify each animal to be moved with the ICVI, 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 written in ink in the identification column on the original and each copy of the ICVI 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 unique 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 ICVIs. As an alternative to typing or writing ownership brands on an ICVI, 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 ICVI;

(2) Each copy of the official brand inspection certificate must show the ownership brand of each animal to be moved with the ICVI, 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 ICVI 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.

20. Section 79.6 is amended as follows:

a. In paragraph (a) introductory text, by adding the words “, including scrapie surveillance activities,” after the words “control activities”.

b. By redesignating paragraphs (a)(10)(i) through (vi) as paragraphs (a)(12) through (17), respectively, and revising paragraph (a)(10).

c. By adding paragraph (a)(11).

d. In paragraph (b), by adding the words “from the date the State is notified of the deficiency” after the words “2-year extension”.

The revision and addition read as follows:

§ 79.6 Standards for States to qualify as Consistent States.

(a) * * *

(10) Has effectively implemented ongoing scrapie surveillance that meets the following criteria:

(i) Collects and submits surveillance samples from targeted animals slaughtered in State-inspected establishments and from slaughter establishments within the State that are not covered under § 71.21 of this subchapter, or allows and facilitates the collection of such samples by USDA personnel or contractors; and

(ii) Transmits required submission and epidemiological information for all scrapie samples using the electronic submission system provided by APHIS for inclusion in the National Scrapie Database and for transmission of the submission information to an approved laboratory; and

(iii) Achieves the annual State-level scrapie surveillance minimums for sheep and goats originating from the State as determined annually with input from the States and made available to the public at <http://www.aphis.usda.gov/animal-health/scrapie> at least 6 months before the start of the collection period; or

(iv) Conducts annual surveillance at a level that will detect scrapie if it is present at a prevalence of 0.1 percent in the population of targeted animals originating in the State, with a 95 percent confidence.

(11) If a State does not meet the requirements of paragraph (a)(10) of this section as of [EFFECTIVE DATE OF FINAL RULE], the State must provide APHIS with a plan and a timeline for complying with all the requirements of paragraph (a)(10) by [DATE 12 MONTHS AFTER EFFECTIVE DATE OF FINAL RULE] and must meet the requirements of paragraph (a)(10) by [DATE 2 YEARS AFTER EFFECTIVE DATE OF FINAL RULE].

* * * * *

Done in Washington, DC, this 28th day of August 2015.

Gary Woodward,

Deputy Under Secretary for Marketing and Regulatory Programs.

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