Footvax in the U.S.

Erica Sanko
California Wool Growers Association
Background…Footrot in California

• Top priority for many California producers…more so than predators at times.
• Direct & Indirect Costs in the thousands of dollars:
  • Sheep health
  • Reproduction & feed efficiency
  • Treatment – Footbaths, hoof trimming, Zactran (antibiotic – vet script required)
  • Labor Hours

• Animal Welfare Issue & Public Image Concerns
Approach #1...Develop a Vaccine

- California Wool Growers Assn. (CWGA) working to develop an autogenous footrot vaccine produced in the U.S.
  - In 2015, informed by Merck it does not plan to reintroduce Footvax in the U.S.
- Since 2016 collecting footrot samples (swab & tissue).
- To date, samples have been inconclusive.
  - Timing, overtreatment, comprised samples, potential sampling error.
- Continue to collect samples in 2018.
Approach #2...Import Footvax

- CWGA applied for a USDA-APHIS Veterinary Biological Permit for Research & Evaluation to Import Footvax
  - Footvax already proven to be an efficacious vaccine for treating footrot.
  - CWGA developing it’s own footrot vaccine but sampling challenges delaying effort.
  - Viewed as short-term approach to long-term strategy.
  - Support from ASI & State Veterinarians.
Research & Evaluation Permit Requirements

• Verify no significant changes to the manufacture or source of animal derived material since it was last approved for commercial import.
• Application Process
• Develop & approval of product protocols for product distribution.
• Distributed exclusively by CWGA to CWGA members in good-standing.
• Approval from State Veterinarians
  • California, Idaho, Nevada, Oregon, & Utah
• Quarterly sales reports to appropriate State Veterinarians
CWGA Footvax Protocols

• Coordinate directly with Merck NZ.
• Product shipped directly to & properly stored on-site at the CWGA office.
• Distributed exclusively by CWGA to CWGA members.
• Maintain distribution records (5 years).
• Notify state veterinarian & the Center for Veterinary Biologics of adverse reactions reported.
• Include information sheet with following information: product details, directions & disclaimer “unlicensed vaccine that is no longer approved for sale…”
• Survey producers on efficacy of Footvax relative to other products/treatments.
Timeline of Footvax in the U.S.

- **March – June:** Gather information to verify no significant changes to product or source of animal derived materials since sold in U.S.
- **August:** Research & Evaluation Permit to Import Footvax Approved.
- **September:** Members required to pre-order & pay for product.
- **October:** Order placed.
- **November – December:** Footvax arrives in California & distributed to members.
- **December:** Placed order for summer 2018.
Footvax in the U.S.

- Product only sold in 250 dose packs, requires booster.
- Total # of members that ordered Footvax – 34
- Represented three (3) states – CA, ID, OR
- Total Order = 95,000 doses or 380 250-dose packs
- Largest Order – 14,320 doses or 58 packs
- Smallest Order – 250 dose pack or 1 pack
- Small carryover available until next order.
Lessons Learned

• It takes longer than expected – release dates, shipment logistics, etc.

• Import logistics:
  • Manufacturer – Payment required prior to shipment.
  • Customs – Required bonds, etc.
  • Broker – Pay fees prior to delivery

• Plan ahead for product distribution…shipping, scheduling pick-up, supplies, etc.

• Find ways to make it work for all producers, large & small.
  • Small producers located in one area shared a 250-dose pack.
Current Efforts

• Long–term approach – develop an autogenous vaccine produced in the U.S.
  • Year-round availability
  • Available to all sheep operations – offer different vial sizes (i.e. 50 dose, 100 dose).
  • Reasonable cost; eliminate exchange rate impacts, import expenses.
  • Remove import regulatory burdens.

• Depending on 2018 samples, will re-evaluate long-term approach.
  • Reapply for one year renewal on Research & Education Permit.
Pre-Footvax Example – 2015

• Direct to Consumer Lamb & Targeted Grazing Operation
• 1,500 ‘Crippled’ Ewes
• No protocol was universally successful in curing footrot.
  • Tetracycline (LA 200), trimmed hooves & infected hooves bathed in antibiotics & antiseptics
  • Able to cure all but last 10% (150 ewes)... last resort was Zactran (Gamithromycin) by prescription
• Reported to animal control numerous times for animal cruelty (limping ewes).
• Estimated cost in loss of gain, labor hours & materials – At least $25,000.
Post-Footvax Example – 2018

• Vaccinated 450 ewe lambs in November (vaccine available).
• To date none of the ewe lambs show symptoms of footrot.
• The rest of the flock will be vaccinated after lambing.
  • Producer believes Footvax causes stress & does not want to stress the unborn lambs during gestation.
• Rate of infected hooves in the unvaccinated population has dropped to below 2% of the flock….tolerable until producer can vaccinate the remaining ewes.
Thank you…Questions