Veterinary Services

NCIE/NIES Organizational Update
BSE/Scrapie/TSE Rulemaking Update
Schmallenberg Update

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October 22, 2013
BSE, Scrapie and other TSEs in Sheep, Goats and Other (non-bovine) Ruminants

- BSE has previously been addressed in APHIS’ regulations in terms of ruminants of all types (revisions between 1998 and 2007)
- Currently, only bovines, camelids and cervids are eligible for import to the U.S. from ‘minimal risk regions’ (Canada) as determined by APHIS
- No BSE restrictions for semen/embryos of any ruminants
- ‘BSE Comprehensive Rule’ aligns APHIS’ live animal import requirements more closely with OIE recommendations for regions of negligible, controlled or unknown BSE status
- OIE classification and/or other mitigations used in exporting regions will be assessed by APHIS
BSE, Scrapie and other TSEs in Sheep, Goats and Other (non-bovine) Ruminants

• Comp Rule was published as a proposed rule in 2012 and is close to becoming final; but only includes provisions for bovines (cattle/bison), camelids and cervids

• Separate proposed rule is being developed for other ruminants not covered in Comp Rule

• This rule covers BSE, Scrapie and other TSEs in sheep, goats and other/non-bovine ruminants; live animals, germplasm, products and by-products are addressed
BSE, Scrapie and other TSEs in Sheep, Goats and Other (non-bovine) Ruminants

- Scientific supporting documentation (SSD) used to develop a risk-based import position aligning more closely with OIE recommendations for BSE and scrapie in sheep and goats

- Extremely few cases of BSE in non-bovine ruminants (such as sheep/goats) or other animals; APHIS’ import risk tolerance developed accordingly

- Some post-entry conditions may apply for zoo ruminant species
BSE, Scrapie and other TSEs in Sheep, Goats and Other (non-bovine) Ruminants

- This proposed rule also develops/updates standards for scrapie in sheep and goats
- Objective is to harmonize import and domestic movement eligibility
- Rule will provide criteria to evaluate the scrapie status of exporting regions (including applicable scrapie programs)
- Risks of transmission in semen/embryos and products/by-products also included in SSD
BSE, Scrapie and other TSEs in Sheep, Goats and Other (non-bovine) Ruminants

• Proposed rule sets additional standards for post-entry requirements regarding emerging/unknown TSEs in ‘zoo ruminant’ species intended to move between zoos
• Criteria for approval of ‘PEQ zoos’ expanded
• Rulemaking follows the ‘performance standards’ model where possible; some technical details are included but others will be provided through policy/guidance documents
• Proposed rule is currently in RAD clearance; outreach to be developed soon.
‘Schmallenberg’ Syndrome (SBV)

• Orthobunya virus (similar to Akabane, Aino and others)
• First reported in late 2011 in Europe; origins in Africa/Middle East?
• Vector-transmitted (Culicoides, others?); little evidence for horizontal transmission
• Many ruminants susceptible; especially bovines, ovines and caprines (but equines, camelids, cervids and canines can all become infected and/or diseased)
• No movement controls or notification requirements were placed by the European Commission
At present, nineteen Member States (Austria, Belgium, Czech Republic, Denmark, Estonia, Finland, France, Hungary, Germany, Ireland, Italy, Latvia, Luxembourg, Netherlands, Poland, Slovenia, Spain, Sweden and United Kingdom), and 3 other European countries (Switzerland, Norway and Croatia) have reported cases of SBV.

- Steady expansion to north and east throughout 2012 and 2013
- Overwintering in insect vectors likely
- Wildlife reservoirs
SBV

- Morbidity/mortality variable by species; <5% to >50% in sheep/goats
- Transient viremia (4-9 days); duration of immunity uncertain
- Virus is shed in semen and other excretions; present in embryos of infected dams
- Disease effects are variable by species; no effective treatments
- Transient fever and short-term production-related effects in adult animals
- Arthrogryposis-Hydranencephaly Syndrome (AHS) in fetuses/neonates
SBV

- Most disease research conducted in Germany
- NVSL and FADDL also involved in research
- EFSA studies on prevalence/between-herd impacts
- OIE factsheets
- Diagnostic tests include VI, PCR, VNT, ELISA
- Diagnostic sensitivity and specificity considered adequate if two testing endpoints are used for bovines
- Validations ongoing
SBV

- Critical risk period for bovines thought to be between days 40 and 150 of pregnancy
- Critical risk period for sheep thought to be between days 20 and 80 of pregnancy
- Midges in much of Europe are active between April and November
- Other modes of transmission of the virus are still being investigated
SBV

• APHIS restrictions for ruminant germplasm originally placed in early 2012
• Most available scientific information has continued to be bovine-related
• Modifications to restrictions are made as additional information received
• Current bovine restrictions include collection prior to 6/1/2011; or donors tested negative twice by VN tests within 30 days prior to collection and again 30-60 days after collection
• Cutoff titer 1:8
SBV

- Canadian import position (Fall of 2013): bovine mitigations utilized for S/G semen
- Prior to government shutdown, APHIS was considering allowing similar mitigations for sheep/goat semen from EU countries
- NVSL consulted regarding differences between bovine and ovine/caprine serology; 1:16 cutoff titer recommended for VN testing
SBV

- ‘Emerging/emerged’ vs. FAD designations
- Import vs. export-related repercussions (including bovine trade)
- US vector competence (unknown but presumed)
- APHIS has developed case definitions for SBV
- Reporting, follow-ups, surveillance and other contingency plans also developed in case of US outbreak
- NVSL collaborating with EU researchers; independent infectivity trials and virus research
SBV: Vaccines

- In the UK alone, reports from farmers suggest that at least 1,700 farms have tested positive for SBV virus
- UK farmers now have access to a licensed SBV vaccine
- Bovilis SBV® by MSD Animal Health (Merck)
- Inactivated (whole-killed) formulation
- One or two SQ doses recommended
- Not for use in pregnant animals; sheep should be >4 months of age at time of vaccination
- Cost up to $7/dose/animal
- Onset and duration of immunity not fully characterized
Questions?