

National Scrapie Risk-Based Incentive Program Summary December 2023

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Background

Since 1952, the U.S. Department of Agriculture (USDA) has worked to control and eradicate scrapie in the United States. The National Scrapie Eradication Program (NSEP) goals are to eradicate classical scrapie from the United States and to meet World Organisation for Animal Health (WOAH) criteria for disease freedom. Veterinary Services (VS), a program within the USDA Animal and Plant Health Inspection Service (APHIS), modernized the NSEP in 2001. This has reduced scrapie prevalence in the national flock/herd to <0.0020 percent in sheep and <0.0048 percent in goats (calculated using slaughter surveillance data from fiscal year (FY) 2019 through FY 2023). This low prevalence requires

additional surveillance efforts to detect the remaining cases, such as increased targeted sampling (sampling subpopulations with a higher prevalence than the general population).

The VS Surveillance Design and Analysis (SDA) unit completed an internal evaluation of the scrapie surveillance system in March 2018. The evaluation included multiple recommendations to meet surveillance metrics. One recommendation was to develop a risk-based system for targeted sampling efforts to support eradication. SDA formally elicited input from a group of seven experts with field scrapie experience to create a points system. SDA worked with the Sheep and Goat Team (SGT) to develop a system to incentivize submitting samples from higher-risk animals and animals from higher-risk farms based on the expert-elicited points system. The SDA and GST accomplished this by using knowledge of the United States' current scrapie status and experience implementing a scrapie surveillance program. This paper describes an incentive system that provides risk-based surveillance credit using animal-level and flock-level risk factors that will be fully implemented in FY 2024.

In this paper, we explain surveillance components, and then we go in-depth about surveillance using Risk-based Incentives in Phase 1 and Phase 2 of the project. Phase 1 of the incentive system was implemented during FY 2022 and focused on the animals that have the greatest likelihood or infection. Phase 1 provides extra sample credit at the individual animal-level for samples from animals of specific age categories that show clinical signs compatible with scrapie (see Footnote 3 of Tables 1 and Tab

Phase 2 was developed during FY 2022-23 and focuses on farm-level risk factors. In phase 2, states earn more credit towards yearly surveillance minimums when surveillance is conducted on higher-risk farms. This encourages states to conduct surveillance on premises characterized as having a higher likelihood of scrapie infection based on a set of risk factors.

The future phases of the project will happen from FY 2024-FY 2026. Phase 3 will achieve full implementation of the incentive system in FY 2024. Phase 4 is expected to occur in FY 2025-2026, during this phase VS staff will evaluate the surveillance effectiveness and make necessary adjustments to the process.

Methods

A true points system assigns point value to an animal or farm based on risk factors. Points measure relative risk, adjusted for the frequency of occurrence of the risk factor in the general population. When mathematically evaluating the probability of disease detection, points can be used in place of sample size; that is, sampling one two-point animal equals sampling two one-point animals in probability calculations. SDA's expert elicitation resulted in an estimated points system that targeted sampling efforts to individual animals or to flocks/herds with the greatest likelihood of infection, according to expert experience and expectation. The system assigned points both to individual animals based on the expert-identified factors predictive of scrapie in sheep and goats, and to farms based on farm-level factors predictive of scrapie in sheep flocks and goat herds. For some factors, practical experience suggested that the incentive or disincentive provided by the expert-elicited points would be inadequate for targeted sampling efforts or inappropriate to support the goal of scrapie eradication. SGT and SDA therefore adjusted the expert-elicited points system in some categories to provide risk-based credit more likely to encourage sampling of animals and farms with the highest surveillance value. The incentive system does not discourage submissions in some categories the way the expert-elicited points system would have.

Surveillance Components

Surveillance includes sampling of both healthy and unhealthy sheep and goats, with an emphasis on:

- Unhealthy animals and other higher-risk animals and groups,
- Underrepresented flocks and herds, and
- Underrepresented geographic regions that previous surveillance efforts may have been missing.

Prior to the implementation of Phase 1, each sheep and goat tested for scrapie was counted as one surveillance sample, whether the animal was submitted through live or dead on-farm testing or Regulatory Scrapie Slaughter Surveillance (RSSS), and regardless of its genotype. The differences between the prior surveillance system and the current risk-based incentive system are discussed in the surveillance using risk-based credits section of this document.

There are two main surveillance components used by animal health officials to identify infected sheep and goats and meet the surveillance objectives in the <u>National Scrapie Surveillance Plan</u>: on-farm surveillance and RSSS.

On-farm Surveillance

On-farm surveillance includes both regulatory testing of scrapie-exposed and potentially exposed sheep and goats, and testing sheep and goats on-farm for routine surveillance. On-farm surveillance consists of samples from both live and dead animals tested for one of the following reasons:

- Scrapie Free Flock Certification Program (SFCP) to obtain certification or monitored status.
- Post Exposure Monitoring and Management Plan (PEMMP) samples from a flock previously infected with or exposed to scrapie and currently under a monitoring and management plan.
- Voluntary on-farm surveillance (not part of SFCP) of mature sheep or goats that die or are euthanized.
- Testing clinically suspect, exposed or potentially exposed animals as part of disease investigations.

- Voluntary live animal testing of susceptible sheep or goats in flocks/herds with risk factors for scrapie, or from sheep and goats that reside in States that cannot meet their sampling minimums through other methods.
 - a. Sheep are typically genotyped using a blood sample taken prior to or at the same time as the collection of rectal biopsy samples to reduce the costs associated with immunohistochemistry (IHC) testing.
 - b. Genotyping is performed before IHC testing and only QQ¹ sheep are tested using IHC.
 - c. Prior to the implementation of the risk-based incentive credit system all sheep sampled received one surveillance credit for each sheep. Following implementation of the credit system sheep that are known to be QQ before selection for testing receive four credits.

Regulatory Scrapie Slaughter Surveillance

The RSSS samples mature sheep and goats slaughtered or condemned at participating slaughter facilities, as well as dead or disabled animals found at other concentration points, such as markets and cull feedlots. Prior to the current incentive system, each sheep or goat sampled through RSSS was worth one surveillance sample.

In most cases, genotyping is only performed if a submitted sample tests positive for scrapie. However, based on a pilot project conducted from 2019 to 2021, APHIS determined that it is cost effective to do genotype testing and only test samples for scrapie from susceptible normal slaughter sheep that are collected at the Indiana and Michigan VS sample collection sites. This is a relatively small number of animals and we do not expect this number to increase because only a few collection sites can manage the sampling process in a cost-effective manner. For reference, in FY 2019-2021, 8,065 sheep were genotyped and 5,809 (72 percent) of these animals were not genetically susceptible.

Overview of surveillance using risk-based credits

Using either on-farm surveillance or RSSS, the implementation of the scrapie surveillance risk-based incentive system has four phases:

Phase 1 (Implemented Animal Level Risk-based Credits)

VS staff began partial implementation of the incentive system by focusing only on assigning risk-based credits according to individual animal risk factors. These credits are computed with data that was already being captured either in the Data Integration System (DIS) during sample collection, or the laboratory test submission and resulting process being captured in the Veterinary Services Laboratory Submissions (VSLS) system. These additional credits only apply if the tests are deemed valid by the laboratories on at least one tissue. The final step in Phase 1 was to correctly apply rules for receiving credit based on animal-level risk factors in DIS.

¹ As used in this document QQ stands for any genotype at codon 171 that does not include R, such as QH, QK, KH, HH or KK.

Phase 2 (Developing Flock Level Risk-based Credits)

VS staff created and approved farm survey questions, and additional data fields, needed for animal health officials to capture information required to assign risk-based credit according to farm-level risk factors. Ensuring data management of newly collected information in DIS as well as applying rules for receiving credit are also part of Phase 2 and are still being developed and tested for farm-level credit.

Phase 3 (Implementing Flock Level Risk-based Credits)

VS staff will fully implement and maintain the incentive system, using both animal and farm-level risk factors, to incentivize collection of high value surveillance samples. Once fully implemented, the system will incentivize the collection of sheep and goats more likely to be infected by scrapie and will help VS staff to identify sheep and goats from farms more likely to be scrapie-affected for sampling. Phase 3 is expected to begin in FY 2024.

Phase 4 (Review Impact of Risk-based Credits)

VS staff will evaluate the surveillance effectiveness and adjust the incentive plan if needed. Phase 4 is expected to begin in FY 2025-2026.

Phase 1: Individual animal-level risk-based credits

Starting October 1, 2022 (FY 2023), VS assigned risk-based credits for each animal tested for scrapie. These credits were assigned to data that was already being recorded in VSLS system during the sample submission process for all on-farm and RSSS scrapie testing. The Center for Informatics (CFI) designed an algorithm to automate this process and it is now fully implemented. The incentive system improves scrapie eradication efforts by focusing surveillance sampling on higher-risk animals and flocks/herds. The incentive system may also help states meet their yearly surveillance minimums, especially in those states that struggle to reach their yearly goal. Incentive credits are only assigned for animals meeting the criteria and where at least one tissue submitted has a valid result as determined by the testing laboratory. For example, no incentive credit is assigned, regardless of the animal-level risk factors, if there are insufficient follicles in a rectal biopsy sample or the incorrect tissue or location is submitted for both the retropharyngeal lymph node (RLN) and obex. Zero points are assigned for samples not received by the lab.

Risk-based credits for animal-level factors

Additional credit (see <u>Tables 1 and 2</u>) is assigned for individual animals that meet certain risk factor criteria related to clinical signs, age, and susceptible genotypes (such as QQ) for sheep on-farm testing when the owner knows the genotype of the animals before sampling. One risk-based credit in this new system is the equivalent of one surveillance sample in the previous system. For example, if an animal were assigned 30 risk-based credits, it would be the equivalent of having tested 30 animals in the previous system. Sheep and goats are given the same credit for the same risk factors. This system encourages reporting and testing of clinical suspects in the most likely age groups. The system discourages testing animals that have a very low likelihood of infection, such as the very young or the very old, by providing credit less than one.

Clinical Signs

Mature animals exhibiting clinical signs compatible with scrapie are more likely to be infected than apparently healthy animals. The expert elicitation determined three categories for clinical signs:

- Classic clinical signs
- Less specific clinical signs, and
- No clinical signs (see Footnote 3 of Tables 1 and 2)

The SGT only awards risk-based credits for the classic clinical signs category with approved documentation. The animal health official must submit a video or detailed signalment and description of observed clinical signs to the scrapie@usda.gov email address for SGT concurrence. SGT and VS appreciate video submissions and will use them for training presentations. Mature animals exhibiting clinical signs typically qualify for indemnity.

There are differences between credits assigned to clinical signs depending on whether samples are submitted by on-farm testing or RSSS. Only on-farm testing submissions receive additional credits for submissions from age-appropriate animals exhibiting less specific clinical signs (see age indicators section below). Samples collected from age-appropriate animals through slaughter channels continue to receive credit for one surveillance sample per animal with no additional credit for animals exhibiting less specific clinical signs.

RSSS animals exhibiting classic clinical signs are eligible for the additional credit if the SGT receives video documentation or signalment and detailed descriptions of clinical signs observed by the animal health official, or the animal is over 12 months and condemned by the Food Safety Inspection Service (FSIS) for central nervous system (CNS) signs (see <u>Table 2</u>). Incentive credits for sampling any one sheep or goat are capped at 30 percent of the State's annual minimum sample requirements. For example, if a State has a minimum quota of 30 sheep samples and the animal health official submits an on-farm sample from a 3-year-old sheep exhibiting classic clinical signs, that State would be awarded 9 incentive credits, (30 incentive credits x 30% cap = 9 incentive credits), instead of the 30 credits stated in Table 1

It is important to note that if multiple on-farm samples will be collected from animals showing no clinical signs, then the sample collector will be encouraged to complete the farm-level survey discussed in the Phase 2 section. This will potentially allow for more sampling credit per animal tested when the farm-level risk is considered.

Age

According to the expert elicitation panel, literature, and historic data provided by the SGT, animal age is strongly associated with presentation of clinical signs for scrapie-infected animals. Using current NSEP policy for age-appropriate animals as the foundation, the incentive credits are assigned according to seven age categories: less than 12 months, 12 to <18 months, 18 to <24 months, 24 to <36 months, 36 to <48 months, 48 to <72 months, and greater than or equal to 72 months.

Most animals become infected with scrapie at or near birth. Very young animals (less than 12 months) that do not have additional tissues collected as part of the lamb protocol are very unlikely to have scrapie detected and should not be sampled for routine surveillance. Animals that are 12 months to 18 months of age should be tested if they present clinical signs but are unlikely to have had time to be

clinically affected with scrapie. Animals between 18 months and 72 months (6 yrs.) of age are the most likely to have scrapie detected and should be tested regardless of clinical signs. Those presenting classical or less specific clinical signs should be preferentially sampled on the farm over those with no clinical signs. Testing animals that present classic clinical signs is especially valuable for animals in the 3-to-5-year range, as this is the period when clinical signs are most likely to occur. Animals infected at or near birth rarely live more than 72 months, so very old animals are less likely to be infected with scrapie. Animals exposed to scrapie after weaning are less likely to become infected, but it does happen and can result in animals over 72 months of age presenting with clinical scrapie.

Genotype

Animal-level incentive credit for genotyping pertains only to sheep. At this time, all goat genotypes are considered genetically susceptible for disease response purposes; however, there is evidence that goats with a single copy of one of three goat prion gene alleles (D146, S146, or K222) may be less susceptible to scrapie. Due to the low prevalence of these alleles in United States' goats, it isn't cost effective to use genotype to screen goat surveillance samples.

The majority of RSSS sheep are not genotyped. Positive scrapie cases are genotyped. Since there is no opportunity for incentivizing sampling of QQ genotypes in the slaughter population, the incentive system does not include risk-based credit for the susceptible genotype animal collected through RSSS.

For states that struggle to meet their scrapie surveillance state minimums, the current practice is for the State or VS to identify a flock for sampling and submit up to 30 samples for scrapie testing along with blood samples for genotyping. The lab makes a "submit/don't submit" decision after running all blood samples; only corresponding samples from QQ sheep are processed for scrapie testing. All sheep, regardless of genotype, will receive one credit unless State or VS personnel complete and submit a farm-level survey. Additional incentive credit will then be assigned per the guidelines in the Farm-level risk-based credit section. Only samples from the sheep that had a valid rectal biopsy test and that reside on a breeding farm for which a correctly completed farm-level survey was submitted will qualify for the additional farm level sampling credits.

If the owner/producer knows the genotypes of their sheep and can pre-select the QQ sheep for testing, they will receive four risk-based credits for each QQ sheep 18 months or older to a maximum of 40 credits per flock. However, if a farm-level survey is completed and the farm-level risk factors result in a higher number of credits, the farm will be awarded the higher of the two values. If one or more of these QQ sheep displayed clinical signs, they would get the higher of the clinical sign credits or the genotype credits. Risk-based credits for clinical signs would follow Table 1. No risk-based credits would be given for rectal biopsy tissue submitted from live nonclinical sheep known to be QR² or RR prior to VS genotyping them, as typically these animals should not be re-genotyped or biopsied. However, dead animals, other than from healthy slaughter, of any genotype should be tested and will receive the credits listed in Table 1.

² As used in this document QR refers to any genotype that includes one R at codon 171, such as HR or KR.

Laboratory Submission

The VSLS process for submitting the samples to the laboratory remains the same for RSSS samples, though to receive additional credit for animals exhibiting classic clinical signs, the submitter must submit the animal as a clinical suspect and put the FSIS condemnation tag's number in one of the secondary ID fields.

There was one small, but important, change made in FY 2022 to the VSLS process for submitting onfarm samples. Under the "Designation" drop-down found in the "Sample Details" section (see the area labeled with a blue triangle in Figure 1), the available options have changed from the five options displayed in Figure 2 to the six options displayed in Figure 3. The first four options, "Positive", "Suspected", "Exposed" and "Missing Ewe," have remained the same and their definitions can be found in Footnote 4, VSLS On-Farm Designations, as well as a newly added help menu in VSLS. The "No Designation" option has been split into two options, now called "No Designation-Less Specific Signs" and "No Designation-Non-Clinical". Briefly, the "No Designation-Less Specific Signs" should be selected when submitting samples from an animal exhibiting less specific clinical signs and "No Designation-Non-Clinical" should be selected when an animal does not fit into one of the other categories and is not exhibiting any classic or less specific clinical signs.

The "Designation" data field is the algorithm used in DIS to assign the appropriate surveillance credits which is why it is important to ensure the correct selection is made. If "Suspected" is selected, that animal will be assigned the age-appropriate credit for the "less specific signs" category until video or written documentation is sent to and approved by the SGT, at which point the SGT will manually adjust the credit received for that animal in DIS.

Figure 1. On-farm VSLS Sample Details



Figure 2. On-farm VSLS Original Designation Options

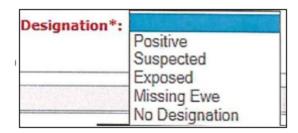


Figure 3. On-farm VSLS Updated Designation Options

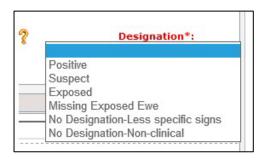


Table 1. Risk-based credits for individual animal-level on-farm submissions*

Age ¹ (months)	<12 months	12 to <18 months	18 to <24 months	24 to <36 months	36 to <48 months	48 to <72 months	≥72 months			
Age (VSLS dropdown menu options) ²	NA	12 to <18 months	18 to <24 months	2 years	3 years	4 years OR Full mouth – minimal (5 years)	Full mouth-moderate (6-7 Years) OR Full mouth-severe (8+years)			
Clinical Sign	Clinical Signs ^{3,4}									
Classic clinical signs	0 [†]	1	2	15+++	15+++ 30+++ 20+++		2			
Less specific clinical signs	O [†]	0.5†	1.5	1.5	3	1.5	1			
No clinical signs	O [†]	0.5 [†]	1++	1++	1++	1++	0.5			

^{*} This table reflects the risk-based credits for on-farm submissions that do not have an accompanying farm-level (Phase 2) survey.

Table 2. Risk-based Credits for RSSS Submissions

Age ¹ (months)	<12 months	12 to <18 months	18 to <24 months	24 to <36 months	36 to <48 months	48 to <72 ⁵ months	≥72 months	
Age (VSLS drop-down menu options) ²	N/A	12 to <18 months	18 to <24 months	2 years	3 years	4 years OR Full mouth – minimal to moderate (5-6 years) OR Full mouth- moderate (6-7 Years)	Full mouth- severe (8+ years)	
Clinical Signs	s ³							
Classic clinical signs	0 [†]	1	2	15+++	30+++	20+++	2	
No or less specific clinical signs	0 [†]	1	1	1	1	1	0.5	

¹Determined through dentition unless the submitter provides a registration certificate showing birth date. Due to difficulty in making an age determination via dentition in the RSSS system, any animal displaying broken, missing, splayed, or severely worn teeth will be assessed as greater than 72 months.

- <12 months (no permanent incisors)
- 12 to <18 months (initial eruption of first incisor)
- 18 to <24 month (first incisor fully erupted to eruption of second incisor)
- 24 to <36 months (second incisor erupted and third incisor not erupted)
- 36 to <48 months group (third incisor erupted to fourth incisor fully erupted)
- 48 to 72 (fourth incisor fully erupted and no broken, splayed, or missing teeth and/or severe wear)
- ≥ 72 months (broken, missing, splayed and/or severe wear)

²When known, VS recommends entering the age in months into VSLS rather than using the drop-down menu estimates.

³ Clinical Sign Categories

Classic clinical signs – 1) CNS signs including ataxia, incoordination, biting at legs or side, lip smacking, defensiveness, star gazing, change in behavior, ear tremors, and/or general tremors or 2) Intense rubbing and bilateral abrasions with bare areas/wool or hair loss suggestive of rubbing or chewing, thickened and/or hyperpigmented skin with bare areas.

Less specific clinical signs - 1) non-ambulatory prior to slaughter or death, 2) condemned at slaughter other than for CNS signs (and over 12 months of age), 3) signs of wasting (poor body condition) or being unthrifty with good teeth, 4) wool or hair loss without intense rubbing being observed and/or 5) dead of unknown cause. (Note that this category includes fallen stock defined as non-ambulatory prior to slaughter and dead of unknown causes, i.e., dead, down, or disabled.)

⁴ VSLS On-Farm Designations

The following are the definitions for the on-farm designations in VSLS that are correlate to the <u>clinical signs</u> <u>categories</u> for awarding credit:

Positive: A sheep or goat that has been confirmed positive for classical scrapie by the National Veterinary Services Laboratories (NVSL).

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

- A mature sheep or goat as evidenced by eruption of the first incisor that has been determined to be suspicious for scrapie by an accredited veterinarian or a State or USDA representative, based on one or more of the following signs and the severity of the signs: Weakness of any kind including, but not limited to, stumbling, falling down, or having difficulty rising, not including those with visible traumatic injuries and no other signs of scrapie; behavioral abnormalities; significant weight loss despite retention of appetite or in an animal with adequate dentition; increased sensitivity to noise, light, or sudden movement; tremors; star gazing; head pressing; bilateral gait abnormalities such as but not limited to incoordination, ataxia, high stepping gait of forelimbs, bunny-hop movement of rear legs, or swaying of back end, but not including abnormalities involving only one leg or one front and one back leg; repeated intense rubbing with bare areas or damaged wool in similar locations on both sides of the animal's body or, if on the head, both sides of the poll; abraded, rough, thickened, or hyperpigmented areas of skin in areas of wool/hair loss in similar locations on both sides of the animal's body or, if on the head, both sides of the poll; or other signs of CNS disease. An animal will no longer be a suspect animal if it is redesignated in accordance with Title 9, *Code of Federal Regulations* (9 CFR) 79.4.
- A sheep or goat that has tested positive for scrapie or for the proteinase resistant protein associated with scrapie on a live animal screening test or any other test, unless the animal is designated a scrapie-positive animal.
- A sheep or goat that has tested inconclusive or suggestive on an official test for scrapie.

Exposed animal: Any animal or embryo that:

- Has been in a flock/herd with a scrapie-positive female animal.
- Has been in an enclosure with a scrapie-positive female animal at any location.
- Resides in a noncompliant flock.
- Has resided on the premises of a flock/herd before or while it was designated by a designated scrapie epidemiologist (DSE) as an infected or source flock/herd and before a flock/herd plan was completed. An animal shall not be designated an exposed animal if it only resided on the premises before the date that infection was most likely introduced to the premises as determined by a Federal or State representative.

Missing Ewe: If one or more high-risk female animals that may have lambed in the flock ("may have lambed" refers to any ewe/doe old enough to lamb, unless it can be documented that she did not lamb) are no longer available (e.g., sold, died, cannot be positively identified), this designation is selected when testing their progeny and any birth cohorts of their progeny remaining in the flock/herd, and when appropriate, subsequent lambing cohorts.

No Designation (Less Specific Signs): Any animal that has any of the clinical signs listed for a scrapie suspect animal, that was not condemned for CNS signs and was <u>not</u> deemed to be a scrapie suspect by an accredited veterinarian or a State or USDA representative. In addition, this designation includes animals that are euthanized due to any type of ailment or disorder, or that died, even if another diagnosis has been made.

No Designation (Non-Clinical): Not displaying any clinical signs associated with scrapie-routine surveillance.

⁵ For RSSS incentive credits we combined minimal and moderate because of the difficulty in accurately differentiating age based on dental wear.

[†]Zero or reduced points assigned for sheep or goats less than 18 months of age unless submitted on an approved lamb protocol

^{††}If the situation arises where QQ genotype live sheep showing no clinical signs can be pre-selected prior to testing (submit/don't submit decision needs to be made), those animals can receive an additional four risk-credits per sheep. Any samples from live sheep showing no clinical signs with <u>previously identified</u> QR or RR genotypes should not be sampled and if submitted will receive no risk credits.

***Incentive credits for sampling any one sheep or goat will be capped at 30 percent of the State's annual minimum sample requirements.

Phase 2: Farm (flock/herd)-level risk-based credits

The Phase 2 incentive system encourages States and VS to conduct surveillance on premises characterized as having a higher likelihood of scrapie infection based on a set of risk factors. Higher risk farms are incentivized to conduct surveillance because they receive more credit towards State's yearly surveillance minimums. Farm-level risk-based credits will only be applied to on-farm testing. Samples tested through RSSS channels are only eligible for incentive credit at the individual animal level.

On-farm surveillance is incentivized because, when compared to RSSS, on-farm surveillance can target higher risk and previously unsampled subpopulations, which supports disease eradication. This increases the chances of detecting the low numbers of scrapie infected animals remaining in the United States. On-farm surveillance involves testing live animals and requires more time, skill, and resources, but because the chance of finding cases is increased, targeting high-risk farms maximizes the effectiveness of available resources.

Like the individual animal incentive, the farm-level incentive system only gives credit for animals tested on-farm when at least one tissue submitted has a valid result as determined by the testing laboratory. For example, if there are insufficient follicles in a rectal biopsy sample or the incorrect tissue or location is submitted for both the RLN and obex, no credit will be assigned regardless of farm or animal level risk factors. No credit is assigned for samples not received by the lab.

Risk-based credits for farm-level factors

Information needed to identify the higher risk farms is not routinely captured. This is unlike the individual animal level incentive in Phase 1, where the information used to identify higher risk individual animals was already being captured by the animal health officials collecting scrapie samples. For this Phase 2 part of the project, VS staff designed a farm-factor survey in Excel to be used by the field. Using the expert elicited point system as a foundation, SDA and SGT established the rules for receiving credit based on farm-level risk factors. CFI is currently developing a DIS algorithm to automate the credit calculation.

Farm-level Risk Factor Survey and Algorithm

The Farm-level Risk Factor Survey is a screening tool, developed in Excel, to identify farms with a higher likelihood of having scrapie infected animals. It can be used by animal health officials prior to conducting on-farm surveillance. The screening tool consists of a short list of distinct farm-level risk factors and the user checks a box for any behavior that is true for the farm being evaluated. These factors are discussed in greater detail in the following <u>section</u>. The farm-level risk factors are based on the factors identified by expert panel and reworded using practical experience from the SGT.

The screening tool uses a built-in algorithm to assign each risk factor (excluding the genotyping factors) a numeric value between one and three according to perceived relative level of risk of scrapie infection. The tool assigns a value of zero if the factor is not selected. Larger values are assigned to factors with greater risk. When factors related to birthing practices are selected, the value of other selected factors are increased by a small multiplier. The genotyping factors (other than complete selective genotyping) are protective and are assigned negative values. These factors also reduce the risk of other factors through a small negative multiplier. The values assigned to the factors including the multiplied values but excluding the selective genotyping factor are summed to obtain a total score. The resulting numerical values are only meaningful as relative values.

The farm is scored as low risk and the survey ends when the most protective score is reached either when 1) all breeding rams/bucks are genetically resistant (sheep RR171, goat SS or DD146/KK222), 2) all of the sheep and goats are genetically resistant or less susceptible (sheep RR171/QR171, goats S146/K222), or 3) the flock is SFCP export certified.

Other selected genotyping factors on a farm are assigned a negative value since they are protective factors and reduce the numerical score that is used to determine the final Farm Risk Score (Table 3). The assigned negative value is then multiplied by the previously calculated subtotal, reducing the subtotal by 15 to 50 percent. If these genotyping factors are not selected, that is not using selective genotyping in flock/herd management, the algorithm assigns a value of 0.5 for each genotyping factor.

The algorithm then adds the genotyping factor values to the subtotal for a final numerical overall risk score. The algorithm uses that final numerical overall risk score to assign the farm a Farm Risk Score of low, medium, or high. The Farm Risk Score is used by the animal health official to determine whether the surveillance value of that farm is high enough to warrant the resources needed for sampling. If that farm is selected for sampling, the score is then used by the DIS algorithm to determine the number of incentive credits to apply to the State when surveillance is conducted on-farm.

Farm-level risk factor survey criteria

The intended goal is to identify higher risk farms, and so to save time, the survey has several criteria listed at the beginning of the survey that aim to identify the very low-risk farms (Figure 4). The criteria that will exclude a farm from being eligible for farm-level incentive credit are:

1.

A: <u>All</u> sheep/goats are genetically resistant/less susceptible (sheep RR171/QR171, goats S146/K222) **OR**

B: <u>All</u> the breeding rams/bucks are genetically resistant (sheep RR171, goats SS or DD146/KK222) **OR**

C: the flock is SFCP export certified OR

D: the flock is on the do not collect list OR

E: 30 or more animals from this farm have been sampled in the last 5 years

Two additional criteria pertain to selective genotyping practices:

- 2. Most (>50%) rams/bucks actively used for breeding are known to be genetically resistant (sheep RR171, goats D or S146/K222) to scrapie.
- 3. Most (>50%) breeding sheep and goats added to the premises are known to be genetically resistant (sheep RR171/QR171, goats D or S146/K222) or have had previous rectal biopsies for scrapie testing OR if female genotypes are not known or are susceptible, no female breeding animals have been added in the last 5 years (i.e., closed ewe or doe flock for 5 or more years)

If either of the selective genotyping practices are used by the farm, they are considered protective and will lower the overall numerical risk factor score by 35% and 15% respectively, for a total of 50% if both are selected. If the farm does not perform the specified selective genotyping, a numeric value of 0.5 will be added to the overall risk factor score for each factor for a total of one, if neither practice is used.

One criterion pertains to equipment and transportation biosecurity behaviors. If the farm does either behavior, a value of 1 will be assigned. Sharing either workers or equipment with other breeding farms increases the risk of introducing scrapie into the farm's flock/herd, especially if there is inadequate biosecurity and equipment cleaning:

4. Animal handlers work on other sheep/goat breeding farms **OR** the farm shares equipment with other sheep/goat breeding farms.

If the farm does either behavior, a value of 1 will be assigned. Sharing either workers or equipment with other breeding farms increases the risk of introducing scrapie into the farm's flock/herd, especially if there is inadequate biosecurity and equipment cleaning.

The next criteria pertain to exposure of the herd to lower status animals within the last five years. :

- 5. Young stock are fed colostrum or milk from another sheep or goat flock/herd source.
- **6.** Breeding animals with unknown or susceptible genotype are brought on this premises from other sources (e.g., farms, sale barns, markets, dealers).
- **7.** Newborns, young stock, or non-breeding animals from other farms of lower status are sometimes reared here (e.g., if also running a feedlot or raising orphans)
- **8.** Stock are reared off-site and brought back.

9. This farm has previously been infected with scrapie.

The values assigned for these risk factors are 2, 2, 1, 1, and 1.5 respectively. The riskiest of the factors are related to exposure of the herd to a lower status animal and are assigned a value of 2. These behaviors include breeding animals with unknown or susceptible genotypes and feeding young animals colostrum or milk from another sheep or goat flock/herd source with unknown risk factors. If a farm was previously infected with scrapie, affected animals have been culled and it has likely been tested numerous times. However, since scrapie is not something that can be disinfected from the environment, there is a slight increase in risk and this factor was assigned a value of 1.5.

The final criteria pertain to birthing and placenta management behaviors:

- **10.** Birthing takes place in confined places that aren't or can't be cleaned (it doesn't matter if this is a dry lot, a small pasture, or individual pens)
- **11.** Placenta or contaminated bedding are disposed of on the operation in a location that animals have access to
- **12.** Farm workers don't wash clothing or clean and disinfect equipment daily after exposure to placentas and birthing materials from THIS farm.

When the survey is complete, the built-in algorithm results in a final score and assigns the overall farm risk according to <u>Table 3</u>. The highest a farm can score if they do not do selective genotyping and have every risk factor listed is 15.4, but the value of this score is only meaningful as a relative value.

Table 3. Farm Risk Score

Overall numerical risk factor score	Farm Risk Category
0 to <= 2	Low
>2 to <= 7.7	Medium
>7.7	High

Farm Risk Category

Once a farm has been assigned a <u>Farm Risk Score</u>, an algorithm in DIS that is currently under development will automatically tabulate the incentive credits assigned to that farm according to <u>Table</u> 4:

Table 4. Farm-level Risk-based Credits

Farm Risk Category	Incentive Credits per Animal
Low	1 (no additional credits)
Medium	1.5
High	2

Incentive credit will be capped at 30 percent for any one farm of a state's minimum to ensure that no one farm will meet the surveillance minimum and will encourage the testing of multiple flocks/herds within a state, therefore improving the eradication surveillance.

Farm-Level Data Submission

The method of collecting this data will be in electronic spreadsheet format, with a MiCo form as the eventual proposed collection tool.

Figure 4. Snapshot of Farm-level survey tool

Factors	Check if behavior is true	Conversion of checkbox	Default Risk Factor Value	Risk Factor Scores	Calculations
Selective Genotyping Behaviors (protective if checked, risky if not checked):	13 true	Conversion of Checkbox	Value	Scores	Calculations
All sheep/goats are genetically resistant/less susceptible (RR/QR)(S146/K222) OR All the breeding rams/bucks are genetically resistant (RR)(S146/K222) OR this flock is SFCP export certified OR the flock is on the do not collect list?		FALSE	-100% of total if True, no deductions if false	NA	Continue
Most (>50%) rams/bucks actively used for breeding are known to be genetically resistant (RR/S146/K222) to scrapie		FALSE	TRUE= -35% of total FALSE= 0.5	0.5	
3. Most (>50%) breeding sheep and goats added to the premesis are known to be genetically resistant (RR/QR)(\$146/K222) or have had previous rectal biopsies for scrapie testing OR if female genotypes are not known or are QQ, no female breeding animals have been added in the last 5 years (ie: closed ewe or doe flock for 5 or more years)		FALSE	TRUE= -15% of total FALSE= 0.5	0.5	0.5
Equipment and transportation biosecurity behaviors (risky):					
 Animal handlers work on other sheep/goat breeding farms OR the farm shares equipment with other sheep/goat breeding farms 		FALSE	1	0	0
Exposure to lower status animals (in the last 5 years) behaviors (risky):					
5. Young stock are fed colostrum or milk from another sheep or goat flock source		FALSE	2	0	0
Breeding animals with unknown or susceptible genotype are brought on this premises from other farms, sale barns, markets, or dealers, etc.		FALSE	2	0	О
 Newborns, young stock, or non-breeding animals from other farms of lower status are sometimes reared here (e.g. if also running a feedlot or raising orphans) 		FALSE	1	0	0
8. Stock are reared off-site and brought back		FALSE	1	0	0
This farm has previously been infected with scrapie		FALSE	1.5	0	0
Birthing and placenta management behaviors (risky):					
 Birthing takes place in confined places that aren't or can't be cleaned (it doesn't matter if this is a dry lot, a small pasture, or individual pens) 		FALSE	1+ 10% of total of exposure/biosec/ba d geno behaviors	0	0
11. Placenta or contaminated bedding are disposed of on the operation in a location that animals have access to		FALSE	1+ 10% of total of exposure/biosec/ba d geno behaviors	0	0
12. Farm workers don't wash clothing or C&D equipment daily after exposure to placentas and birthing materials from THIS farm		FALSE	1+ 10% of total of exposure/biosec/ba d geno behaviors	0	0
		SubTotal (bio/exp/"bad"geno (no protective geno)):		1	
click on the heading cells to the right for further descriptions	-	Total (bio/exp/bad geno/birthing (no protective geno)):		1	
		Total farm risk factor score (includes protective geno):		1.0	
		Farm Overall Risk:		LOW	