

REPORT OF THE USAHA COMMITTEE ON SCRAPIE

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Vice Chair: Larry Forgey, MO

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The Committee met on October 18, 2016 at the Sheraton Greensboro Hotel in Greensboro, North Carolina from 9:00 a.m. to 12:00 p.m. There were 15 members and 13 guests present. Meeting was called to order by the chairman, Cheryl Miller. All attendees were asked to sign in.

Diane Sutton announced that USDA is proposing to discontinue providing the free plastic ear tags due to budgetary cut backs. T. J. Myers explained the reasoning for USDA's proposed actions. Myers and Sutton responded to committee members' questions and concerns relating to this issue.

Presentations and Reports

Scrapie Program Updates

Diane Sutton, USDA-APHIS-VS

Scrapie Eradication Program Results*

- The National Scrapie Eradication Program continued to make progress in FY 2016.
- As a result of the hard work of industry, the states and APHIS, we have decreased scrapie prevalence in cull sheep from 1 in 500 to less than 1 in 20,000 (based on upper confidence level). At the end of FY 2015, the percent of cull sheep found positive at slaughter and adjusted for face color was 0.0036 percent. As of September 30, 2016, this measure was 0.0014 percent (upper confidence limit 0.005%) a 61 percent decrease; however, due to sample size this is not significantly different from FY 2015.
- At the end of FY 2015, the percent of cull black face sheep found positive at slaughter was 0.025 percent. The current value of this measure is 0.009 percent, a 99 percent decrease compared to FY 2003 and a 62 percent decrease from FY 2015. The upper confidence limit of the measure is 0.025 percent so the change from FY 2015 is not statistically significant.
- One infected and three source flocks were designated in FY 2015. Two infected and three source flocks have been designated in FY 2016.
- In November 2014, the first positive goat found through Regulatory Scrapie Slaughter Surveillance (RSSS) was identified. Based on all goats sampled at slaughter, the prevalence of scrapie in U.S. cull goats is 0.003 percent with an upper 95 percent confidence limit of 0.011 percent. To date, no other goats have tested positive at slaughter.

Slaughter Surveillance*

As of September 30, 2016, 39,978 animals have been sampled for scrapie testing in FY 2016:

- 37,878 RSSS samples and 2,100 on-farm samples;
- Of which 32,356 were sheep and 7,622 were goats.

Scrapie Surveillance Plan

- Implementation FY 2016
 - States with RSSS collection sites will continue to sample targeted sheep and goats.
 - The annual State-of-origin sampling minimum for sheep is 20 percent of the number required to detect a scrapie prevalence of 0.1 percent with 95 percent confidence or 1 percent of the breeding flock in the State, whichever is less. The objective is to sample sufficient sheep in a 5-year period to detect a scrapie prevalence of 0.1 percent with 95 percent confidence or 5 percent of the breeding flock in the State, whichever is less.

- The annual State-of-origin sampling minimum for goats is determined based on the States' goat scrapie case incidence.
 - If a State has not had a goat scrapie case in the previous ten years, its annual goat sampling minimum is its prorated share of 3,000 samples, based on its proportion of the U.S. goat population as determined by the NASS Sheep and Goat annual report.
 - If a State has had a goat scrapie case in the previous ten years, its annual goat sampling minimum is determined using the same method as is used for determining its annual sheep sampling minimum.

Note: These are minimums. The plan is to continue to collect samples from the maximum number of targeted animals given the available budget.

ID Compliance:

- All scrapie positive animals in FY 2016 were traced back to their flock of origin.
- APHIS is considering changes to the types of official eartags provided at no cost to producers and others who handle sheep or goats in commerce.

Proposed Rules Published:

- VS published proposed revisions to 9 CFR parts 54 and 79. The proposed changes are intended to improve the effectiveness and cost efficiency of surveillance and to increase animal identification compliance by addressing gaps in identification and by requiring States to meet reasonable surveillance targets to remain consistent States. States must meet these targets for VS to demonstrate geographically appropriate surveillance to meet the criteria for freedom and have confidence that all of the remaining cases have been found.
- The rule proposes to:
 - Give the APHIS Administrator authority to relieve requirements for sheep and goats exposed to scrapie types, such as Nor98-like, that do not pose a significant risk of transmission;
 - Increase flexibility in how investigations can be conducted and allow the epidemiology in a specific flock to be given more consideration in determining flock and animal status;
 - Add a genetic-based approach to regulation;
 - Make goat identification requirements similar to those for sheep to support ongoing slaughter surveillance in goats (no changes will be made in the consistent State requirements regarding identification of goats in intrastate commerce);
 - Tighten the definition of slaughter channels;
 - Expand the individual identification requirement to all sexually intact animals unless moving as a group/lot (allows mixed-source groups moving in slaughter channels at under 18 months);
 - Limit the use of tattoos and implants to animals not moving through markets and not in slaughter channels; and
 - Reduce recordkeeping requirements by making them similar to the current uniform methods and rules compliance guidance.
- A final rule has been drafted and is in clearance.
- APHIS also published a proposed rule to revise its scrapie import regulations to bring them more in line with the OIE scrapie chapter.

Scrapie Flock Certification Program (SFCP)

- At the end of FY 2016 there were 410 producers enrolled in the program – 34 Export Certified, 98 Export Monitored and 278 Select

*FY 2016 numbers are not final and may change.

“K” at Codon 171 in Sheep

Justin Greenlee, Research Veterinary Medical Officer, National Animal Disease Center (NADC), ARS-USDA

Susceptibility or resistance to sheep scrapie is a function of genotype with polymorphisms at codon 171 in the sheep prion gene playing a major role. Glutamine (Q) at 171 contributes to scrapie susceptibility while arginine (R) is associated with resistance. In some breeds, lysine (K) occurs at codon 171, but its effect on scrapie resistance has not been determined. Biochemical similarities (charge and polarity) between K and R would suggest that they may contribute to prion disease susceptibility in a similar way, but studies have not been performed to confirm this. The purpose of this study was to

compare susceptibility, tissue distribution of abnormal prion protein (PrP^{Sc}), and incubation times of AA₁₃₆RR₁₅₄QQ₁₇₁ (where the letter denotes the amino acid and the number the position) with AA₁₃₆RR₁₅₄QK₁₇₁ or AA₁₃₆RR₁₅₄KK₁₇₁ sheep after either intracranial or oronasal inoculation with scrapie. After inoculation, sheep were observed daily for clinical signs and were euthanized and necropsied after clinical signs were unequivocal. Tissues were collected at necropsy for immunohistochemistry and enzyme-linked immunosorbent assay (ELISA) analyses. After intracranial (IC) inoculation, all genotypes of sheep developed scrapie. IC inoculated QQ₁₇₁ sheep had clinical signs approximately nine months after inoculation with widespread PrP^{Sc} in the brain and peripheral tissues (including retropharyngeal lymph node (RPLN) and rectal mucosal biopsy (RAMALT)). IC inoculated QK₁₇₁ animals had an average incubation time of 27 months to onset of clinical signs with PrP^{Sc} in the brain of 6/6 and RPLN of 3/6 sheep. The incubation period of IC inoculated KK₁₇₁ sheep was greater than 46 months and PrP^{Sc} was only detected in the brain. After oronasal (ON) inoculation, QQ₁₇₁ sheep had clinical signs approximately 22 months after inoculation with widespread PrP^{Sc} in the brain, RPLN, and RAMALT. There was evidence of PrP^{Sc} in 4/5 ON inoculated QK₁₇₁ sheep with incubation times greater than 53 months. PrP^{Sc} only was detected in RAMALT of one of the QK₁₇₁ sheep. PrP^{Sc} was not detected in oronasally inoculated KK₁₇₁ sheep in any tissue sample collected at any time. Results of this study indicate that sheep with a single K allele at 171 are susceptible to scrapie after oronasal inoculation, but with a prolonged incubation time and less peripheral distribution of PrP^{Sc}. In the challenge model used in this study, KK₁₇₁ sheep appear to have a high level of resistance to challenge with the agent of scrapie.

Genetic Resistance to Scrapie in Goats

Stephen White, ARS, USDA

Update on Scrapie Research from the Animal Disease Research Unit

Scrapie is the transmissible spongiform encephalopathy of sheep and goats, and goats may serve as a scrapie reservoir for sheep. To date there has been no experimental inoculation confirming strong, lifelong genetic resistance in goats. Goats bearing S146 or K222 amino acid substitutions in the prion protein have been present in scrapie-exposed herds but significantly underrepresented in disease cases. In an oral scrapie challenge, all controls homozygous for the most common goat haplotype showed clinical scrapie by an average of 24 months post-inoculation; in contrast, none of the S146 and K222 heterozygotes have scrapie-positive lymphoid biopsy tests or confirmed scrapie at incubation times now approaching seven years or longer (P<0.0001). Recent reports identified natural scrapie in less than five S146 and K222 heterozygotes, suggesting heterozygotes will not have truly complete resistance. However, scrapie incubation times are now as long as or longer than many commercial operations keep goats for production purposes, so S146 or K222 may reduce the probability of clinical scrapie during commercial goat productive life spans. In a separate experiment, goats bearing S127 showed extended scrapie incubation times compared to common GG127 homozygous goats. These results suggest longer relevant trace-back histories for goats with these genotypes.

Additional experiments addressed two questions regarding scrapie transmission. Ewes experimentally infected with Nor98-like scrapie were tested for placental deposition of PrP^{Sc}. To date none has been found, but studies are ongoing. A separate study examined transmission of classical scrapie through goat milk. Very recent work has shown this is possible, and our study extended previous findings by demonstrating transmission with milk from later in lactation and to both lambs and goat kids.

Committee Business:

- Cheryl Miller presented the purpose of the Committee on Scrapie.
- The response by USDA to last year's resolution was presented to and discussed by the committee.
- A resolution to USDA to encourage the continuation of free plastic scrapie ear tags was presented to the committee by Joan Rowe. Paul Rodgers moved that the committee accept this resolution. It was seconded by Jim Logan. After discussion by the committee, the committee voted 9 in favor of accepting the resolution, 0 opposed, and 2 abstained.
- A second resolution to USDA to allow the use of pilot programs to further explore genetic resistance to scrapie in goats was presented by Joan Rowe. Amy Hendrickson moved that we accept this resolution. It was seconded by Jim Logan. After discussion by the committee, the committee voted 9 in favor of accepting the resolution, 0 opposed, and 2 abstained.
- A third resolution to USDA to identify non-traditional marketing and slaughter channels of sheep and goats was presented to the committee by Linda Detwiler. Paul Rodgers moved that the committee

accept this resolution. It was seconded by Jim Logan. After discussion by the committee, the committee voted 9 in favor of accepting the resolution, 0 opposed, and 2 abstained.

- Cheryl Miller informed the committee that USAHA is considering a new format for the committees and in the draft proposal the Committee on Scrapie would become a Subcommittee of the Committee on Sheep and Goat.
- Paul Rodgers moved that the meeting be adjourned. Joan Rowe seconded this motion.

Prior to the Committee on Scrapie Meeting the following presentation was given by Diane Sutton as part of the National Scrapie Oversight Board meeting.

USDA-APHIS Scrapie Free Flock Certification Program (SFCP)

National Scrapie Oversight Committee Update

Diane Sutton and Dr. Alan Huddleston

USDA-APHIS-VS

SFCP Participation

- As of September 30, 2016, there were 416 participating flocks in the SFCP
 - 281 Select Monitored
 - 102 Export Monitored
 - 33 Export Certified
- In FY2016 10 Export Monitored flocks advanced to Export Certified
- 48 sheep breeds and 17 goat breeds are represented in the SFCP
- As of September 30, 2016, there are active State SFCP boards in nine States

Canada's Import Requirements

- February 2016, Canada published new import requirements for small ruminants imported from the United States for breeding, domestic or captive purposes.
 - Female small ruminants must be certified as originating from "Negligible Risk Premises" defined as *"A premises that has maintained the flock or herd of origin and has complied with conditions equivalent to those required for Export Monitored category for at least five (5) years."*
 - Male small ruminants must meet at least one of the following conditions:
 - The animal must have originated from a "Negligible Risk Premises";
 - The animal must be a sheep that is officially genotyped¹ and determined to be AA/QR or AA/RR at codons 136/171, respectively; and/or
 - The animal must be imported into a Canadian SFCP flock with at least one year of status, maintained separate from the females/offspring, and tested when it dies or is euthanized.

Export Monitored Flock FY 2016 Review

- In FY 2016 APHIS continued to review Export Monitored flocks with six or more years of status to determine if they had met the required sampling threshold to advance to six years.
 - In FY 2016 APHIS identified 55 flocks with 6 or more years of status, and of these 23 had not met the sampling threshold.

¹ *The genotype test must meet all of the following requirements to be recognized as official:*

- *The blood is drawn by an authorized Federal or State animal health employee or an accredited veterinarian;*
- *The sheep is officially identified;*
- *The sample is submitted with a VS Form 5-29, "Cooperative State-Federal Scrapie Control Program, Scrapie Test Record" or an electronic or State issued equivalent; and*
- *APHIS has approved the laboratory (a list of approved laboratories is available on the APHIS Web page).*

- The status dates for these flocks were reset to five years, and notification letters were sent to producers explaining their new status dates and steps they can take to regain six years of status.
- APHIS will continue to monitor flocks that are approaching six years of status to determine if they meet the sampling threshold, and will take action to address those that have not.

Select Category

- Participation in the Select category was slightly higher in FY 2016 than in FY 2015 (an approximately 1.5 percent increase).
- APHIS is currently reviewing Select category sampling compliance. Flocks that are not in compliance with the sampling requirement are placed in suspended status pending submission of a sample.
- APHIS' goal in FY 2017 is to more robustly increase participation in this category, thereby increasing the SFCP contribution to scrapie on-farm surveillance.

SFCP Standards

In May 2016, APHIS published revised SFCP Standards. Major updates to the SFCP Standards included the following items (see Appendix for full list and citations).

- In the Select category, animals collected through Regulatory Scrapie Slaughter Surveillance (RSSS) will count toward the sampling requirement if at least ten animals are collected through RSSS in the same sampling period.
- Sampling requirements in genetically resistant Export Monitored flocks following the Standard sampling protocol: if there are no genetically susceptible animals in the flock (i.e. the flock is composed entirely of QR/RR ewes, RR rams, and no goats), the annual, 6-year, and 7-year sampling requirements are waived (assuming all other sampling requirements are met).
- Criteria for exempting lambs born in genetically resistant flocks from genotyping for Standard and Alternative 1 sampling protocol: if there are no genetically susceptible animals in the flock and the owner only has mature RR rams on the premises from that point forward lambs do not need to be genotyped. Note: these conditions will be confirmed at each subsequent annual inspection, and if an inspector believes at any time that one or more of the animals in the flock may be a QQ animal, the inspector will require that the animal(s) be officially genotyped.
- How to treat "Lost to Inventory" animals in Export Monitored flocks following the Alternative 1 sampling protocol:
 - The flock owner may elect to switch to the standard sampling protocol, and the flock's status date will be reset to the lesser of the flock's current status date or 12 months of status for each test eligible animal sampled and must meet the additional sampling requirements of the standard sampling protocol to retain more than five years in status; or
 - The flock owner may elect to stay in the Alternative 1 category, and the flock's status date will be reset to the date the VS office was notified (or the lost to inventory animal became known to the VS office) that the animal was lost to inventory.
- Alternative testing protocol allowed in place of a status reduction when a found dead/euthanized animal is not tested for scrapie, limited to rare circumstances when VS determines that the flock owner was in a situation that made him/her fail to comply with this testing requirement.
- Animals from Inconsistent States not in slaughter channels must be from either an Export Monitored/Export Certified flock or from a Select Monitored flock in which it was born. There are no changes for animals in slaughter channels.
- Retesting animals to meet the annual sampling requirement:
 - If a flock following the Standard sampling protocol has live-animal tested all genetically susceptible test eligible animals at least once and must test an additional animal to meet the annual sampling requirement, previously tested animals can be repeat live-animal tested.
 - If all genetically susceptible animals in the flock have been live animal tested four times, the annual sampling requirement is waived.
- Export category flocks must report the use of milk/colostrum from a lower status flock.
- Animals tested within 12 months of another animal being "Lost to Inventory" can meet the lost to inventory sampling requirement in Export Certified flocks if the flock had already tested 30 animals (this does not apply to "Found Dead" animals).
- How to treat previously live-animal tested "Found Dead" and "Lost to Inventory" animals in Export Monitored flocks:

- Lost to inventory – if the animal had been tested in the previous 12 months, no change in status and no additional animals need to be tested (and if the flock is following the Alternative 1 sampling protocol it does not have to switch to the Standard sampling protocol).
- Found dead – APHIS will determine if the animal reasonably could have been sampled. If so, the animal will be treated as any other found dead. If not the animal is considered lost to inventory and will be treated the same as other lost to inventory animals.

In FY 2017, APHIS will review and update the Standards as needed, with the goal of publishing updated Standards June 2017.

Appendix: SFCP Standards – Significant Revisions

In May 2016, APHIS revised the Scrapie Free Flock Certification Program (SFCP) Standards. Updates to the SFCP Standards included the following items:

Revision	Location
Clarified the requirements for animals originating from Inconsistent States.	<i>Part II.C [p20] & Part IV.L [p52]</i>
Moved the requirement that all cull animals are inspected by a veterinarian for signs of scrapie to its own section for clarity.	<i>Part III.I [p26]</i>
Added clarification on requirements to import goat/sheep embryos	<i>Part III.L.2 [p28]</i>
Added requirement that Export category flocks must report the use of milk/colostrum from a lower status flock.	<i>Part III.M.2 [p29]</i>
Added a waiver from the annual sampling requirement in genetically resistant following the standard sampling protocol.	<i>Part III.P.3.d [p34]</i>
Clarified the status date for Export Flocks that have not advanced to Export Certified status.	<i>Part III.P.4.c [p35]</i>
Clarified the waiver for advancing to 6 years of status in the Standard and Alternative 2 sampling protocols.	<i>Parts III.P.5.b.(4-5) [p35] & III.P.5.d.(4)(c) [p37-38]</i>
Clarified the waiver for advancing to Export Certified status in the Standard, Alternative 1 and Alternative 2 sampling protocols.	<i>Parts III.P.5.b.(5) [p35], III.P.5.c.(5) [p36-37] & III.P.5.d(4)(e) [p38]</i>
How to treat “Lost to Inventory” animals in Export Monitored flocks following the Alternative 1 sampling protocol: <ul style="list-style-type: none">○ The flock owner may elect to switch to the standard sampling protocol, and the flock’s status date will be reset to the lesser of the flock’s current status date or 12 months of status for each test eligible animal sampled and must meet the additional sampling requirements of the standard sampling protocol to retain more than 5 years in status; or○ The flock owner may elect to stay in the Alternative 1 category, and the flock’s status date will be reset to the date the VS office was notified (or the lost to inventory animal became known to the VS office) that the animal was lost to inventory.	<i>Part III.P.5.c.(3) [p36]</i>
Added that animals tested within 12 months of another animal being “Lost to Inventory” can meet the lost to inventory sampling requirement in Export Certified flocks if the flock had already tested 30 animals (this does not apply to “Found Dead” animals).	<i>Part III.P.6.b.(3) [p39]</i>
Added a waiver from genotyping natural additions in genetically resistant flocks following the Standard and Alternative 1 sampling protocols.	<i>Part III.P.7.b [p39]</i>
Adds an alternative testing protocol in place of a status reduction when a found dead/euthanized animal is not tested for scrapie, limited to rare circumstances when VS determines that the flock owner was in a situation that made him/her fail to comply with this testing requirement (example: the	<i>Part III.R.5.a [p41-42]</i>

<p>flock owner called the local VS or State office and was instructed not to sample the animal).</p>	
<p>How to treat previously live-animal tested “Found Dead” and “Lost to Inventory” animals in Export Monitored flocks:</p> <ul style="list-style-type: none"> ○ Lost to inventory – if the animal had been tested in the previous 12 months, no change in status and no additional animals need to be tested (and if the flock is following the Alternative 1 sampling protocol it does not have to switch to the Standard sampling protocol). ○ Found dead – APHIS will determine if the animal reasonably could have been sampled. If so, the animal will be treated as any other found dead. If not the animal is considered lost to inventory and will be treated the same as other lost to inventory animals. 	<p><i>Part III.R. 16 [p45-46]</i></p>
<p>Added waivers for sampling requirement in genetically resistant flocks in the Select category.</p>	<p><i>Part IV.G.2.b [p50]</i></p>
<p>Removed language explaining the 2013 program revision (revised Part II.A and removed Part VII).</p>	
<p>Additionally, minor clarifications and edits were made throughout the document.</p>	