



# Veterinary Services

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

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## 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

# SBV

- 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<sup>®</sup> 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?

