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Service

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# National Scrapie Surveillance Plan



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## 1. Disease Description

Scrapie is a progressive disease affecting the central nervous system (CNS) of sheep and goats and belongs to a group of diseases called transmissible spongiform encephalopathies (TSEs). Scrapie is the oldest known TSE. The scrapie agent is thought to spread most commonly from the ewe to her offspring and other lambs through contact with the placenta and placental fluids. Sheep and goats are typically infected as young lambs or kids. Once infected, the animal remains infected for life. The disease is always fatal; however, it is common for infected animals to be slaughtered or to die first of other diseases or trauma. The scrapie agent may be found in some lymphoid tissues by the age of 4 months and in the brain by 2.5 years, approximately 6 months before the onset of clinical signs (Detwiler and Baylis, 2003).

### *Geographic distribution*

Scrapie was first recognized in sheep in Great Britain and other countries of Western Europe over 250 years ago. It has been reported in sheep, goats, or both throughout most of the world. Only Australia and New Zealand are recognized by the United States as being free of classical scrapie.

Scrapie was first discovered in the United States in 1947 in a flock of imported sheep of British origin from Canada. Since 1952, Veterinary Services (VS) has worked to control and eradicate scrapie in the United States. The national prevalence of scrapie in cull sheep in 2003 was estimated to be 0.2 percent (National Animal Health Monitoring System, 2004). The national prevalence in sheep has decreased significantly since 2003 and is tracked in monthly and annual reports that can be viewed on the [APHIS National Scrapie Eradication Program website](#).

VS conducted a study from May 2007 through March 2008 to estimate the prevalence of scrapie in goats in the United States. The study featured goats with potentially higher likelihood of infection combined with routine samples collected through regulatory scrapie slaughter surveillance (RSSS). Through the study, VS determined the prevalence of classical scrapie in goats to be less than 0.1 percent (USDA, unpublished data). Monthly and annual reports of U.S. goat scrapie surveillance can be viewed on the [APHIS National Scrapie Eradication Program website](#).

### *Genetics*

Sheep breeders have successfully used genetic-based resistance to reduce scrapie susceptibility within their flocks. For classical scrapie in sheep, the codons at positions 136 and 171 in the gene that codes for amino acids in the prion protein (PrP) have been associated with scrapie susceptibility. Codon 171 is thought to be the major determinant of susceptibility, with glutamine (Q) and histidine (H) conferring susceptibility and arginine (R) resistance. Lysine (K) at codon 171 appears to reduce scrapie susceptibility particularly in the homozygous (KK) state; however, the number of scrapie-inoculated or exposed sheep with the K allele that has been studied is small. Codon 136 affects susceptibility to valine-dependent classical scrapie, which is less common in the United States than valine independent scrapie, with alanine (A) and valine (V) conferring resistance and susceptibility respectively. The effect of other rare alleles at codons 136 and 171 is unknown, so they are considered susceptible for program purposes.

All goats are currently considered genetically susceptible for program purposes. However, in fiscal year (FY) 2020 VS began conducting a study to determine the prevalence of goat PrP codons associated with scrapie resistance in the United States in anticipation of using genetics as an eradication tool.

## 2. Purpose and Rationale

The purpose of the National Scrapie Surveillance Plan is to meet the goals of the National Scrapie Eradication Program (NSEP), which are:

1. To eradicate classical scrapie from the sheep and goat populations in the United States.
2. To document the eradication of classical scrapie.
3. To achieve scrapie-free status in the United States, as described by the World Organisation for Animal Health (WOAH)<sup>1</sup>.

Currently, to meet WOAH guidelines for freedom, a country or region must conduct surveillance for at least 7 years, with 95 percent confidence of detecting scrapie at a prevalence of 0.1 percent of the target population and with no cases of classical scrapie reported during this period.

This surveillance plan is designed to speed the eradication of classical scrapie. Cases of nonclassical (Nor98-like) scrapie will be found because of testing for classical scrapie but the plan is not designed to maximize these detections. Nor98-like scrapie has its own unique characteristics, and the Animal and Plant Health Inspection Service (APHIS) and the WOAH have concluded that it is “clinically, pathologically, biochemically, and epidemiologically unrelated to classical scrapie, may not be contagious and may, in fact, be a spontaneous degenerative condition of older sheep.” As a result, APHIS does not restrict or depopulate animals exposed to Nor98-like scrapie.

The rationales for conducting surveillance and scrapie eradication include:

### *Economic Impact on Industry:*

The presence of scrapie in the United States is estimated to cost American sheep producers \$10 million to \$20 million per year, principally in lost exports of sheep and goat products and breeding stock, semen, and embryos; decreased value of and, in some cases, increased expenditures for offal and carcass disposal; and increased production costs. Infected flocks with a high percentage of susceptible animals can experience significant production losses. Over several years, the number of infected animals in a flock increases and onset of clinical signs occurs in younger animals, making these flocks economically unviable. Susceptible female animals sold from infected flocks can spread scrapie to other flocks.

### *Public Health Perceptions:*

While there is no evidence that scrapie is a human health risk, and there is no significant epidemiological evidence, there is a perception of risk. Consumer concerns about the presence of a TSE in food have increased since the apparent transmission of bovine spongiform encephalopathy (BSE), another TSE, to humans in the United Kingdom. That experience resulted in a call for the eradication of all TSEs in food-producing animals.

## 3. Surveillance Objectives

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<sup>1</sup> Formerly known as the OIE (Office International des Epizooties, its European name); the organization adopted the new acronym earlier this year.

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The surveillance objectives will be addressed in three stages:

*Stage 1: Eradicate scrapie in the U.S. sheep and goat populations by efficiently finding the remaining cases.*

*Stage 2: Continue high-level surveillance to ensure that no cases remain.*

*Stage 3: Maintain sufficient ongoing monitoring to meet WOAHA requirements.*

VS will accomplish the surveillance objectives by detecting infected sheep and goats through active and passive surveillance, tracing infected animals to their flocks or herds of origin, and locating exposed and potentially exposed animals for testing. Depopulation of high-risk animals and long-term monitoring of the flocks in which they resided will follow.

Surveillance will include sampling of both healthy and unhealthy sheep and goats with an emphasis on higher-risk groups, underrepresented flocks and herds, and underrepresented geographic regions missed by current surveillance efforts.

### **4. Changes to the National Scrapie Surveillance Plan**

This plan replaces the 2019 National Scrapie Surveillance Plan. In 2019 we updated the plan to align our scrapie surveillance with the current disease situation and the recently published final rule amending VS' domestic scrapie regulations. These changes included:

- No longer using face color targeting for sheep because there is no longer a measurable difference in scrapie prevalence between the different face colors.
- Sampling untraceable sheep and goats that meet sampling criteria to assure that cases are not missed in this population but limiting the total number sampled per year for cost efficiency. VS credits untraceable animals to the collecting State based on the average percent of animals slaughtered in-State that originated in-State.
- Implementing a risk credit sampling system in FY 2022 to better target sampling toward groups considered to be at higher risk for scrapie.

We are updating the 2019 plan to eliminate regions to make State sampling levels proportional to their respective populations for States with the same risk level.

### **5. Expected Outcomes**

Detection of infected sheep or goats will result in disease control actions that promote eradication of classical scrapie. The expected outcome of the comprehensive surveillance program outlined in this document is the progressive reduction of scrapie prevalence, resulting in the eradication of disease in the U.S. sheep and goat populations. Summary surveillance reports will be [posted](#) monthly and annually. The surveillance system should ideally be evaluated every 3 years or as needed. The data generated from the surveillance program will inform decision-makers about future surveillance needs and trade-related issues.

## 6. Stakeholders and Responsible Parties

**Table 1. Stakeholders and their responsibilities and interests**

Stakeholder	Interest/Responsibility
USDA APHIS VS	<ul style="list-style-type: none"> <li>• Cooperative data sharing</li> </ul>
Field Operations	<ul style="list-style-type: none"> <li>• Jointly responsible with State animal health officials for field implementation, sample collection, data collection, traceability, identification of epidemiological changes related to disease, and coordination of disease response</li> </ul>
Strategy and Policy	<ul style="list-style-type: none"> <li>• Development, evaluation, and revision of the scrapie surveillance plan</li> <li>• Risk-based analysis</li> <li>• Policy and budget</li> <li>• Import, export, and international health status management</li> <li>• Surveillance data management, analysis, and reporting</li> <li>• Coordination of disease response</li> <li>• Development of and implementation planning for pilot projects to test surveillance and response initiatives to increase program efficiency and efficacy</li> </ul>
Diagnostics and Biologics	<ul style="list-style-type: none"> <li>• Diagnostic laboratory support and oversight, reference laboratory services, sample testing and data reporting, diagnostic test development, and validations</li> <li>• Supporting development and implementation of pilot studies</li> </ul>
National Animal Health Laboratory Network (NAHLN)	<ul style="list-style-type: none"> <li>• Sample testing and electronic submission of test information</li> </ul>
APHIS-Marketing and Regulatory Programs Information Technology	<ul style="list-style-type: none"> <li>• Development, modification, and maintenance of data management software and systems to support program efficiency and efficacy</li> </ul>
State animal health officials and field staff	<ul style="list-style-type: none"> <li>• Jointly responsible with VS Area Veterinarians in Charge for field implementation, sample collection, data collection, traceability, identification of epidemiological changes</li> </ul>

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Stakeholder	Interest/Responsibility
	related to disease, and coordination of disease response
Veterinarians, industry field representatives, and individual producers	<ul style="list-style-type: none"> <li>Animal health and production monitoring, rapid disease detection and reporting, sample collection and submission, biosecurity plans, traceability, and support for business continuity</li> </ul>
Academia	<ul style="list-style-type: none"> <li>Research on new diagnostic tests, genetic resistance, disease transmission, introduction pathways, agent inactivation, and risk assessments</li> </ul>
Agricultural Research Service	<ul style="list-style-type: none"> <li>Research on new diagnostic tests, genetic resistance, agent inactivation, and disease transmission</li> <li>Support diagnostic test validation</li> </ul>
Food Safety and Inspection Service (FSIS)	<ul style="list-style-type: none"> <li>Share condemnation information with APHIS</li> <li>Support sample collection of clinical suspects</li> <li>Collect samples at small establishments</li> </ul>
Industry producer groups	<ul style="list-style-type: none"> <li>Industry outreach on disease prevention and detection, sample submissions, clinical suspect reporting, and traceability to enhance producer support for the program</li> <li>Partnering with VS to evaluate and improve program policy</li> </ul>
USDA Foreign Agricultural Service and APHIS International Services, trading partners	<ul style="list-style-type: none"> <li>Trade issues and international disease status report updates</li> </ul>
Commercial diagnostic equipment and reagent companies	<ul style="list-style-type: none"> <li>Manufacture and sales of test platforms, commercial reagents, and assays</li> </ul>
Tag manufacturers	<ul style="list-style-type: none"> <li>Manufacture and record distribution of official sheep and goat identification to support traceability</li> </ul>

## 7. Population Descriptions and Characteristics

Sheep and goat production occur throughout the United States, with the largest adult ewe population concentrated in the west and north. Based on the 2017 Agricultural Census (USDA, NASS, 2019), States producing the most sheep are California, Colorado, Texas, Utah, and Wyoming, collectively representing 42.4 percent of the U.S. inventory. Medium and fine wool white-faced sheep are approximately 58.7 percent of the population, followed by black-faced at 14.9 percent and hair breeds at 11.8 percent (USDA, 2012). In Texas and other western States, sheep production is mainly in range flocks that graze

on large, open rangeland. In the East, sheep production tends to be in concentrated farm settings. The value of the sheep industry is related to the two major uses for sheep: Meat production (lamb) and pelts and wool production, with meat production being the primary source of income.

The U.S. goat population is heavily concentrated in Texas, followed by California, Iowa, Missouri, Oklahoma, Tennessee, and Wisconsin, which collectively represent 53 percent of the U.S. inventory (USDA, NASS, 2019). Goats are primarily used for meat production, 70.1 percent, and milk production, 12.1 percent (USDA, 2010a).

## 8. Terms and Definitions

*Clinical Signs:* Some sheep and goats infected with the scrapie agent may not develop clinical signs before death or culling. Clinical disease only develops when the infection enters the CNS. Due to the influence of host genotype and scrapie agent type, clinical signs vary among individual animals. In general, due to nerve cell damage, affected animals often show behavior changes such as nervousness or aggression, rubbing, and/or incoordination, that progress to recumbency and death. Other clinical signs may include tremors (especially of head and neck), head pressing or “star gazing,” significant weight loss with no decrease in appetite, wool pulling, and hyperesthesia. Additional signs in affected goats may include difficulty milking, premature kidding, and pica. Because of the variability in clinical presentation, clinical diagnosis of scrapie can be difficult. Incoordination is the most common clinical sign.

*Confirmed positive case:* A positive test result on brain or lymphoid tissue at NVSL (or a laboratory to which NVSL has referred a case for testing) that is not consistent with nonclassical scrapie; through: (1) Histopathological examination of CNS tissues from the animal for characteristic microscopic lesions of scrapie; (2) the use of proteinase-resistant protein analysis methods including but not limited to immunohistochemistry, Western blotting (WB), and/or enzyme-linked immunosorbent assay (ELISA) on CNS and/or peripheral tissue samples from a live or a dead animal for which a given method has been approved by the APHIS Administrator for use on that tissue; (3) bioassay; or (4) scrapie-associated fibrils detected by electron microscopy.

(Note: Only those sheep and goats tested using an official test that are *confirmed positive* for classical scrapie by NVSL or a laboratory to which NVSL referred a case for such testing are designated as classical scrapie cases. The identification of *suspect cases* leads to further investigation, but these cases are not considered classical scrapie cases until confirmatory test results have been reported.)

*Incubation period:* Scrapie-infected animals rarely show clinical signs of infection before the age of 2 years, with the typical age of clinical onset between 3 and 4 years.

*Presumptive positive case:* Has tested positive on an official test at an approved laboratory (reported by the laboratory as “suspect”) but has not been confirmed positive.

*Suspect animal:* A sheep or goat meeting at least one of the following criteria is considered a scrapie suspect:

- 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 CNS signs, or that 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 title 9, *Code of Federal Regulations* (9 CFR) 79.4.

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

## 9. Diagnostic Testing

Nearly all scrapie testing in the United States is conducted using immunohistochemistry (IHC) at laboratories within the NAHLN or at NVSL. Testing is performed on CNS and/or lymphoid tissues (i.e., obex and rarely cerebellum or other brain tissue; or lymph node, tonsil, third eyelid, anorectal lymphoid tissue, or other lymphoid tissue). The IHC test on obex or lymphoid tissue is considered the gold standard, and VS considers this test 100 percent specific and, for acceptable obex samples from clinical animals, 100 percent sensitive.

Scrapie type may be characterized as classical or nonclassical (Nor98-like) scrapie by performing IHC or WB assay on obex samples; WB is 98 percent sensitive and 100 percent specific relative to IHC on the same tissue. All cases that produce non-negative results are submitted to NVSL for further evaluation. NVSL may use other methods alone or in combination, including IHC, WB, histopathology, ELISA, or animal inoculation studies (i.e., bioassay) to determine whether a sample presents classical or nonclassical (Nor-98-like) scrapie.

## 10. Sampling Parameters, Sources, and Criteria

VS and State officials will sample mature sheep and goats to meet the State's surveillance stage objectives. Stage 1 of eradication focuses surveillance on sampling at higher levels in States with unknown or higher risk status. States will progress to Stage 2 based on meeting their surveillance minimums and not detecting any scrapie cases. In Stage 2, their required sampling minimums will decrease while maintaining a high degree of statistical confidence for disease detection. States that have a scrapie case will be returned to Stage 1 sampling until they requalify for Stage 2. Once the United States has been free of scrapie cases for 7 years all States will move into Stage 3 ongoing nationwide monitoring that meets or exceeds WOAHP requirements for disease freedom.

State-level annual sampling targets will be set based on the population demographics of mature sheep and goats in each State. Population estimates are based on the NASS Census of Agriculture and annual sheep and goat inventory information. Annual State sampling minimums will continue to be published on the Sheep and Goat Health [SharePoint site](#) by April 1 for the upcoming fiscal year. States will then have time to review their minimums and can appeal any potential discrepancies in the population figures, surveillance stage, or published minimums.

FY 2020 surveillance minimums were increased for goats in most States to bring sampling to a similar detection level as for sheep. The scrapie program final rule was published March 25, 2019, making the Federal goat identification requirements the same as for sheep. The new mandatory goat identification requirements allow a greater number of mature goats to be sampled and credited to the correct State for surveillance purposes, which minimized the impact of these increases. The planned risk credit incentive system to target higher-risk animals should also provide alternative opportunities to meet the sampling minimums. There will be a 2-year period to ramp up (FY 2021 and 2022) to the surveillance minimums before any negative impacts on Consistent State status will apply (see [VSG 7207.1 Scrapie Consistent State Status Compliance](#)). States will be expected to meet their minimums for FY 2023.

### ***Sampling parameters:***

*Stage 1 States: Eradicate scrapie in the U.S. sheep and goat population by finding the remaining cases*

Stage 1 State sampling minimums for targeted mature sheep will provide samples for 6 out of every 1,000 breeding ewes in the population (0.6 percent), except Texas which is set at 1,000 sheep per year. Surveillance for mature goats was initially set at Stage 2 for all States to allow time for the new goat ID requirements to be implemented.

States that meet their sampling targets for a minimum of 4 out of the preceding 5 years and that have not detected a positive classical scrapie case in sheep or goats in the past 7 years will then be eligible to move into Stage 2 surveillance.

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### *Stage 2 States: Continue high-level surveillance to ensure that no cases remain*

Stage 2 States for mature sheep surveillance are those that have completed Stage 1 sampling requirements and are given reduced State-level annual sampling minimums. Stage 2 State sampling minimums for targeted mature sheep require sampling of 4 out of every 1,000 breeding ewes in the population (0.4 percent).

Stage 2 sampling minimums for targeted mature goats require sampling of 4 out of every 1,000 mature does in the population (0.4 percent), except Texas which is set at 1,000 goats per year. If a positive sheep or goat is detected, then that State will be moved to Stage 1 in the following year for sheep and goats. Stage 1 mature goat sampling minimums are the same as for Stage 1 for mature sheep (0.6 percent).

Additional States will be added to surveillance Stage 2 annually as they meet the Stage 1 criteria. If a State detects a positive scrapie case in either sheep or goats, that State will be reclassified to Stage 1 status.

Sampling capacity freed up because of these reductions will be redirected to increase sampling in undersampled populations. When all States have reached their proportionate State-level annual sampling targets for a minimum of 7 consecutive years (including previous Stage 1 years) without a positive scrapie case being identified in either sheep or goats, national surveillance will move to Stage 3.

### *Stage 3 States: Maintain sufficient ongoing monitoring to meet WOAHP requirements*

The WOAHP requires demonstrating freedom from disease annually by adequate sampling of targeted sheep and goats for 95 percent confidence of detection at less than 0.1 percent prevalence nationally for 7 years. Once all States have met Stage 2 criteria, total sampling nationally will be at least 3,000 sheep and 3,000 goats annually, geographically proportionally distributed, to maintain the surveillance above the level required by the WOAHP for disease freedom and provide confidence to our trading partners.

### ***Sampling sources:***

The U.S. scrapie surveillance program consists of multiple components:

*Regulatory scrapie slaughter surveillance (RSSS).* The RSSS targets mature sheep and goats slaughtered or condemned at participating slaughter facilities, as well as dead or disabled animals found at other concentration points, including markets and cull feedlots.

*On-farm monitoring:* This component consists of samples from animals tested on a premises for one of the following reasons: 1) Scrapie Flock Certification Program (SFCP) - to obtain certification or monitored status, or 2) Post Exposure Monitoring and Management Plan (PEMMP) – samples from a flock that was previously exposed to scrapie and is under a monitoring and management plan, or 3) voluntary on-farm surveillance (not part of SFCP) of mature sheep or goats that die, from live animal testing of susceptible sheep or goats in flocks with risk factors for scrapie, or from sheep and goats that reside in States that cannot meet their sampling minimums through other methods.

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### *Disease investigations:*

*Exposed susceptible animals.* This component includes samples from scrapie-exposed susceptible animals that are not being managed under a PEMMP, typically submitted from animals with known exposure to infected females or that resided in a flock at a time it was believed to have been infected, based on the epidemiology of the flock/herd. Source/infected flocks are often identified through epidemiological trace investigations from classical scrapie-confirmed cases discovered through RSSS or from on-farm components.

*Potentially exposed susceptible animals.* This component consists of testing animals exposed to a traced high-risk ewe or doe that is not available for testing (missing ewe investigations). These animals serve as surrogates for the high-risk animal.

*Suspect animals.* The suspect animal component consists of samples from animals submitted with clinical signs consistent with scrapie. This includes animals reported to APHIS or the State veterinarian by accredited veterinarians or owners, mature animals submitted for necropsy to diagnostic laboratories, sheep and goats condemned at slaughter for CNS signs, and animals submitted to public health laboratories that test negative for rabies. Samples from this component have the highest probability of having scrapie.

### **Sampling criteria:**

#### *RSSS*

All sheep and goats 18 to 72 months of age, regardless of traceability, are eligible to be sampled at slaughter. This change was made in 2019 because RSSS data analysis has shown that the apparent prevalence of scrapie in 2-, 3-, or 4-year-old sheep is higher than in sheep that are age 1-year or over 5 years and that there is no longer a measurable difference in the prevalence of scrapie in sheep of different face colors<sup>2</sup>. Also, as we approach freedom, it is critical to demonstrate that we are not missing cases in the untraceable population.

In addition to the apparently healthy sheep and goats sampled at slaughter for scrapie surveillance, all animals presenting with clinical signs of scrapie at slaughter are to be tested for scrapie regardless of age. Signs used to target clinical animals are nonspecific (i.e., severe rubbing, wool loss with abraded or hyperpigmented skin, incoordination, weakness, nonambulatory, and/or other evidence of a potential CNS disorder). Other mature sheep and goats that are dead prior to slaughter or condemned on antemortem inspection should also be tested.

#### *On-Farm*

Non-slaughter surveillance is targeted toward groups considered to be at higher risk for scrapie or that are not being sampled at participating slaughter facilities. This includes suspect animals reported to

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<sup>2</sup> Among cull sheep entering slaughter in 2002-2003, the prevalence of scrapie in apparently healthy black- and mottled-faced sheep was greater than in white-faced sheep (0.85 percent, 0.12 percent, and less than 0.01 percent, respectively) and black-faced sheep were 38 times more likely to be infected than white- or mottled-faced sheep (NAHMS 2004). Since the implementation of RSSS in 2003, the estimated prevalence of scrapie in apparently healthy black- and mottled-faced sheep has decreased significantly. There is no longer a statistical difference in prevalence between white-, mottled-, and black-faced sheep. The decline in prevalence in black- and mottled-faced sheep is primarily due to breeding for genetic resistance along with the removal of infected flocks.

APHIS or the State veterinarian by accredited veterinarians or owners, animals that are part of a PEMMP, mature animals submitted for necropsy to diagnostic laboratories, animals submitted to public health laboratories that test negative for rabies, live animal testing, and samples from mature dead animals voluntarily submitted by producers for scrapie testing. Additionally, non-slaughter animals are tested as part of the SFCP to obtain certification or monitored status. Sheep and goat producers participating in the SFCP are required to report and submit for testing any animals that exhibit clinical signs and mature animals that die on the farm while enrolled in the program.

***Risk Factors and Risk Credit Incentive System:***

In addition to the sample collection criteria, a risk credit sampling system will be partially implemented in FY 2022, with full implementation expected by FY 2023, to better target sampling toward groups considered to be at higher risk for scrapie (risk credit incentive sampling criteria will be posted at [USDA APHIS | National Scrapie Eradication Program](#)). Unlike previous targeting for scrapie, the final risk credit sampling system will include both individual animal and flock characteristics, which will allow credits to be assigned based on risk information for animals sampled on farm. As our information system evolves, it may also be possible to apply flock risk criteria to some RSSS samples. Animals with higher risk characteristics (e.g., higher risk age, genotype, or observed clinical signs/slaughter condemnation codes) or coming from farms with higher risk characteristics (e.g., breeding stock genetic selection practices or exposure to high-risk animals) will be of higher surveillance value than the animals with lower risk characteristics. In this way, the sampling efforts can be targeted toward a broader collection of higher surveillance value animals compared to the targeted sheep sampling on age and face color alone that has been performed since RSSS started in 2003. Sample collectors will enter relevant information when submitting samples and credits will be assigned during data aggregation and analysis.

Untraceable animals will be credited to the collecting State based on average percent of animals slaughtered in-State that originated in-State. The credit totals, by State, will be reported monthly so that States can monitor their progress toward achieving their sampling minimums.

## **11. Data Collection and Storage**

Surveillance data is captured via the Surveillance Collaboration Services Scrapie (SCS SCR) database and the Veterinary Services Laboratory Submission System (VSLS), or their successor data collection systems. SCS SCR is an electronic database that captures animal, flock, and associated data entered by VS or State field personnel. VSLS is an electronic laboratory submission system intended as a common entry vehicle for APHIS laboratory accession and results data.

RSSS summary data collected on the day of submission includes the number of mature animals with official identification, the number of goats slaughtered, the number of sheep slaughtered, the number of black- and mottled-faced sheep slaughtered, and the total number of heads sampled, in addition to collector and collection site information. Data collected for each individual animal sampled include the following: Animal identification, age, gender, face color (sheep), and designation (i.e., non-clinical, clinical, suspect, known exposed, SFCP, or tested at discretion of the scrapie regional epidemiologist). Additional data needs to be collected from on-farm sample collections to assign risk credit values to the samples collected. These additions to the current system are still under construction and will be developed so that sample collection staff can easily enter the data.

## 12. Data Reporting

Monthly and annual surveillance reports are posted on the external Sheep and Goat Health [SharePoint site](#) that is accessible to State and Federal animal health personnel. These reports include State, district, and national-level collection data that allow animal health officials to track their progress toward surveillance targets and to review their historical submission data. Enhancements to the current system are in progress and will use Palantir (Data Integration Service or DIS) software to refine the detail of the reported surveillance data and to better use other sources of surveillance data (e.g., Animal Identification Number Management System animal identification data). This information is summarized in monthly and annual reports available to the public on the [APHIS VS NSEP web page](#).

## 13. Data Analysis, Interpretation, and Metrics

Data will be analyzed for the following:

1. Prevalence estimation until eradication is achieved.
2. Representativeness.

Evaluate representativeness by considering targeting criteria. For example, operations with more risk factors should make up a greater proportion of the on-farm sampling efforts. To achieve greater representativeness of the entire State, the number of samples from any individual premises should not exceed 30 per year. Additionally, for individual animals, targeted age groups and clinical suspects should result in a greater proportion of samples in the target age range or number of clinical suspects tested.

### *Geographic*

The geographic distribution of samples should generally reflect the population distribution of U.S. sheep and goats within each stage as described above. Animals will be assigned to States based on their official ear tag, other official identification, or by other means of identification (lot numbers, back tags, etc.). With targeted sampling as outlined in this plan, we expect that more samples will come from Stage 1 States as a percentage of population.

### *Temporal*

Surveillance sampling efforts for both sheep and goats should be continuous throughout the fiscal year. Due to the seasonal, economic, and weather impacts on culling rates, there will be increases after offspring are weaned, if extreme weather conditions exist, or if there is a marked decline in slaughter lamb value.

3. Targeting criteria.

Compliance with targeting criteria and whether the targeting criteria remain appropriate.

4. Appropriateness of the risk credit incentive sampling system.

Appropriateness of the risk credit values and effect of the risk credit system on the frequency of sampling classes of animals with different surveillance values.

5. Sample quality.

The number of invalid specimens should remain below the historical value of 0.02 percent of total specimens collected.

6. Timeliness.

Samples should be submitted as quickly as possible, but no later than 1 week after collection to ensure that samples submitted are also useable for genotype testing. Contract laboratories are required to return test results within 10 business days of sample receipt.

## **14. Surveillance Plan Implementation**

This surveillance plan and the new sampling minimum calculations are in effect for FY 2022. Historical scrapie surveillance will be analyzed at the conclusion of each fiscal year and those States that have met the criteria will be moved to the appropriate surveillance stage for the following fiscal year. Goat surveillance minimums for FY 2022 are intended to bring goat-sampling levels in line with sheep and reflect the new VS district population calculations. The levels will change in some States.

## References and Website Links

USDA APHIS VS: National Scrapie Surveillance Plan, June 2019

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USDA APHIS VS CEAH National Animal Health Monitoring System. Phase II: Scrapie: Ovine Slaughter Surveillance Study 2002-2003, January 2004

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OIE Manual of Diagnostic Tests and Vaccines for Terrestrial Animals 2021. Chapter 3.8.11. Scrapie.

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USDA APHIS 9 CFR Parts 54 and 79 Scrapie in Sheep and Goats; Interstate Movement Restrictions and Indemnity Program; Final Rule

[https://www.aphis.usda.gov/animal\\_health/animal\\_diseases/scrapie/downloads/final-rule-07-127-3.pdf](https://www.aphis.usda.gov/animal_health/animal_diseases/scrapie/downloads/final-rule-07-127-3.pdf)

USDA APHIS VS CEAH SDA: A Comprehensive Analysis of National Scrapie Surveillance in U.S. Sheep and Goats, FY 2012 – 2016 (2018) (Internal VS Document; not linkable)

[VSG 7207.1 Scrapie Consistent State Status Compliance \(Internal VS Sharepoint Link\)](#)

Annual State minimums and risk credit sampling value table

[Sheep and Goat Health - State Sampling Minimums - FOR OFFICIAL USE ONLY - All Documents \(sharepoint.com\)](#)

Monthly and annual surveillance reports

<https://usdagcc.sharepoint.com/sites/aphis-vs-sgh/Nation%20Scrapie%20Reports/Forms/Item%20Alpha.aspx?viewpath=%2Fsites%2Faphis%2Dvs%2Dsgh%2FNation%20Scrapie%20Reports%2FForms%2FItem%20Alpha%2Easpx>

[USDA APHIS | National Scrapie Eradication Program](#)