

REPORT OF THE COMMITTEE ON SCRAPIE

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The Committee met on October 23, 2012 at the Sheraton Greensboro Hotel in Greensboro, North Carolina from 9:00 a.m. to 12:25 p.m. Thirteen members and 11 guests were present.

Presentations

Extended Scrapie Incubation Time in Goats Singly Heterozygous for PRNP S146 or K222

Stephen White

USDA, Agricultural Research Service (ARS)

Dr. Stephen White from USDA, Agriculture Research Service (ARS) Animal Disease Research Unit (ADRU) presented an update for Katherine O'Rourke (Washington State University) and David Schneider (USDA-ARS). The USDA-ARS unit in Pullman, Washington, conducts an integrated research program involving studies on scrapie transmission, diagnosis, and susceptibility genetics in domestic sheep and goats. A study on Nor98-like scrapie in breeding ewes is now in its fifth year. Ewes were experimentally inoculated via the intracerebral route with brain homogenate from a Nor98-like affected sheep and bred annually to examine the placenta for evidence of a transmissible agent. Placentas shed in 2009, 2010 and 2011 were negative for the abnormal form of the prion protein; placentas shed in 2012 are being analyzed.

Another investigation underway involves transmission of scrapie in goats. Current studies are underway to determine the roles of the goat placenta, milk and co-infection with small ruminant lentiviruses in transmission to other goats and to sheep. Analysis is underway with the goal of improving the application of tissue-based (rectal biopsy) live animal testing for scrapie in goats. In addition, a long-term study examining the effect of genotype on susceptibility to goat scrapie and the effect of genetic changes on accuracy of live animal testing are in their fourth year. Following oral inoculation at birth with scrapie-positive goat tissues, recipient goats with the highly susceptible genotype all developed clinical disease within 24 months. Goats with the less susceptible or long incubation genetics (S146 or K222) are clinically normal with no evidence of prions in rectal biopsy tissues. These goats will be monitored for seven years.

Scrapie Research at the National Animal Disease Center

Justin Greenlee

USDA-ARS

Dr. Justin J. Greenlee from USDA-ARS, National Animal Disease Center (NADC), Virus and Prion Diseases Research Unit presented an update on scrapie research at the NADC.

Prion disease research at the NADC in Ames Iowa includes work done in scrapie, bovine spongiform encephalopathy, chronic wasting disease (CWD) of cervids, and transmissible mink encephalopathy. Research in scrapie can be divided generally into two categories: interspecies transmission studies and sheep scrapie pathogenesis studies. Interspecies transmission studies afford the opportunity to better understand the potential host range and origins of prion diseases. In the first of these studies, it was demonstrated that scrapie does not transmit to cattle by the oral route and that while it does transmit after intracranial inoculation, the resultant disease has features distinct from bovine spongiform encephalopathy. Subsequent studies demonstrated that scrapie does not transmit to domestic cats and scrapie in elk is distinct from CWD in that the abnormal prion is not present in lymphoid tissues. The most recent interspecies transmission studies demonstrated that scrapie transmits to white-tailed deer by intracranial or combined intranasal/oral routes of inoculation. In scrapie-affected deer, the abnormal prion is distributed throughout nervous and lymphoid tissues and shares some western blot and microscopic features of CWD. However, western blot using a panel of antibodies demonstrates the scrapie in white-tailed deer is distinguishable from both the original scrapie inoculum and CWD.

Numerous sheep scrapie pathogenesis studies have been performed at the NADC to better understand sheep scrapie and improve scrapie diagnostics. Important findings include demonstrating that neonates are far more susceptible to scrapie by oral route than weaned lambs, various routes (intralingual, conjunctival, intraperitoneal) can be used to transmit scrapie, and scrapie isolates exist with very rapid incubation times in some genotypes of sheep. In addition, we have demonstrated that when preferred samples are unavailable, acceptable western blot results can be obtained from formalin fixed tissue and genotyping, western blot, or ELISA can be performed from paraffin embedded, archived tissue. Studies focused on development of an animal-side scrapie screening test have focused on the retina and have led to the identification of the

specific retinal cell types affected in sheep scrapie and development of a patented screening test that utilizes electroretinograms, a test of retinal function.

National Scrapie Eradication Program Update

Diane Sutton

USDA, Animal and Plant Health Inspection Service (APHIS) Veterinary Services, (VS)

Scrapie Eradication Program Results

- There has been a 96 percent decrease in the percent positive sheep sampled at slaughter adjusted for face color, from 0.15 to 0.0057 percent, since the start of Regulatory Scrapie Slaughter Surveillance (RSSS) in FY2003 thru September 30, 2012.
- There were eight new infected or source flocks reported in FY2012 as of September 30, 2012. A decrease of 47 percent compared to the same date in FY 2011.

Slaughter Surveillance

- The number of animals sampled through slaughter surveillance in FY 2012 through September 30, 2012 was 40,776 compared to 37,192 in FY2011; this represents an increase of 10 percent. The increase was due in part to increased sampling of goats.

Scrapie Surveillance Plan

- Implementation
 - States with Regulatory Scrapie Slaughter Surveillance (RSSS) collection sites will continue to sample all targeted sheep and goats
 - States have State-of-origin sampling minimums for sheep
 - 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
 - States achieved improved sample numbers in FY2012, but approximately 20% will not achieve the sampling minimums this fiscal year. If this minimum number was not collected in FY2012 through RSSS, the State will be expected to find other sampling sources to meet the minimum in FY2013
 - Ongoing sampling of nonclinical goats 2, 3, 4 and 5 years old began in FY2011.
- VS plans to set annual State-of-origin sampling minimum for goats once the proposed rule revising title 9, *Code of Federal Regulations* (9 CFR) parts 54 and 79 is finalized. Proposed sampling minimums were provided for FY2012 and FY2013.

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

FY2013 Priorities

- VS priorities for scrapie are to focus on improving the effectiveness and cost efficiency of surveillance and to increase animal identification compliance. This will be accomplished in part by publishing a proposed rule that would address gaps in identification and require 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 cases have been found.
- The rule would propose 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 under 18 months)
 - Limit the use of tattoos and implants to animals not moving through markets and not in slaughter channels
 - Reduce recordkeeping requirements by making them similar to the current uniform methods and rules compliance guidance
- APHIS is also revising its scrapie import regulations to bring them more in line with the World Animal Health Organization (OIE) scrapie chapter. This will ensure that we meet OIE criteria for free status and prevent the reintroduction of scrapie after free status is achieved.

Scrapie Flock Certification Program (SFCP) Standards

APHIS is revising the SFCP standards to increase the program's ability to identify infected flocks quicker and to prevent infected flocks from becoming certified, to reduce costs associated with the program, and to increase SFCP contribution to scrapie surveillance. Scrapie program staff collected input from SFCP enrolled producers, industry representatives, and State and federal stakeholders. The public will have a final opportunity to comment on the revised standards through a federal register notice.

The proposed revised SFCP structure eliminates the Complete category; revises the Select category, and slightly modifies the Export category.

- **Select category:** APHIS will redirect monitoring from inspections to sampling. Select category flocks do not become certified. Specifics for this category include:
 - There will be no annual inspections
 - Owners must report clinical signs of scrapie
 - Herd owners will follow 9 CFR 79 requirements for recordkeeping and animal ID for their flocks
 - Flock owners can acquire animals from any other flock, whether or not that flock is enrolled in the SFCP
 - The sampling and testing requirements include:
 - Sheep or goats displaying clinical signs over 12 months of age;
 - Animals of any age that either test suspect, inconclusive or positive on a live animal scrapie test or have been determined to be a scrapie suspect by a State, Federal or accredited veterinarian; and
 - An annual minimum of 1 animal per 1-3 years, depending on flock size.
- **Export Category:** APHIS will continue a high level of monitoring including inspections and sampling. Flocks can become Export Certified. Specifics for this category include:
 - Annual inspections will be required
 - Owners must report clinical signs of scrapie
 - Animals must be identified with official scrapie flock certification program (SFCP) ID
 - Flock owners must meet rigorous recordkeeping requirements including maintaining records on every animal that leaves the flock for seven years
 - Flock owners must have all cull animals inspected, including home slaughtered animals, for clinical signs of scrapie at least 30 days before culling
 - Flock owners can acquire female animals and embryos only from other Export category flocks of equal or higher status
 - The sampling and testing requirements include:
 - Sheep or goats displaying clinical signs over 12 months of age;
 - Animals of any age that either test suspect, inconclusive or positive on a live animal scrapie test or have been determined to be a scrapie suspect by an State, Federal or accredited veterinarian;
 - All found dead mature animals, including euthanized animals;
 - An annual sampling minimum of one test eligible animal tested for each year of status held. A flock will be removed from the program if the flock owner fails to submit at least one test eligible animal for two consecutive years;
 - To gain six years in status, 15 test eligible animals must be sampled; and
 - The requirements for Export Certified status include:
 - Seven years in status
 - Meet one of three sampling protocols
 - Standard: 30 test eligible animals
 - Alternative 1: test all genetically susceptible animals sold
 - Alternative 2: test all foundation flock animals.
- Participants in the Complete category will have the following options once the revised proposed SFCP are implemented: 1) join the Export category with up to five years of status; 2) join the revised Select category; or 3) withdraw from the program.
 - If participants that hold "Certified" status in the Complete category join the Export category, APHIS will continue to publish their "Certified" status on its website for three years following the start date of the revised program, in addition to their new "Export Monitored" status, to allow them sufficient time to become Export Certified; and
 - If they join the Select category or withdraw from the program, APHIS will not continue to publish their "Certified" status on its website.

Committee Business:

The final responses from the Committee's 2011 resolutions were reviewed. In response to Resolution 28 USDA-APHIS-VS requested a separate Sheep and Goat Health line item for fiscal year 2013, and it has been included in the President's

budget. Before the new line item can be established, it must be approved by Congress. In response to combined Resolution 29/33 from 2011, USDA-APHIS-VS confirmed its intention to maintain scrapie surveillance levels as high as possible, given the current and expected budget.

A resolution was introduced and discussed which urged the USDA-APHIS-VS to “replace the terminology Scrapie Flock Certification Program in any existing protocols when negotiating health protocols and replace it with language that the animals/flocks conform to the requirements of the National Scrapie Eradication Program”. After discussion, a vote was taken; the resolution did not pass. The Committee then drafted a related resolution encouraging USDA-APHIS-VS to expand their negotiating tools for the export of sheep and goats beyond those that rely on SFCP participation alone and to encourage other countries to recognize current National Scrapie Eradication Program prevalence and surveillance data along with the use of other tools such as genotyping when appropriate.