National Scrapie Surveillance Plan

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Animal and Plant Health Inspection Service
Veterinary Services
Centers for Epidemiology and Animal Health
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Executive Summary

Scrapie is a transmissible spongiform encephalopathy (TSE) affecting sheep and goats. The presence of this disease in the U.S. sheep and goat population economically affects industry through production losses, lost exports, and increased production and disposal costs. Potential public health concerns related to the transmission of bovine spongiform encephalopathy (BSE) to humans have resulted in efforts to eradicate all TSEs in food-producing animals.

Surveillance for scrapie in the United States is conducted through the National Scrapie Eradication Program (NSEP), a cooperative State-Federal-industry program. The current surveillance components of the NSEP include:

1. Regulatory Scrapie Slaughter Surveillance (RSSS);
2. Non-slaughter surveillance (e.g., trace investigations, on-farm testing); and
3. The Scrapie Flock Certification Program (SFCP).

The program's goals are to eradicate classical scrapie in the United States and to meet World Organization for Animal Health (OIE) criteria for disease freedom. Since 2002, the prevalence of scrapie has decreased significantly through existing eradication efforts, largely a result of effective slaughter surveillance.

In order to achieve the goal of eradication, efforts must focus on improving the flock-level sensitivity and increasing surveillance to find the remaining cases. This will require a transition to demographic-based surveillance and subsequently to flock-level surveillance. This will be accomplished by sampling apparently healthy and clinical sheep and goats at slaughter and enhancing on-farm surveillance efforts, including specifically targeting underrepresented flocks/herds and geographic regions. This effort will require enhancing the following surveillance activities:

1. Passive observation and reporting, by enhancing disease awareness of producers and veterinarians;
2. Laboratory surveillance, by ensuring appropriate samples from targeted and clinical animals are forwarded to Veterinary Services' National Veterinary Services Laboratories (NVSL) or an approved contract laboratory; and
3. Active surveillance, by expanding existing slaughter surveillance, enhancing on-farm surveillance, conducting trace investigations, and incorporating monitoring of SFCP participants.

VS regional and field staff will need to work together to develop effective implementation plans to achieve their State-level targets, including expanding surveillance into underrepresented areas and/or flocks and herds, and increasing identification compliance.

Additional surveillance initiatives have been implemented or are under development to address existing gaps in surveillance. These include surveillance to establish the prevalence of scrapie in goats sent to slaughter and surveillance of export cull ewes.

This surveillance plan focuses on the eradication of classical scrapie from the U.S. sheep and goat population. Until more is known about the epidemiology and impact of nonclassical scrapie (i.e., Nor98, Nor98-like and atypical scrapie), it is unknown whether eradication of nonclassical scrapie is necessary or feasible. Once eradication has been achieved, surveillance efforts will need to shift from detecting (and removing) the remaining cases to high-level monitoring to document the absence of disease in the United States. This will require revisions to the National Scrapie Surveillance Plan.

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).

A. Etiologic Agent

The agent responsible for scrapie and other TSEs is smaller than the smallest known virus and has not been completely characterized. There are a variety of theories regarding the nature of the agent. The most widely accepted is that disease is caused by an infectious protein or prion that causes the normal cellular version of the protein to change shape such that it can no longer be degraded by the cell, causing the protein to accumulate and damage the cell. The agent is extremely resistant to heat and to normal sterilization processes and does not evoke any detectable immune response or inflammatory reaction in sheep and goats.

Scrapie isolates have been classified into "strains" by various researchers. Strains of scrapie differ by the incubation period, brain pathology, clinical manifestations, interspecies transmission capability, and biochemical characteristics (Morales et al. 2007). However, because much still remains unknown about the disease agent, the significance of grouping scrapie isolates into the different strains based on these characteristics remains unclear. Another way to group scrapie isolates or cases into types is by their epidemiology in sheep and goats. Only three epidemiologically distinct types of scrapie are known to exist in the United States: valine-dependent classical scrapie, valine-independent classical scrapie and Nor98-like nonclassical scrapie. Since the United States Department of Agriculture (USDA) Animal and Plant Health Inspection Service (APHIS) Veterinary Services (VS) does not use strain classification to determine regulatory action when a scrapie-case is detected, this document will refer to the epidemiological types of scrapie that have been observed in the United States.

B. History and Distribution

Scrapie is the oldest known TSE. It was first recognized in sheep in Great Britain and other countries of Western Europe over 250 years ago. Scrapie has been reported in sheep worldwide, affecting many sheep-producing regions. Naturally occurring scrapie has also been reported in goats in the United States, Canada, Cyprus, Finland, France, Greece, Italy, Switzerland, and the United Kingdom. Only Australia and New Zealand are recognized by the United States as being free of scrapie.

Scrapie was first discovered in the United States in 1947 in a flock that had imported sheep of British origin from Canada. Since 1952, VS has worked to control and eradicate scrapie in the United States. The latest prevalence estimate for scrapie in the United States was determined in 2003, when the overall weighted national prevalence in mature cull sheep was estimated to be 0.2 percent (National Animal Health Monitoring System, 2004). In the United States, scrapie has primarily been

reported in the Suffolk breed, although it has also been identified in a number of other breeds and in crossbreeds (Wineland et al. 1998).

Two types of classical scrapie have been identified in the United States. The more prevalent type is valine-independent scrapie, whereas the less common is valine-associated scrapie. However, Nor98-like scrapie, a nonclassical scrapie, has been detected in the United States since 2006.

C. Epidemiology

Under natural conditions, only sheep and goats are known to be affected by scrapie. However, experimentally, scrapie can be transmitted to other ruminants, primates, cats, and a variety of rodents. Once infected, the animal remains infected for life. The disease is always fatal; however, it is common for infected animals to die first of other diseases or trauma. The scrapie agent may be found in some lymphoid tissue 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).

Transmission of the scrapie agent is not completely understood, and apparently healthy sheep infected with the agent can transmit disease. Susceptibility to infection and incubation period in sheep has been shown to be affected by sheep genetics and breed (Baylis and Goldman 2004; Baylis et al. 2002; Belt et al. 1995; Hunter et al. 1996; Hunter et al. 1997). The long incubation period between exposure and clinical disease may allow animals to shed the agent for an extended period. 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, and sheep and goats are typically infected as young lambs or kids. Placental infectivity occurs in the incubation/preclinical stage of disease but is not constant with every pregnancy. Genetically susceptible lambs born to dams that develop clinical scrapie have a higher risk of developing the disease. Ram genetics will contribute to scrapie susceptibility in their offspring. Infected rams are not known to transmit scrapie.

Direct horizontal transmission likely accounts for scrapie cases in heavily infected flocks, where spread most likely occurs via an oral route. Infection also likely occurs via ocular exposure or contact with abraded skin or mucous membranes (Detwiler and Baylis 2003). Transmission to lambs through milk from infected ewes has been reported, as well as subsequent horizontal transmission among lambs (Konold et al. 2008). Other infectious tissues have also been found, including: central nervous tissue, lymphoid tissue, peripheral nerves, blood, muscle, liver, nasal mucosa, and salivary glands (Detwiler and Baylis 2003). Environmental contamination with the disease agent also likely plays a role in the introduction of scrapie into new flocks and its spread. Scrapie has recurred on farms after culling; studies show the agent may survive in the environment for years, with the longest reported duration at least 16 years (Georgsson et al. 2006).

Risk factors for introduction and maintenance of scrapie in a flock are related to movement of animals, flock size, breeding practices, and lambing management.

Specifically, these include: purchasing infected breeding animals, sharing pastures, breeding and raising home-bred replacements, ewes lambing in group pens (vs. unconfined on pasture or in individual pens), and the number/proportion of genetically susceptible sheep within a flock (Detwiler and Baylis 2003).

Genetics

For classical scrapie commonly found in the United States, the codons at positions 136 and 171 in the gene that code 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. The effect of lysine (K) at codon 171 on scrapie susceptibility is unknown due to its infrequent occurrence. Codon 136 affects susceptibility to the less common valine-dependent classical scrapie, with alanine (A) and valine (V) conferring resistance and susceptibility, respectively.

All QQ sheep are susceptible to the more common valine-independent classical scrapie and can transmit the disease to susceptible flock mates. Conversely, AARR sheep are nearly completely resistant to this classical scrapie. These sheep are highly unlikely to carry or transmit scrapie. AAQR are rarely infected, and it is unknown whether infected AAQR sheep can transmit scrapie.

Like the valine-independent scrapie, there is a genetic difference in an animal's susceptibility to the valine-dependent scrapie. AARR sheep appear to also be resistant to the valine-dependent scrapie. However, AAQQ, AAQR, and AARR sheep appear to be resistant to the valine-dependent scrapie, while AVQQ, VVQQ, and AVQR sheep are susceptible (Evoniuk et al. 2007). Infected rams are not known to transmit scrapie; however, horizontal transmission among lambs has been reported (Konold et al. 2008).

Most dam-offspring transmission likely occurs perinatally; however, placental infection could occur. Placental infectivity is not constant with every pregnancy, occurs during the incubation/preclinical and clinical stages of disease, and requires QQ in the fetus for scrapie prion protein (PrPsc) accumulation (Androletti et al. 2002; Tuo et al. 2002; Alverson et al. 2006).

At present, there is an insufficient understanding of genetically-based scrapie resistance in goats to reliably assign goat risk categorically based on genetics. Therefore, all goats are considered to be genetically susceptible.

Nonclassical scrapie

Nonclassical scrapie includes those cases of scrapie reported in the literature as the Nor98, Nor98-like, or "atypical" scrapie. Nonclassical scrapie was first detected in Norway in 1998 and was designated Nor98. With increased surveillance, other countries have since detected nonclassical scrapie. Nonclassical scrapie differs pathologically and biochemically from classical scrapie and can be differentiated from classical scrapie and BSE using Western Blot (WB), enzyme-linked

immunosorbent assay (ELISA), and immunohistochemistry (IHC). Clinical signs in nonclassical scrapie cases are often absent or nonspecific.

In addition to the pathologic and biochemical differences, there are epidemiological differences between classical and nonclassical scrapie (Benestad et al. 2008; Lühken et al. 2007). In the European Union (EU), where most of the nonclassical cases have been detected, additional positive animals were found infrequently when exposed animals in the flock of origin were euthanized and tested. Additional cases were found to be associated with flocks larger than 500 sheep, and it was uncommon to detect more than one additional case per flock. In contrast, more than 10 percent of genetically susceptible animals were identified as infected following the depopulation of flocks infected with classical scrapie. Nonclassical scrapie cases have been reported to be more widely distributed geographically and to affect mostly sheep older than 5 years, whereas classical scrapie cases were somewhat geographically limited and generally affected sheep between 2 and 4 years of age. It has been speculated that nonclassical scrapie may occur through a spontaneous process – possibly not transmissible under natural conditions or not transmissible at a rate that could be sustained naturally (McIntyre et al. 2008; Lühken et al. 2007).

Genetics
Less is understood about the genetic susceptibility to nonclassical scrapie. Sheep carrying PrP genotypes known to be less susceptible or resistant to classical scrapie have been affected by nonclassical scrapie. It is thought that codons 141 and 154 affect susceptibility to nonclassical scrapie. At this time, it is unknown whether infectivity accumulates in the placenta of nonclassical scrapie-infected animals.

Implications for scrapie surveillance and eradication
The differences in genetic susceptibility to classical and nonclassical scrapie are of particular concern to countries, including the United States, which use selective breeding for genetic resistance as a tool for scrapie eradication. In addition, in sheep carrying nonclassical scrapie, there has generally been little or no vacuolation or accumulation of the abnormal prion protein detectable by IHC in the obex, the tissue commonly tested for scrapie in surveillance programs. Detection of nonclassical scrapie in tissues other than brain has not yet been reported, making it unlikely that live animal tests (e.g. third eyelid tests) will detect nonclassical scrapie cases. This has led to concerns about the adequacy of many scrapie surveillance programs to detect all scrapie cases and the potential implications of the breeding program and selecting for sheep that are not resistant to nonclassical scrapie (De Boschere et al. 2007; Seuberlich et al. 2007; Everest et al. 2006).

D. Clinical Signs

Clinical signs of scrapie usually do not appear until at least 2 to 5 years after infection; therefore, infected animals rarely show clinical signs of infection before the age of 2 years, with the average age of clinical onset being 4 years. The prolonged incubation period and the subclinical nature of the infection, as well as the most sensitive diagnostic tests currently available requiring brain or lymphoid tissue, make

detection of scrapie difficult. Sheep may live 1 to 6 months or longer after the onset of clinical signs, but some may live only 1 to 2 weeks. Duration of clinical signs may depend on the observational abilities of the producer. Some sheep may simply be found dead. Estimates of the average life expectancy for sheep with scrapie in the United States is 40.5 months in rams and 44.8 months for ewes, with most dying at less than 54 months.

On the farm, veterinarians suspect scrapie based on the clinical signs combined with knowledge of the animal's history. However, the clinical presentation of scrapie includes a wide range of nonspecific signs. Signs of scrapie vary widely among individual animals and develop very slowly. Due to damage to nerve cells, affected animals often show behavior changes, such as nervousness or aggression, rubbing, and locomotor 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 decreased appetite, wool pulling, and hyperesthesia. Additional signs in affected goats may include difficulty milking, premature kidding, and pica.

E. Control and Prevention

The best method for preventing scrapie from occurring in a flock or herd is to maintain a closed flock/herd, particularly with regard to breeding females. Any replacement females or breeding males should originate from flocks/herds not known to be affected with scrapie and under management practices precluding the introduction of scrapie or, in the case of sheep, should be of resistant PrP genotypes. Susceptible ewes of unknown or questionable disease status should be bred to RR rams or separated from the rest of the flock prior to and following lambing until there is no vaginal discharge to minimize spread to other animals. Another method used by some producers is selective breeding to reduce overall flock susceptibility based on PrP genotype. This method consists of breeding only with rams that are RR or QR.

Once an infected animal is detected, control and eradication of the disease from the flock or herd may consist of either selective depopulation of certain higher-risk exposed animals (e.g., only those that are genetically susceptible, heavily exposed, test positive or inconclusive, and/or showing clinical signs) or, less commonly, complete flock depopulation, as well as cleaning and disinfection of the premises. Owners may opt to restock with rams that are RR and ewes of resistant genotype.

The use of selective breeding and culling to increase genetic resistance to scrapie infection raises concern regarding the practices effect on the genetic diversity of the domestic sheep population and on production traits. A number of studies have been completed evaluating effect of PrP genotype selection and production traits (e.g., meat, milk production, litter sizes), with some studies providing limited evidence of associations between PrP genotype and traits (e.g., Isler et al. 2006; Man et al. 2007; Sawalha et al. 2007) but not all (de Vries et al. 2004; Alvarez et al. 2006; Alexander et al. 2006; Sweeney et al. 2007). Overall, when observed, associations between PrP genotype and performance traits tended to be neither strong nor consistent across

populations, and there was no tendency for associations between scrapie-resistant PrP alleles and performance traits to be adverse (Dawson et al. 2008; Sweeney and Hanrahan 2008). A study did find that producer perception of animal quality (based on the physical characteristics of hardiness, wool quality, conformation, and body size) was not influenced by animal susceptibility to scrapie (as determined by PrP genotype). In other words, farmers were not able to predict the genotype of their sheep based on their performance, and farmers' assessments of their best-performing animals were not biased toward scrapie-susceptible genotypes (Nicholls et al. 2006).

2. Purpose and Rationale for Surveillance

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

a. To eradicate classical scrapie from the sheep and goat population in the United States, then

b. To document the eradication of classical scrapie, and

c. To achieve scrapie-free status, as described by the World Organization for Animal Health (OIE), in the United States. Currently, the OIE requires that a country or region be able to provide, for at least 7 years, 95 percent confidence of detecting scrapie at a prevalence of 0.1 percent of the total number of chronic wasting conditions in populations of sheep and goats older than 18 months and that no case of scrapie has been reported during this period--assuming that chronic wasting conditions within populations of sheep and goats older than 18 months occur at a rate of at least 1 percent (OIE 2007).

This surveillance plan focuses on the eradication of classical scrapie, as little is understood about the epidemiology and impact of nonclassical scrapie in sheep and goat populations. At the time of this plan development, too little is still known of the epidemiology and economic and animal health significance of nonclassical scrapie. Because it has been suggested that nonclassical scrapie occurs through a spontaneous process and either is not transmitted or is transmitted at an unsustainable rate in natural conditions, it is unclear whether eradication of nonclassical scrapie in the United States is necessary or feasible. As more becomes known about the epidemiology and significance of nonclassical scrapie in the United States and abroad, a study may be needed to assess the prevalence and demographics of nonclassical scrapie in U.S. sheep and goat populations and the National Scrapie Surveillance Plan appropriately revised.

The rationale for conducting surveillance and scrapie eradication are as follows:

Economic Impact on Industry: Scrapie is a non-febrile and insidious disease. 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 inviable. Female animals sold from infected flocks can spread scrapie to other flocks. The presence of scrapie in the United States is estimated to

cost American sheep producers $10-20 million per year, principally in lost exports of sheep 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. It has been estimated that the eradication of scrapie would offer U.S. producers an increase in revenue of at least $10.8 million annually, particularly in export markets (Seitzinger, Paarlberg and Lee, 2006).

Potential Public Health Concerns: The apparent transmission of bovine spongiform encephalopathy (BSE), another TSE, to humans in the United Kingdom has resulted in a call for the eradication of all TSEs in food-producing animals. Recent research has demonstrated that BSE could be successfully transmitted to sheep and goats orally, and that sheep genotypes traditionally resistant to scrapie were susceptible to BSE. This has resulted in increased public concern. There is no scientific evidence to indicate that scrapie poses a risk to human health or that scrapie of sheep and goats is transmitted to humans. Because BSE in sheep is detected using the same tests as scrapie, however, early detection and eradication of scrapie would protect human health from the theoretical risk of BSE in sheep, should it occur, by eliminating the risk of BSE being masked by scrapie. This would increase consumer confidence both domestically and internationally.

This scrapie surveillance plan in the United States calls for transitioning to demographic-based surveillance, and ultimately to flock-level surveillance, at a critical period in scrapie eradication efforts. The United States has been involved in scrapie control efforts for more than 50 years. Since 2002, the prevalence of scrapie has decreased significantly through existing eradication efforts, largely a result of effective slaughter surveillance. In order to achieve the goal of eradication, efforts must focus on improving flock-level sensitivity and increasing surveillance efforts to find the remaining cases.

3. Surveillance Objectives

In general, scrapie surveillance is conducted to:

1. Detect infected sheep and goats, and
2. Trace infected animals to their flocks or herds of origin.

This will be done in three stages: eradication of the disease in the U.S. sheep and goat population by finding the remaining cases (expected timeline: FY 2008-2016), high-level monitoring to ensure that no cases remain (FY 2017-2020) and ongoing monitoring to meet OIE requirements (FY 2021 and beyond). This surveillance plan document addresses the first stage (disease eradication by detecting remaining cases). This will be accomplished by increasing sampling of apparently healthy and clinical sheep and goats from underrepresented flocks and herds and underrepresented geographic regions that are being missed through current surveillance efforts.

Scrapie eradication will be accomplished by increasing efforts in the following areas:

1. Passive observation and reporting: This effort requires enhancing awareness of the disease and associated clinical signs through educational programs/materials to increase the sensitivity of producers and veterinarians to detecting clinical cases in the field and submitting appropriate samples to diagnostic laboratories.

2. Laboratory surveillance: This requires ensuring that diagnostic laboratories forward appropriate tissues from all mature sheep and goats presented for necropsy and diagnostic testing to NVSL or an approved contract laboratory for scrapie testing, regardless whether another diagnosis is made. Additionally, this requires ensuring that public health laboratories forward appropriate tissues from sheep and goats of any age that test negative for rabies to the NVSL or an approved contract laboratory for scrapie testing.

3. Active surveillance: This involves expanding existing slaughter surveillance sampling into additional federally- and State-inspected plants, custom and ethnic slaughter facilities, and other concentration sites where targeted sheep and goats may be found, such as markets, cull ewe feedlots and exporters. In addition, enhanced on-farm surveillance will be increasingly incorporated in targeted geographic areas and/or flocks to fill gaps in the concurrent slaughter surveillance effort. Active trace investigations of exposed animals and potentially exposed flocks that are initiated upon identification of an infected animal will continue to contribute to the identification of infected flocks. Finally, SFCP flocks that may not be tested through slaughter channels will also be incorporated in monitoring flock-level sensitivity of surveillance, as participating flocks are required to be annually inspected by an official representative or accredited veterinarian. SFCP flocks are also required to follow reporting requirements for scrapie-suspect animals, animals suspected of other neurologic and chronic debilitation (prolonged wasting) illnesses, and any mature animals found dead.

4. Expected Outcomes

Detection of infected sheep will result in actions, as described in the Scrapie Eradication Uniform Methods and Rules (UM&R), which promotes eradication of the disease agent. The expected outcome of the comprehensive surveillance program described in this document is the progressive reduction of scrapie prevalence resulting in the eradication of disease in the U.S. sheep and goat populations. The data and information generated from the surveillance program will also inform decision makers about future surveillance needs and trade-related issues.

5. Stakeholders and Responsible Parties

- National Surveillance Unit (NSU): Surveillance planning and evaluation
- National Center for Animal Health Programs (NCAHP), VS regional staff and NVSL: Surveillance planning, implementation, and oversight; training; communication;

- Regional staff, VS Area-Veterinarians-in-Charge (AVICs), State animal health authorities: Surveillance implementation and communication with local producers and industry;
- VS Office of the Chief Information Officer (OCIO): Development, training, deployment and maintenance of scrapie Veterinary Services Laboratory Submission (VSLS) and Mobile Information Management (MIM) modules, including integration of Animal Identification Number Management (AINM) system, scrapie mapping module and the Animal Health and Surveillance Management (AHSM) System to allow rapid data analysis at the flock level; and
- Sheep and goat organizations: communication with producers and industry, including:
    - American Sheep Industry Association
    - American Meat Goat Association
    - American Dairy Goat Association
    - American Boer Goat Association
    - American Goat Society
    - U.S. Boer Goat Association
    - National Institute for Animal Agriculture

6. Population Description and Characteristics

Sheep and goat production occurs throughout the United States, but the top sheep-producing states are Texas, California, Wyoming, Colorado and South Dakota (Table 1; NASS Farms, Land in Farms and Livestock Operations, February 2008). In Texas and other Western states, sheep production is largely in range flocks that are grazed on large, open rangeland. In the East, sheep production tends to be in concentrated farm settings. Nationally, 28.1 percent of operations have Suffolk sheep comprising the majority of their flocks. Suffolk is the breed with the most reported scrapie cases in the United States.

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 total commercial slaughter of sheep and lambs was 2.69 million head in 2007, with approximately 95.4 percent of that slaughter being lambs and yearlings (NASS Livestock Slaughter, March 2008). Colorado slaughtered the largest volume of sheep (Table 2). In 2007, 94.4 percent of commercial lamb and sheep slaughter was federally inspected. The total U.S. wool production was 34.5 million pounds with a total value of $30.3 million (NASS Sheep and Goats, February 2008).

The U.S. sheep inventory on January 1, 2008, was 6.055 million head, with 4.505 million head breeding stock. The breeding stock includes over 3.61 million ewes and 193,000 rams 1 year of age or older and 695,000 replacement lambs (NASS Sheep and Goats, February 2008). There were a total of 70,590 sheep operations in the

United States in 2007. Most sheep operations (91.1 percent) had less than 100 head, and these operations accounted for 30.8 percent of the U.S. sheep inventory. Only 1.5 percent of the operations had over 500 head, but these operations accounted for almost half of the U.S. inventory (NASS Farms, Land in Farms and Livestock Operations, February 2008). In 2000, approximately 16.6 percent of the ewes died or were culled. Of those ewes, 10.4 percent were culled or dead with progressive weight loss, despite a normal appetite and no respiratory problems (NAHMS, 2001).

The two major uses for goats are meat production and mohair production. The total U.S. mohair production in 2007 was 1.14 million pounds from 185,000 goats (total value of $4.305 million). On January 1, 2008, there were approximately 2.5 million breeding goats, 498,000 market goats and kids, 2.5 million head of meat and other goats, 305,000 milk goats, 210,000 angora goats, and 1.94 million kids (NASS Sheep and Goats, January 2008). In 2007, over 827,300 goats were commercially slaughtered, with the largest volume slaughtered in New Jersey (Table 2; NASS Livestock Slaughter, April 2008). There were a total of 108,130 goat operations in the United States in 2007 (NASS Farms, Land in Farms and Livestock Operations, February 2008).

The United States is not a major exporter of live sheep, historically accounting for less than 1 percent of the total world trade in live sheep. In 2007, the U.S. exported 116,579 mature sheep, the majority to Mexico (65,075), but also to Canada, the Bahamas, the Netherlands Antilles, Jamaica, Trinidad, and Tobago. In addition, the United States exported 9,241 goats, again the majority to Mexico (7,211), but also to the Cayman Islands, Colombia, Canada, United Arab Emirates, the Netherlands Antilles, the Bahamas, and the Leeward-Windward Islands (USDA ERS, accessed May 5, 2008).

Table 1: Top Sheep and Goat Producing States (NASS Sheep and Goats, 2008)

State	Number Head
All Lamb and Sheep	
Texas	1,000,000
California	600,00
Wyoming	440,000
Colorado	420,000
South Dakota	355,000
Breeding Sheep and Lambs	
Texas	770,000
Wyoming	340,000
California	340,000
South Dakota	285,000
Montana	265,000
Utah	250,000
Market Sheep	
California	260,000
Texas	230,000
Colorado	230,000
Wyoming	100,000
Angora Goats	
Texas	150,000
Arizona	18,000
Milk Goats	
Wisconsin	33,000
California	30,000
Texas	25,000
Iowa	19,000
Meat and Other Goats	
Texas	1,090,000
Tennessee	118,000
California	100,000
Georgia	100,000

Table 2: Top Sheep and Goat Slaughtering States (NASS Livestock Slaughter 2007 Summary, 2008)

State	Volume (Head)
Sheep and Lamb (All Commercial Slaughter)	
Colorado	1,053,600
Iowa	409,800
Michigan	179,700
Illinois	169,800
New Jersey	116,500
Goats (Federal Inspected Slaughter)	
New Jersey	237,562
Delaware-Maryland	53,736
Illinois	41,602
California	32,396

7. Case Definition

For the purpose of scrapie surveillance and disease eradication, only those sheep and goats tested using an official test with scrapie positive results confirmed by NVSL (or a laboratory to which the NVSL has referred a case for such testing) are designated as scrapie cases. The identification of suspect cases leads to further investigation, but these cases are not considered to be scrapie cases until confirmatory test results have been reported.

Case Description:

Sheep and goats of many breeds have been affected. Most cases of clinical scrapie in sheep occur when the animal is between 2 and 5 years of age. Although rare, clinical

signs may arise in sheep under 1 year. In some instances, the commercial life span of sheep may be too short to allow clinical signs to develop. Progression of the clinical disease is variable, from weeks to months, with a fatal outcome. Since signs may not appear until months or years after transmission to other sheep or goats in the flock, relying on clinical signs to detect cases is not ideal. Therefore, **the primary focus of scrapie surveillance is the identification of subclinical cases.**

Clinical Description

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 damage to nerve cells, affected animals often show behavior changes, such as nervousness or aggression, rubbing, and locomotor 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 decreased 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.

Epidemiologic criteria and restrictions

The case definition pertains to all captive and/or domestic sheep and goat populations in the United States. Animals of the genus *Ovis* are considered to be sheep, and animals of the genus *Capra* are considered to be goats.

Laboratory criteria

Infection with the scrapie agent is determined by the detection of the abnormal prion protein accumulation in nervous tissue and/or lymphoreticular tissues and/or histopathologic lesions in central nervous tissue in susceptible species. The abnormal prion protein can be detected by the use of an approved screening ELISA, WB, and/or by performing IHC on CNS and/or lymphoid tissues (i.e., third eyelid or anorectal lymphoid tissue, tonsil or lymph node, obex, cerebellum or other brain tissue). The characteristic histopathologic change of nervous tissue is vacuolation of neurons, producing a distinctive appearance of spongiform change. The vacuolar changes may be accompanied by other microscopic features, such as neuronal degeneration, neuronal loss, gliosis, and cerebrovascular amyloidosis. Typically, the histopathologic lesions have bilaterally symmetrical distribution, although the distribution pattern and changes may vary between type of agent and host genetics. The scrapie type may be further characterized as classical or nonclassical scrapie by performing IHC and/or WB assay. All cases that produce positive, suggestive, or inconclusive results or that show any unusual staining when initially tested by an approved laboratory are submitted to the NVSL for further evaluation. Confirmatory testing may include any of the following methods, used alone or in combination: IHC, WB, histopathology, Enzyme Immunosorbent Assay (EIA) or ELISA or animal inoculation studies (i.e., bioassay). A case must be confirmed positive by NVSL or a laboratory to which the NVSL has referred a case for such testing to be designated a scrapie case.

Case Classification

Suspect

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

1. Has been condemned by the Food Safety and Inspection Service (FSIS) or a State inspection authority for CNS signs or rabies, or
2. Exhibits any of the clinical signs compatible with scrapie and has been determined to be suspicious for scrapie by an accredited veterinarian or a State or USDA representative. Compatible clinical signs may include, but are not limited to:
   - Weakness of any kind, not including those with visible traumatic injuries and no other signs of scrapie. Signs of weakness may include:
     - stumbling,
     - falling down, or
     - having difficulty rising;
   - Significant weight loss, despite retention of appetite in an animal with adequate dentition;
   - Increased sensitivity to noise and sudden movement;
   - Tremors;
   - Star gazing;
   - Head pressing;
   - Bilateral gait abnormalities, not including abnormalities involving only one leg or one front and one back leg. Signs of gait abnormalities may include:
     - incoordination,
     - ataxia,
     - high-stepping gait of forelimbs,
     - bunny-hop movement of rear legs, or
     - swaying of back end;
   - Repeated intense rubbing with bare areas or damaged wool in similar locations on both sides of the 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;
3. Has a positive test result for scrapie or for a protease-resistant protein associated with scrapie on an unofficial test or screening test; or
4. Has a suspect, inconclusive or suggestive test result on an official test.

Confirmed

Laboratory testing of a submitted sample(s) by the NVSL or a laboratory to which the NVSL has referred a case for such testing has returned positive result(s).

Required comments

Per 9 CFR parts 54, 79, and 161.3 and the Scrapie Eradication Uniform Methods and Rules (UM&R), all suspect and presumptive cases require reporting to State animal

health officials and the VS Area Veterinarian-in-Charge (AVIC) for follow-up investigation and sampling.

8. U.S. Surveillance for Scrapie: National Scrapie Eradication Program (NSEP)

The NSEP is a cooperative State-Federal-industry program administered by APHIS and consistent States to control and eradicate scrapie. Its components consist of: producer/industry education and compliance, identification monitoring and compliance, slaughter- and nonslaughter-based surveillance, trace investigations, monitoring flocks for occurrence or recurrence of scrapie, and the SFCP.

A. Regulatory Scrapie Slaughter Surveillance (RSSS)

Implemented in 2003, the RSSS is a targeted surveillance program consisting of sample collection from mature sheep and goats sent to participating cull ewe slaughter facilities, as well as dead, disabled, or suspect animals found at concentration points for mature ewes, including markets and cull ewe feedlots.

Sampling method:

The RSSS targets mature sheep and goats that meet specific criteria based on age, face color and/or clinical signs at slaughter. A study found that among cull sheep entering slaughter in 2002-2003, the prevalence of scrapie in apparently healthy black- and mottled-faced sheep was greater than that in white-faced sheep (0.85 percent, 0.12 percent and less than 0.01 percent, respectively) and that black-faced sheep were 38 times more likely to be infected than white- or mottled-faced sheep (NAHMS 2004). Additionally, analysis of 2005 RSSS data showed that the majority of positive sheep sampled at slaughter were older than 1 year of age (NSU, 2006). Therefore, sampling of the apparently healthy sheep at slaughter has primarily been targeted based on age (those at least 14 months of age) and face color (black- and mottled-faced).

Since the implementation of RSSS, the prevalence of scrapie in black- and mottled-faced sheep at slaughter has steadily decreased to 0.27 percent and 0.05 percent, respectively, in FY2007. Analysis of RSSS data has shown that sheep 3 years of age or older are 6.5 times more likely to be identified as scrapie-positive. Therefore, the age group targeted is being adjusted to target those apparently healthy sheep at least 24 months of age (as evidenced by at least two sets of permanent incisors), unless records show that the animal is at least 18 months of age.

Analysis of RSSS data of mottled-faced sheep sampled at slaughter FY2005-2007 shows a possible association between the degree of mottling and being identified as scrapie-positive; sheep with more than 40 percent mottling are more likely to be scrapie-positive than those with less than 10 percent

mottling. Therefore, the targeting of mottled-faced sheep has been revised to exclude those apparently healthy sheep with minimal mottling.

In addition to the apparently healthy sheep sampled at slaughter for scrapie surveillance, all animals presenting with suspect clinical signs at slaughter are tested for scrapie under RSSS. Signs used to target clinical suspect animals are nonspecific (i.e., wool loss, rubbing, unthrifty appearance, weakness, nonambulatory and/or other evidence of central nervous system disorder). Analysis of RSSS data of clinical sheep sampled at slaughter FY2003-2007 showed very few of these animals with clinical signs identified as scrapie-positive, and there was insufficient data to support any change of targeting criteria for clinical suspect animals.

Based on these analyses, animals sampled through RSSS are those animals at least 18 months of age that meet one of the following criteria:

- All black-faced sheep;
- Only those sheep that are brown, red and mottled-faced (specifically the mottled-faced sheep with at least 10 percent colored hair mixed with white on the face, ears, lips or around the eyes) and are traceable (i.e., have individual identification tags or other identifying information); and
- White-faced sheep meeting the following criteria:
  - originate from an SFCP export-certified flock;
  - are considered to have been exposed to scrapie; or
  - are chosen by the Scrapie Program for surveillance sampling based on other factors.
- All clinical or suspect sheep (regardless of face color) and goats at slaughter meeting at least one of the following criteria are sampled for surveillance testing:
  - Dead prior to slaughter,
  - Nonambulatory,
  - Displaying CNS signs,
  - Indications of intense rubbing,
  - Less than 5 years old and very thin, or
  - Less than 5 years old and with nonspecific signs (e.g., wool or hair loss, suggestive of rubbing, biting at legs or sides, lip smacking, or intense rubbing without bare areas).

Appropriate tissues (obex and retropharyngeal lymph nodes) are collected from targeted animals and submitted to an approved veterinary diagnostic laboratory for scrapie testing.

State-level Sampling Targets

State-level sampling targets are established based on the population demographics of mature sheep in each State. Population estimates were based

on NASS Census of Agriculture information and annual sheep and goat farm information (2002, 2006, and 2007) and flock premises data entered in the generic database (GDB). The number of mature sheep culled annually was estimated based on producer reporting of the primary breed/face color and cull rates on their sheep operation (NAHMS 1996, 2001). The NAHMS data assumes that the percentages reported by the participating producers represented the overall population in the State and/or region and that the population demographics have not changed significantly since the study was conducted. The overall prevalence of scrapie in black- and mottled-faced sheep sent to slaughter (0.15 percent) was estimated from the FY 2007 slaughter surveillance (RSSS) sampling. Using this prevalence, the minimum number of samples needed to detect disease in the black- and mottled-faced sheep sent to slaughter with 95 percent confidence was determined for each State (Cannon and Roe, 1982). These sampling targets are presented in Tables 3 and 4.

The following assumptions were made to calculate these minimum sample numbers:

i. Random sampling of mature black- and mottle-faced sheep is conducted at slaughter establishments in each State. This is not likely to hold, as there are flock owners that home-slaughter or sell animals for noncommercial slaughter. There is insufficient knowledge of these practices within the United States to consider them in the calculations.
ii. All flocks are of one face color. This is not likely valid, as it is known that there are mixed flocks; however, insufficient knowledge of individual flock composition exists. The 1996 NAHMS study recorded the primary face color of the flock (as reported by the producer) and all sheep on those operations were summarized as that face color.
iii. All black- and mottled-faced sheep in a State have an equal likelihood of contact with an infected animal, regardless of separations (e.g., fences, rivers) and geographic location and landscape: Limited information is available regarding distribution of sheep at a local level. NASS census data is most readily available at the State level. NASS records census data at the zip code level, but even at this level, there is limited ability to consider man-made and natural barriers of contact between populations within an area or State. This would require knowing the specific geographic location of all flocks in a State in order to use landscape and other geographic information systems (GIS) data and recording of all barriers preventing contact between adjacent flocks (as well as recording of those flocks that may share pasture

Table 3: State-level sampling targets to detect scrapie in black- and mottled-faced sheep at slaughter, VS Eastern Region.

State (of Tag Origin)	Surveillance Targets	
	EXPECTED NUMBER of targeted cull ewes	IDEAL Sampling target
Alabama	1378	1082
Connecticut	169	183
Delaware	34	37
Florida	584	594
Georgia	440	460
Illinois	5259	1675
Indiana	3615	1552
Kentucky	4636	1637
Massachusetts	291	313
Maryland	1047	926
Maine	284	305
Michigan	3672	1558
Minnesota	7178	1754
Mississippi	818	774
North Carolina	838	794
New Hampshire	225	243
New Jersey	515	539
New York	3436	1536
Ohio	7399	1760
Pennsylvania	4057	1601
Rhode Island	38	42
South Carolina	173	184
Tennessee	3090	1490
Virginia	3443	1537
Vermont	448	475
Wisconsin	5916	1707
West Virginia	1843	1250
REGIONAL TOTAL	**60826**	**26008**

Table 4: State-level sampling targets to detect scrapie in black- and mottled-faced sheep at slaughter, VS Western Region.

State (of Tag Origin)	Surveillance Targets	
	EXPECTED NUMBER of targeted cull ewes	IDEAL Sampling target
Alaska	16	18
Arkansas	996	890
Arizona	1079	955
California	9042	1804
Colorado	4280	1620
Hawaii	13	14
Iowa	11148	1835
Idaho	5148	1676
Kansas	4222	1609
Louisiana	944	859
Missouri	3354	1526
Montana	6016	1718
North Dakota	3806	1573
Nebraska	4193	1607
New Mexico	2950	1482
Nevada	1475	1137
Oklahoma	851	790
Oregon	3817	1580
South Dakota	19424	1901
Texas	10200	1818
Utah	6074	1720
Washington	1105	967
Wyoming	8041	1782
REGIONAL TOTAL	**108194**	**30881**

or otherwise have contact). Thus, based on the limited information available, we can only assume that an animal in a State has equal likelihood to contact a scrapie-infected animal in that State (and that contact occurs at a time when the scrapie agent is being shed and that the duration of contact is sufficient for transmission to occur).

iv. The prevalence of scrapie in the sheep sampled at participating slaughter establishments was the same as the prevalence in all of the black- and mottled-faced mature sheep going to slaughter, including the nontraceable mottled-faced sheep not sampled at participating establishments: Federal slaughter establishments participating in RSSS process 86 percent of all mature sheep going through federal inspection. However, the volume of mature sheep

It is important to emphasize that these State-level sampling targets are for sheep that originate in that State and are based only on the estimates of black- and mottled-faced sheep populations. Thus, it is also assumed that scrapie prevalence has not significantly increased in the lower-risk face colors identified in the Scrapie Ovine Slaughter Surveillance study (SOSS; NAHMS 2006), specifically the apparently healthy white-faced sheep, whose targeting criteria are not based on the same factors as the black- and mottled-faced sheep in the current slaughter surveillance program. As the prevalence in black-faced and mottled-faced sheep decrease to the prevalence level in white-faced sheep, sampling targets will need to be readjusted to include sampling of white-faced sheep.

Scrapie sampling does not occur at all slaughter facilities in the country. Participation in the RSSS is voluntary at slaughter establishments that do not engage in interstate commerce. Because of limited resources, sampling has not been implemented at all establishments that do engage in interstate commerce. In FY 2007, 85 slaughter facilities collected samples as part of the RSSS; these include 50 Federal establishments that processed about 86 percent of the volume of mature sheep going through Federal inspection. Approximately 93 percent of the RSSS surveillance samples collected in FY 2007 were from these federally-inspected establishments.

Gaps in existing slaughter surveillance include

- Mature sheep slaughtered at non-participating slaughter plants, including some Federal and many non-Federal slaughter plants (such as State-inspected plants, live animal markets, or custom-exempt plants),
- Ewes exported to Mexico for slaughter,
- Apparently healthy goats, and
- Animals from producers who slaughter at home or sell animals only for noncommercial slaughter.

To fill these gaps, several surveillance initiatives have been implemented or are under development. These include the following:

1. **Caprine Scrapie Prevalence Study (CSPS)**
   Sampling of mature goats was conducted May 2007 through March 2008 by VS, to assess the presence of scrapie in goats in the U.S., specifically to determine if the prevalence in the U.S. goat population is less than 0.1 percent with 95 percent confidence. Samples were collected from goats with potentially higher likelihood of infection, (i.e., those residing in States where scrapie-infected flocks or herds originated), those processed in slaughter establishments where scrapie

has previously been detected or those that process animals from states with infected flocks or herds, and those processed through smaller slaughter establishments likely to slaughter goats from local populations. Random samples from these targeted populations were collected from goats older than 2 years with no worn or broken teeth. No goats in the study have tested positive and final analysis of the data is currently underway. Future surveillance for scrapie will need to accommodate sampling in apparently healthy goats; however, this issue has not been addressed in this surveillance plan.

2. **Export Cull Ewes**
   It is uncertain whether the population being exported is different demographically, particularly with respect to risk for scrapie, than those processed in U.S. facilities. Approximately 20 percent of the mature sheep sold at the major livestock market that sells to export buyers are not exported and may be sampled in the United States. Most of the mature export ewes historically sampled have been white-faced sheep (NAHMS SOSS, 2003); samples from this group would not routinely be collected from U.S. slaughter establishments unless there were clinical or suspect animals. Also, animals that were sold through this market were sampled during the SOSS study and the scrapie prevalence was found to be lower in this population than in those sampled at other sites. However, the number of samples collected was small, particularly from black-faced sheep, and therefore, conclusions regarding lower risk in the exported population could not be drawn. NCAHP is working with the Western Region and Texas VS Area Office to develop and implement a sampling strategy for mature ewes that die or become nonambulatory prior to being exported to Mexico for slaughter as well as those black-faced sheep being exported.
3. **Small-volume slaughter establishments**
   Some non-Federal facilities already participate in RSSS and collected approximately 7 percent of the samples in FY 2007. In FY 2007, 21 new sites entered the RSSS and identified 7 infected animals (or approximately 0.27 percent of the samples collected at these 21 sites). Greater RSSS participation is needed from these smaller-volume plants to reach new sheep and goat populations.

Currently, the animal's State of origin is not part of the targeted selection criteria. This can only be surmised for animals identified with official flock identification tags. Therefore, with the implementation of demographic-based surveillance, compliance with the mandatory identification rule is critical in determining whether a State is meeting its sampling target, as compliance will allow the surveillance program to match a sampled animal back to a flock and a State. However, it is recognized that this identification may not necessarily reflect the State of origin (i.e., birth), but is currently the best data available to provide information on where the sheep has moved geographically.

It is recognized that some flocks have been repeatedly sampled through the RSSS and on-farm surveillance activities. The number of samples needed to designate a flock as low-risk for scrapie is unknown, as is the number of samples needed to subsequently continue monitoring these low-risk flocks. However, even if those parameters were known, no mechanism is currently in place to prevent multiple animals from a single flock from being tested at slaughter over time, regardless of past history of multiple negative results from the flock.

Data Sources
RSSS summary data collected on the day of submission includes the number of sheep/goats slaughtered, number of mature animals with official identification, number of black- and mottled-faced sheep slaughtered, and the total number of head 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 scrapie regional epidemiologist).

Data from RSSS surveillance is captured via the Veterinary Services Laboratory System (VSLS) or its predecessor, the Online TSE Laboratory Submission System (OTLS). Full implementation of VSLS is expected to be completed by the end of FY 2008. VSLS is an electronic laboratory submission system intended as a common entry vehicle for all future APHIS laboratory data. Data entered via VSLS and subsequent test results are stored in the AHSM database to support analysis and investigations.

B. Nonslaughter Surveillance

Nonslaughter surveillance is targeted toward groups considered to be at higher risk for scrapie and those not being seen at participating slaughter facilities. Currently, nonslaughter surveillance primarily includes potentially exposed animals identified through trace investigations from infected animals; source and exposed flocks often identified through RSSS; clinically suspect animals submitted for testing to diagnostic laboratories; animals submitted to public health laboratories that test negative for rabies; animals tested for scrapie as part of the SFCP (see [c] below); and QQ sheep in flocks with risk factors for scrapie (antemortem testing). In addition, a small number of samples are collected through voluntary on-farm surveillance.

Sampling Methods
Non-slaughter surveillance will be increasingly important as the prevalence of scrapie decreases and scrapie surveillance transitions to a more demographic-based and eventually flock-level approach.

Specifically, on-farm testing will increasingly be utilized to help a State meet its targets. In addition, as fewer trace investigations are initiated because of the decreasing prevalence, on-farm surveillance will be essential as we move toward more population-based strategies for surveillance and documenting disease freedom.

1. Targeted flock-level sampling (on-farm)

This increasingly important component of scrapie surveillance consists of sampling of apparently healthy sheep and goats based on certain criteria, including (but not limited to): geographic location, prior testing of animals from flocks or herds for scrapie through other surveillance routes, and other demographic or management practices. The purpose of this component is to specifically target sampling of flocks or herds that have had limited or no scrapie surveillance.

NCAHP and CEAH are analyzing scrapie surveillance data to identify flocks and areas not sampled through current slaughter and nonslaughter surveillance efforts, using official identification tags to designate the flock of origin. It is recognized that these tags may not necessarily reflect flock of birth, but provide the best available information to identify where the animal may have originated. The data are being analyzed to identify which flocks have not been sampled, to identify factors associated with not being sampled (e.g., number of flocks and/or sheep in an area), and to assess associations of positive flocks with these findings. This will allow regional and local field personnel to focus and prioritize efforts to fill in the gaps either by slaughter or nonslaughter surveillance, e.g., recruiting a new local slaughter facility that processes animals from these flocks or working with producers to allow on-farm sample collection.

2. Laboratories

This component requires enhancing awareness of the importance of scrapie testing in mature sheep and goats by ensuring that diagnostic laboratories forward appropriate tissues from all mature sheep and goats presented for necropsy and diagnostic testing to the NVSL or an approved contract laboratory for scrapie testing regardless of the presence of another diagnosis. This also includes ensuring that public health laboratories forward appropriate tissues from sheep and goats of any age that test negative for rabies to the NVSL or an approved contract laboratory, when appropriate samples are available. Information reminders to these laboratories are recommended to ensure they are appropriately submitting these samples for scrapie testing

3. Epidemiological Investigations

This group of surveillance activities consists of surveillance information collected on-farm from clinical suspect sheep and goats or as part of trace investigations of animals from source and infected flocks.

a. Trace Investigations

When a positive sheep or goat is identified through slaughter or other routes, trace investigations (forward and backward) are initiated to identify additional infected and source flocks. These investigations are done by identifying flocks that may have been exposed to an infected animal or served as the source of infection for that animal. Samples collected either from animals from flocks/herds not already found to be infected or from source flocks/herds are included as part of scrapie surveillance. As fewer trace investigations are initiated because of the decreasing prevalence of scrapie, this source of on-farm surveillance is expected to decrease.

b. Reporting of clinically suspect sheep and goats (on-farm)

This component of surveillance is based on reporting of clinical suspects and depends on disease awareness of farmers/producers and veterinary practitioners and their willingness to report a suspect case. According to the 2001 National Animal Health Monitoring System (NAHMS) Sheep Study, awareness of disease is high, with 92.6 percent of the operations reporting they had heard of scrapie. Only 1.2 percent of operations had suspected or confirmed scrapie in the previous 3 years. However, most operations, when they suspected disease in their flocks, did not have the disease diagnosed by either a veterinarian or a diagnostic laboratory. Only 26.7 percent of operations that reported presence of scrapie on their operations had the disease diagnosed by veterinarian or laboratory. Educational campaigns are needed to keep producers and veterinarians aware of scrapie and the importance of testing, particularly of clinical suspects. These efforts will ensure that cases are appropriately identified, reported, and managed.

Data Sources

A number of separate applications and spreadsheets make it difficult to obtain and analyze a complete testing history of animals or flocks/herds using the multiple nonslaughter surveillance approaches. Laboratory submissions and test results of these surveillance samples are currently not entered into VSLS. These data are currently stored in spreadsheets maintained separately from RSSS data, with reporting occurring through NVSL and the regional scrapie epidemiologists. Genotype data, tag distribution data, and trace investigation information are collected through VSLS, Animal Identification Number Management (AINM) system, and the current AHSM and stored in the VS generic database (GDB). Future enhancements to incorporate non-RSSS testing data into VSLS, migration of all data in the current AHSM system to the unified database (UDB), and integration of the other applications will greatly improve the ability to integrate, monitor and analyze scrapie eradication program data collected through the multiple surveillance approaches.

C. Scrapie Flock Certification Program (SFCP)

Implemented in 1992, the SFCP is a voluntary cooperative effort among producers, industry representatives, accredited veterinarians, State animal health officials, and APHIS. Currently, approximately 2,000 flocks are enrolled in the program. This represents only a small proportion (approximately 2%) of the total sheep flocks and goat herds in the United States.

The objectives of SFCP are to reduce the occurrence and spread of scrapie, to identify flocks that have been free of evidence of scrapie over specified time periods, to contribute to the eventual eradication of scrapie, and to enhance the marketability of enrolled animals. Flock certification is based solely on absence of disease, not on genetics. Certification status categories include: complete monitored (enrolled or certified), selective monitored, and export monitored (enrolled or certified). In order to meet and maintain certification status, participants must meet identification, record-keeping, and reporting and testing requirements, and they must follow restrictions on flock additions. Participants also are required to record scrapie susceptibility genotype, if known. If genotypes are known, SFCP participants must sample the susceptible animals.

Data Sources

Sheep and goat producers participating in the SFCP are required to report and submit for testing any animals that exhibit clinical signs and some animals that die on the farm while enrolled in the program. In addition, regulatory personnel conduct annual inspections to assess flock/herd health and assure animal identification requirements are being met. The flock's SFCP status and summary of annual inspections are entered into the AHSM database. Some States enter animal inventories for each SFCP flock into AHSM, but this is not a mandatory requirement.

9. Data Presentation and Reports

Internal Reports for Program Monitoring

RSSS

The NSU provides monthly and annual summary reports for the RSSS that are reviewed in detail by the VS scrapie program staff and regional scrapie epidemiologists to monitor progress toward national sampling targets and program performance measures. These reports are also made available to VS Area Offices and State agencies on the "Scrapie Quickplace" website.

The monthly and annual RSSS summary reports present cumulative (since April 2003) and current fiscal year summaries of RSSS specimen collections and test results in tabular format. Tables that stratify these counts by FY, month of specimen collection, state of specimen collection, collection site, state of animal identification, animal species/face color, and animal age as

well as detailed line listings for samples with positive test results are also included. Revisions to the content and format of these reports are under development to better meet the needs of National, Regional and Area TSE personnel in their surveillance efforts.

Non-Slaughter Surveillance

A similar reporting and review process also occurs for surveillance testing conducted on animals at locations other than slaughter. However, this process is currently done manually using spreadsheets. NVSL provides spreadsheets that list epidemiologic information and test results for third eyelid testing and regulatory scrapie testing submitted by field personnel to scrapie program staff on a monthly basis. These spreadsheets are collated and distributed to the Designated Scrapie Epidemiologist (DSEs) on a quarterly basis. The DSEs identify those samples that meet the criteria to be considered as non-slaughter surveillance samples, and return the completed information to the Scrapie Program staff. Nonslaughter surveillance summary reports are then prepared by Scrapie Program staff and/or the NSU.

A module for the web-based submission of all samples collected through field activities through the VSLS system is in development. Once this module is fully implemented, a reporting process similar to that described for RSSS above will be implemented and these summaries will be incorporated into a single report. This will improve the ability to integrate, monitor and analyze the scrapie eradication program data from the various surveillance components with respect to this demographic-based surveillance plan.

External Reports to Stakeholders

Scrapie Program staff prepares and posts monthly and annual reports on the USDA VS Web site. These reports summarize both regulatory and surveillance activities for interested stakeholders using tables, graphs, figures, and explanatory text. These reports can be accessed by the public at:
http://www.aphis.usda.gov/animal_health/animal_diseases/scrapie/downloads/monthly_scrapie_rpt.pps
http://www.aphis.usda.gov/animal_health/animal_diseases/scrapie/downloads/yearly_report.pps

Scrapie program staff and regional scrapie epidemiologists regularly present these same program data to stakeholders at national animal health meetings including the United States Animal Health Association (USAHA), the American Sheep Industry Association, and the National Institute for Animal Agriculture.

10. Surveillance System Implementation

Available resources will limit implementation and meeting established targets, locally and nationally. The NSEP has been budgeted through 2010 to collect and test approximately 48,000 samples annually for scrapie surveillance. The budget allocation for scrapie surveillance includes not only sample collection at slaughter, but also field investigations of clinical suspects and trace investigations to identify new flocks associated with a confirmed scrapie case. Based on the sampling targets, as established in section 8A (and presented in Appendix A), almost 57,000 slaughter samples are needed to achieve scrapie surveillance targets. States are encouraged to meet these targets, if they are able. However, the number of samples that can be tested within the budget is dependent on a number of factors, most importantly the cost to collect each sample. With efforts focused on reaching into new slaughter facilities, such as small-volume and custom-exempt plants, the cost to collect each sample will increase. Therefore, meeting the State targets established in section 8A of this plan will not be possible in every State without exceeding the budget. In addition, as the prevalence of scrapie continues to decrease, there will be a shift to fewer trace investigations and increased on-farm surveillance of apparently healthy sheep and goats, which will increase the cost to collect each sample. Finally, as the prevalence decreases, State-level (and therefore national) sampling targets will increase to ensure that our surveillance is able find the remaining cases of scrapie and document disease freedom in areas that have not detected any cases. Thus, overall, scrapie surveillance and eradication efforts will be limited with implementation of the plan dependent on available resources.

Due to the resource limitations, State-level targets are being refined to attainable levels within the allocated budget. If more resources become available, the NSEP can increase its efforts and develop higher State-level targets to meet the surveillance targets. These slaughter sampling targets will be developed annually, based on sheep and goat demographics, scrapie prevalence, the evolving epidemiology of scrapie in the United States, previous area performance (of meeting targets) and resource availability. Regional and State TSE staff are responsible for establishing the RSSS and non-RSSS surveillance routes best able to meet the targets, based on local demographics and available resources.

11. Surveillance Plan Performance Metrics

The following metrics will be considered annually to assess the surveillance program and its ability to meet the objectives stated in this surveillance plan:

- Evaluation of States meeting their annual targets of sampling from sheep originating in each State;

- Evaluation of number of surveillance samples collected nationally – specifically, meeting the annual target;
- Evaluation of the percentage of black-faced sheep that test positive at slaughter facilities. The goal is to see a consistent decline in the frequency of cases, such that the rate of positives in this population by the end of 2010 is less than or equal to 0.09 percent. Upon achievement of this prevalence in black-faced sheep, the goals and targeting criteria of the surveillance program will need to be appropriately revised to find remaining scrapie cases and document disease freedom, as defined by the OIE;
- Evaluation of geographic gaps in surveillance sampling and the targeting of the geographic areas with sheep and/or goat populations that are missed
- Evaluation of percentage of flocks in the United States sampled through slaughter or on-farm testing or monitored and tested through SFCP participation. The goal is to see a consistent increase, with an ideal goal of 100 percent of flocks tested or monitored.

12. Surveillance System Evaluation

Annual evaluation of the surveillance system will include: sample collection in new or under-represented geographic areas and flocks, expansion of sampling into new slaughter facilities and other RSSS collection sites, and a documented decline in national scrapie prevalence. The goal will be to re-evaluate and refine sampling plans, and ultimately to allow the development of a revised surveillance plan to document freedom of disease.

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Acronyms Used In This Document

AHSM	Animal Health and Surveillance Management
AINM	Animal Identification Number Management
APHIS	Animal and Plant Health Inspection Service
AVIC	Area Veterinarian-in-Charge
BSE	Bovine Spongiform Encephalopathy
CEAH	Centers for Epidemiology and Animal Health
CNS	Central Nervous System
CSPS	Caprine Scrapie Prevalence Study
DSE	Designated Scrapie Epidemiologist
EIA	Enzyme Immunosorbent Assay
ELISA	Enzyme-Linked Immunosorbent Assay
ERS	Economic Research Service
EU	European Union
FSIS	Food Safety Inspection Service
FY	Fiscal Year
GDB	Generic Database
IHC	Immunohistochemistry
MIM	Mobile Information Management
NAHMS	National Animal Health Monitoring System
NASS	National Agricultural Statistics Service
NCAHP	National Center for Animal Health Programs
NSEP	National Scrapie Eradication Program

NSU	National Surveillance Unit
NVSL	National Veterinary Services Laboratories
OCIO	Office of the Chief Information Officer
OIE	World Organisation for Animal Health
OTLS	On-line Transmissible Spongiform Encephalopathy Laboratory Submission
PrP	Prion Protein
PrPsc	Scrapie Prion Protein
RSSS	Regulatory Scrapie Slaughter Surveillance
SFCP	Scrapie Flock Certification Program
SOSS	Scrapie Ovine Slaughter Surveillance Study
TSE	Transmissible Spongiform Encephalopathy
UDB	Unified Database
UM&R	Scrapie Eradication Uniform Methods and Rules
USAHA	United States Animal Health Association
USDA	United States Department of Agriculture
VS	Veterinary Services
VSLS	Veterinary Services Laboratory Submission
WB	Western Blot

Appendix A: State-level Slaughter Sampling Targets

The Regulatory Scrapie Slaughter Surveillance (RSSS) consists of sampling sheep and goats based on targeting criteria, as described in Section 8A. State-level sampling targets are demographically based on the number of mature ewes in each state (NASS Agricultural Census, 2002; GDB) and the expected number of black- and mottled-faced sheep sent to slaughter annually from each state (NAHMS 1996, 2001). Ideal sampling targets were developed, assuming random sampling of the black- and mottled-faced sheep sent to slaughter to detect scrapie at 0.15% prevalence (FY2007 prevalence) with 95% confidence (Cannon and Roe, 1982). For implementation, adjusted targets have been developed based on previous sampling history and resource availability. Some states are already at or near the ideal target and are highly encouraged to maintain these levels at this time; however, some states have had limited sampling from sheep in their state and numbers have been adjusted to allow a gradual increase in numbers that will allow states to realistically meet the ideal targets in the future. Official animal identification information is used to determine state of "origination." Therefore, compliance with the mandatory identification regulation is essential to determine whether a state has met its annual sampling target.

Table 1: State-level performance relative to proposed scrapie surveillance "state-of-origin" sampling targets, Eastern Region

State (of Tag Origin)	Surveillance Targets				FY2007 Slaughter Surveillance		FY2008 Slaughter Surveillance (through 5/8/2008)	
	EXPECTED NUMBER of targeted cull ewes[1]	IDEAL target # to detect 0.15% prev in (BF+Cross)[2]	ADJUSTED target for implementation FY2009[3]	ADJUSTED target for implementation FY2010[4]	Sheep originating in these states[5]	Percent of EXPECTED NUMBER of targeted cull ewes sampled	Sheep originating in these states[6]	Percent of EXPECTED NUMBER of targeted cull ewes sampled
Alabama	1378	1082	10	20	6	0%	8	1%
Connecticut	169	183	5	10	3	2%	1	1%
Delaware	34	37	8	20	7	21%	2	6%
Florida	584	594	10	20	0	0%	0	0%
Georgia	440	460	35	62	32	7%	61	14%

Illinois	5259	1675	1470	1470	1470	28%	793	15%
Indiana	3615	1552	2074	2074	2074	57%	1088	30%
Kentucky	4636	1637	318	556	289	6%	187	4%
Massachusetts	291	313	42	73	38	13%	26	9%
Maryland	1047	926	66	116	60	6%	27	3%
Maine	284	305	13	23	12	4%	11	4%
Michigan	3672	1558	2440	2440	3140	86%	2248	61%
Minnesota	7178	1754	2202	2202	2202	31%	1193	17%
Mississippi	818	774	17	29	15	2%	2	0%
North Carolina	838	794	88	154	80	10%	32	4%
New Hampshire	225	243	5	10	2	1%	2	1%
New Jersey	515	539	68	119	62	12%	34	7%
New York	3436	1536	498	872	453	13%	199	6%
Ohio	7399	1760	3260	3260	3260	44%	2197	30%
Pennsylvania	4057	1601	331	579	301	7%	202	5%
Rhode Island	38	42	5	10	1	3%	3	8%
South Carolina	173	184	7	20	6	3%	12	7%
Tennessee	3090	1490	411	720	374	12%	250	8%
Virginia	3443	1537	538	941	489	14%	209	6%
Vermont	448	475	26	46	24	5%	13	3%
Wisconsin	5916	1707	1748	1748	1748	30%	889	15%
West Virginia	1843	1250	171	298	155	8%	36	2%
REGIONAL TOTAL	**60826**	**26008**	**15866**	**17893**	**16503**	**27%**	**9725**	**16%**

[1]The expected number of targeted cull ewes was estimated from 2002 NASS census data regarding the estimated size of the sheep population in each state and the estimated proportion of mature animals in each state as well as 1996 NAHMS survey data regarding the percentage of sheep on operations of black-faced and cross breeds and cull rates for sheep (where 2001 NAHMS data was used if available).

[2]The IDEAL sampling targets were established to determine the minimum number of mature BF & MF sheep to randomly sample in order to detect scrapie with a 95% confidence if present at 0.15% prevalence (FY2007 prevalence) in the expected cull ewe population.

[3] Because of budget limitations, we do not expect to be able to fully implement the IDEAL sampling targets based on demographics. Surveillance sampling targets were adjusted to stay within expected budget allocations while moving toward more demographic-based surveillance. Sampling targets for FY2009 were adjusted to maintain current levels of RSSS sampling, initiate surveillance at a minimum level in states without existing RSSS collections, or to increase existing RSSS collections by ~10%. In MI, the FY2009 sampling target was reduced by an additional 700 samples from FY2007 collection levels due to the expected impact of changes in the targeting criteria for RSSS that will be implemented in FY2009.

[4] Sampling targets for FY2010 were adjusted to transition to more demographic-based surveillance by maintaining current levels of RSSS sampling or increasing FY2009 sampling targets.

[5]Additional samples that were collected in FY2007 could not be "credited" to the "origination" state despite extensive efforts to review the animal identification information. This was the result of various factors: the animal was not required to be individually identifed when presented to the slaughter plant (I.e., low-risk commerical sheep, the owner presents a lot of sheep directly to slaughter, etc); the animal was not individually identified with official ID when presented at slaughter; the animal presented with serial tags that could not be assigned to a flock or origin; etc; Also, tags applied to unidentified animals presented at RSSS sites in MI, NJ, and PA were reassigned to the appropriate state-of-origin, where possible.

[6] Additional samples that has been collected to date in FY2008 can not be "credited" to the "origination" state. Information regarding available animal identification will be reviewed in detail at the year-end to attempt to "credit" as many samples as possible to the appropriate "origination" state.

Table 2: State-level performance relative to proposed scrapie surveillance "state-of-origin" sampling targets, Western Region

State (of Tag Origin)	Surveillance Targets				FY2007 Slaughter Surveillance		FY2008 Slaughter Surveillance (through 5/8/2008)	
	EXPECTED NUMBER of targeted cull ewes[1]	IDEAL target # to detect 0.15% prev in (BF+Cross)[2]	ADJUSTED target for implementation FY2009[3]	ADJUSTED target for implementation FY2010[4]	Sheep originating in these states[5]	Percent of EXPECTED NUMBER of targeted cull ewes sampled	Sheep originating in these states[6]	Percent of EXPECTED NUMBER of targeted cull ewes sampled
Alaska	16	18	5	10	0	0%	0	0%
Arkansas	996	890	18	31	16	2%	4	0%
Arizona	1079	955	32	56	29	3%	2	0%
California	9042	1804	344	603	313	3%	142	2%
Colorado	4280	1620	683	1195	621	15%	283	7%
Hawaii	13	14	44	44	44	338%	69	531%
Iowa	11148	1835	4390	4390	4390	39%	3040	27%
Idaho	5148	1676	839	1469	763	15%	457	9%
Kansas	4222	1609	440	770	400	9%	208	5%
Louisiana	944	859	11	19	10	1%	2	0%
Missouri	3354	1526	681	1192	619	18%	489	15%
Montana	6016	1718	2284	2284	2284	38%	1691	28%
North Dakota	3806	1573	1159	1573	1054	28%	486	13%
Nebraska	4193	1607	644	1126	585	14%	344	8%
New Mexico	2950	1482	44	77	40	1%	38	1%
Nevada	1475	1137	66	116	60	4%	69	5%
Oklahoma	851	790	98	171	89	10%	56	7%
Oregon	3817	1580	289	506	263	7%	150	4%
South Dakota	19424	1901	4547	4547	4547	23%	2693	14%
Texas	10200	1818	820	1434	745	7%	353	3%
Utah	6074	1720	855	1496	777	13%	698	11%
Washington	1105	967	74	129	67	6%	51	5%
Wyoming	8041	1782	1686	1686	1686	21%	979	12%
REGIONAL TOTAL	**108194**	**30881**	**20052**	**24923**	**19402**	**18%**	**12304**	**11%**

[1]The expected number of targeted cull ewes was estimated from 2002 NASS census data regarding the estimated size of the sheep population in each state and the estimated proportion of mature animals in each state as well as 1996 NAHMS survey data regarding the percentage of sheep on operations of black-faced and cross breeds and cull rates for sheep (where 2001 NAHMS data was used if available).

[2]The IDEAL sampling targets were established to determine the minimum number of mature BF & MF sheep to randomly sample in order to detect scrapie with a 95% confidence if present at 0.15% prevalence (FY2007 prevalence) in the expected cull ewe population.

[3] Because of budget limitations, we do not expect to be able to fully implement the IDEAL sampling targets based on demographics. Surveillance sampling targets were adjusted to stay within expected budget allocations while moving toward more demographic-based surveillance. Sampling targets for FY2009 were adjusted to maintain current levels of RSSS sampling, initiate surveillance at a minimum level in states without existing RSSS collections, or to increase existing RSSS collections by ~10%. In MI, the FY2009 sampling target was reduced by an additional 700 samples from FY2007 collection levels due to the expected impact of changes in the targeting criteria for RSSS that will be implemented in FY2009.

[4] Sampling targets for FY2010 were adjusted to transition to more demographic-based surveillance by maintaining current levels of RSSS sampling or increasing FY2009 sampling targets.

[5]Additional samples that were collected in FY2007 could not be "credited" to the "origination" state despite extensive efforts to review the animal identification information. This was the result of various factors: the animal was not required to be individually identifed when presented to the slaughter plant (I.e., low-risk commerical sheep, the owner presents a lot of sheep directly to slaughter, etc); the animal was not individually identified with official ID when presented at slaughter; the animal presented with serial tags that could not be assigned to a flock or origin; etc Also, tags applied to unidentified animals presented at RSSS sites in MI, NJ, and PA were reassigned to the appropriate state-of-origin, where possible.

[6]Additional samples that has been collected to date in FY2008 can not be "credited" to the "origination" state. Information regarding available animal identification will be reviewed in detail at the year-end to attempt to "credit" as many samples as possible to the appropriate "origination" state.