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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 (U.S.) as being free of classical scrapie.

Scrapie was first discovered in the U.S. 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 U.S. 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. APHIS estimated prevalence below 0.006 percent in fiscal years (FY) 2016-2018 (95 percent upper bound).

VS conducted a study from May 2007 through March 2008 to estimate the prevalence of scrapie in goats in the U.S. The study featured goats with potentially higher likelihood of infection combined with routine samples collected through Regulatory Scrapie Slaughter Surveillance (RSSS), and the prevalence of classical scrapie in goats was determined to be less than 0.1 percent (USDA, unpublished data). The national prevalence in goats was estimated to be below 0.02 percent from FY 2016-2018 (95 percent upper bound).

Genetics

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 have been studied is small. Codon 136 affects susceptibility to valine-dependent classical scrapie, which is less common in the U.S. 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, VS is considering conducting a genetic-based herd clean-up pilot project for infected and source goat herds. VS is also planning studies to determine the prevalence of goat PrP codons associated with scrapie resistance in the U.S. 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 population in the U.S.,
2. To document the eradication of classical scrapie, and
3. To achieve scrapie-free status in the U.S., as described by the World Organisation for Animal Health (OIE)

Currently, to meet OIE guidelines for freedom, a country or region must conduct surveillance for at least seven years, with 95 percent confidence of detecting scrapie at a prevalence of 0.1 percent of the target population and with no case 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 OIE 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 rationale for conducting surveillance and scrapie eradication include:

Economic Impact on Industry:

The presence of scrapie in the U.S. is estimated to cost American sheep producers \$10-20 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

The surveillance objectives will be addressed in three stages:

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

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Stage 2: Continue high-level surveillance to ensure that no cases remain, and

Stage 3: Maintain sufficient ongoing monitoring to meet OIE requirements.

The surveillance objectives will be accomplished 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 that current surveillance efforts are missing.

4. Changes to the 2010 National Scrapie Surveillance Plan

This plan replaces the 2010 National Scrapie Surveillance Plan. We updated the plan to align our scrapie surveillance with the current disease situation and the recently published Scrapie Final Rule.

- Face color targeting will no longer be used for sheep because there is no longer a measurable difference in scrapie prevalence between the different face colors.
- Untraceable sheep and goats that meet sampling criteria will also be sampled to assure that cases are not missed in this population; however, the total number sampled per year will be limited for cost efficiency. Untraceable animals will be credited to the collecting State based on the average percent of animals slaughtered in-State that originated in-State.
- A point system will be implemented by FY 2021 to better target sampling toward groups considered to be at higher risk for scrapie.

State surveillance minimums will be based on historical sampling and scrapie status and will occur in stages (described in detail later in the document) that meet the surveillance objectives. Specific changes, by species, include:

Sheep

- States that achieve 90 percent or more of their annual minimums for 4 out of the past 5 years, and that have not had a positive scrapie case for a minimum of 7 years; will be placed into surveillance regions with lower surveillance minimums.
- States that remain in the first stage will continue to have surveillance minimums that will facilitate eradication at the State level. Stage 1 States with smaller sheep populations will be grouped with similar nearby States for sample calculations. This will provide better geographically distributed surveillance without overburdening less populated States.
- The final stage will set proportional State sampling minimums at a level that meets or exceeds OIE requirements for disease freedom on a national basis.

Goats

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- The Scrapie Final Rule now requires official identification for goats. This will allow a level of surveillance that we have previously been unable to achieve for goats.
- States will be grouped into their current VS Districts and State minimums will be proportionately calculated at a level that will facilitate eradication at the district level.
- Individual States that achieve 90 percent or more of their annual minimums for 4 out of the past 5 years, and that do not identify a positive scrapie case for a minimum of 7 years; will be placed into surveillance regions with lower surveillance minimums.
- The final stage will set proportional State sampling minimums at a level that meets or exceeds OIE requirements for disease freedom on a national basis.

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. Surveillance reports will be summarized monthly and annually and the surveillance system should ideally be evaluated once every 3 years or as requested by the Sheep and Goat Team. 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"> • Cooperative data sharing
Field Operations	<ul style="list-style-type: none"> • 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
Strategy and Policy	<ul style="list-style-type: none"> • Development, evaluation, and revision of the scrapie surveillance plan • Risk-based analysis • Policy and budget • Import, export, and international health status management • Surveillance data management, analysis, and reporting • Coordination of disease response • Development of and implementation planning for pilot projects to test surveillance and

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Stakeholder	Interest/Responsibility
	<p>response initiatives to increase program efficiency and efficacy</p>
Diagnostics and Biologics	<ul style="list-style-type: none"> • Diagnostic laboratory support and oversight, reference laboratory services, sample testing and data reporting, diagnostic test, development and validations • Support the development and implementation of pilot studies
National Animal Health Laboratory Network (NAHLN)	<ul style="list-style-type: none"> • Sample testing and electronic submission of test information
APHIS-Marketing and Regulatory Programs Information Technology	<ul style="list-style-type: none"> • Development, modification, and maintenance of data management software and systems to support program efficiency and efficacy
State animal health officials and field staff	<ul style="list-style-type: none"> • Jointly responsible with VS Area Veterinarian In Charge for field implementation, sample collection, data collection, traceability, identification of epidemiological changes related to disease, and coordination of disease response
Veterinarians, industry field representatives, and individual producers	<ul style="list-style-type: none"> • Animal health and production monitoring, rapid disease detection and reporting, sample collection and submission, biosecurity plans, traceability and support for business continuity
Academia	<ul style="list-style-type: none"> • Research on new diagnostic tests, genetic resistance, disease transmission, introduction pathways, agent inactivation, and risk assessments
Agricultural Research Service	<ul style="list-style-type: none"> • Research on new diagnostic tests, genetic resistance, agent inactivation, and disease transmission • Support diagnostic test validation
Food Safety and Inspection Service (FSIS)	<ul style="list-style-type: none"> • Share condemnation information with APHIS • Support sample collection of clinical suspects • Collect samples at small establishments
Industry producer groups	<ul style="list-style-type: none"> • Industry outreach on disease prevention and detection, sample submissions, clinical suspect reporting and traceability to enhance producer support for the program

Stakeholder	Interest/Responsibility
	<ul style="list-style-type: none"> Partnering with VS to evaluate and improve program policy
USDA Foreign Agricultural Service and APHIS International Services, trading partners	<ul style="list-style-type: none"> Trade issues and international disease status report updates
Commercial diagnostic equipment and reagent companies	<ul style="list-style-type: none"> Manufacture and sales of test platforms, commercial reagents and assays
Tag manufacturers	<ul style="list-style-type: none"> Manufacture and record distribution of official sheep and goat identification to support traceability

7. Population Descriptions and Characteristics

Sheep and goat production occur throughout the U.S., 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 Texas, California, Wyoming, Utah, and Colorado, 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, Wisconsin, Tennessee, Oklahoma, Iowa, and Missouri, 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. Case Definition and Diagnostics

Please note the case definition is undergoing further review and will be updated when appropriate.

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 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.

Incubation period: Scrapie-infected animals rarely show clinical signs of infection before the age of two years, with the typical age of clinical onset between three and four years.

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For classical scrapie surveillance and disease eradication, only those sheep and goats tested using an official test that are *confirmed positive* for classical scrapie by the National Veterinary Services Laboratories (NVSL—or a laboratory to which the 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.

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

Has been condemned by the Food Safety and Inspection Service (FSIS) or a State inspection authority for CNS signs or rabies; **or**

Exhibits any of the previously listed clinical signs compatible with scrapie **and** has been determined to be suspicious for scrapie by an accredited veterinarian or State or USDA representative; **or**

Has tested suspect or inconclusive on an official test for scrapie at NVSL (or a laboratory to which the NVSL has referred a case for such testing); **or**

Has a positive test result for scrapie or for the protease-resistant protein associated with scrapie on an unofficial test or a screening test and no or inadequate tissue was available for confirmatory testing.

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.

Confirmed positive case: A positive test result on brain or lymphoid tissue at NVSL (or a laboratory to which the 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.

Diagnostic Testing:

Nearly all scrapie testing in the U.S. 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 on obex and/or WB assay; 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 using IHC. Other methods may also be used alone or in combination, including IHC, WB, histopathology, enzyme immunosorbent assay, ELISA, or animal inoculation studies (i.e., bioassay). For an animal to be considered a classical scrapie case, NVSL must confirm that the result is positive for classical scrapie based on testing at NVSL or review tests conducted at another laboratory.

9. Sampling Parameters, Sources, and Criteria

Mature sheep and goats will be selected for sampling within a region to meet the region's surveillance stage objectives. As States/regions progress through each stage, the regional surveillance areas and their associated populations will become larger while maintaining a high degree of statistical confidence for disease detection. The initial stage of eradication will focus surveillance on smaller populations within tighter geographic boundaries. Ultimately, surveillance sampling will reach the goal of ongoing nationwide monitoring that meets or exceeds OIE requirements for disease freedom.

Annual State sampling minimums will continue to be published on the [SharePoint site](#) by April 1 for the upcoming fiscal year¹. States will then have time to review their minimums and have the opportunity to 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 will allow a greater number of mature goats to be sampled and credited to the correct State for surveillance purposes, which should minimize the impact of these increases. There were also changes in sheep sampling numbers, with a few States increasing sampling to implement a more risk-based regional approach. The planned points 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 to the new surveillance targets before any negative impacts on Consistent State status will apply.

Sampling parameters:

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

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. States with small populations of sheep may be grouped with contiguous States when calculating sample sizes, but each State will then be given a minimum proportionate annual sampling target. Because most States have relatively small populations of goats, surveillance targets will be based on the goat population in each VS district (with the exception of Texas) and each State will be given a proportionate annual sampling target.

State sampling minimums for targeted mature sheep will provide 95 percent confidence of detection at 0.1 percent prevalence over a 3-year period (i.e., 1,000 samples per year in each multi-State area; 1,000 samples per year in each single-State area). State sampling minimums for targeted mature goats will also provide 95 percent confidence of detection at 0.1 percent prevalence over a 3-year period (i.e., 1,000 samples per year in each VS District; 1,000 samples per year in Texas).

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 be grouped into larger surveillance regions within the same geographic proximity (Stage 2).

¹ Due to the surveillance plan revision, posting of the minimums was delayed for FY 2020. States are allowed 6 months from the date the minimums are posted to appeal their minimums.

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

Surveillance regions will be formed from States that have achieved Stage 1 sampling requirements and have been given reduced State-level annual sampling minimums. Sampling will be proportionately distributed within the given surveillance regions based on the population demographics of mature sheep and goats in each region. New States will be added to the surveillance regions annually as they meet the Stage 1 criteria (Note: VS districts will be considered when establishing scrapie surveillance regions). If a State detects a positive scrapie case in either sheep or goats, then that State will be reclassified to Stage 1 status.

Sampling levels of targeted mature sheep and goats will provide 95 percent confidence of detection at 0.1 percent prevalence at the regional level over a 1-year period. Sampling capacity freed up because of these reductions would be redirected to increase sampling in under-sampled 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, we will move to Stage 3.

Stage 3 States: Maintain sufficient ongoing monitoring to meet OIE requirements

The OIE 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 approximately 3,000 sheep and 3,000 goats annually to maintain the surveillance above the level required by OIE 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.

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 epidemiologic trace investigations from classical scrapie-confirmed cases discovered through RSSS or from on-farm components.

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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 age 2, 3, 4, and 5 years regardless of traceability will now be eligible to be sampled at slaughter. This change was made 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 colors². 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, non-ambulatory, 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 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 Point System:

² 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.

In addition to the sample collection criteria, a point system will be implemented by FY 2021 to better target sampling toward groups considered to be at higher risk for scrapie. Unlike previous targeting for scrapie, the point system contains both individual animal and flock characteristics, which allow points to be assigned, based on both types of 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 (for example, higher risk age, genotype, or observed clinical signs/slaughter condemnation codes) or coming from farms with higher risk characteristics (for example, breeding stock genetic selection practices or exposure to high-risk animals) will be of higher value than the animals with lower risk characteristics. In this way, the sampling efforts can be targeted toward a broader collection of higher 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 points 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 point totals, by State, will be reported monthly so that States can monitor their progress toward achieving their sampling minimums.

10. 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). 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 point 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.

11. Data Reporting

Monthly and annual surveillance reports are posted on the external [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 software to refine the detail of the reported surveillance data and to better use other sources of surveillance data (e.g., AIMS animal identification data). This information is summarized in monthly and annual reports available to the public on the [APHIS VS NSEP web page](#).

12. Data Analysis, Interpretation, and Metrics

Data will be analyzed for the following:

1. Prevalence estimation until eradication is achieved
2. Representativeness

Representativeness should be evaluated by considering targeting criteria. For example, operations with more risk factors should make up a greater proportion of the on-farm sampling efforts. In order 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 point system

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

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 one 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.

13. Surveillance Plan Implementation

This surveillance plan and the new sampling minimum calculations will go into effect for FY 2020. 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 2020 are intended to bring goat-sampling levels in line with sheep and will reflect the new VS district population calculations. The levels will increase in most States. We anticipate that these increases will be attainable once the Scrapie Final Rule (effective April 24, 2019) is fully implemented. Under the final rule, goat identification is mandatory.

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