Vaccine Availability
Issues Affecting the Sheep Industry

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Overview…

• U.S. Sheep Industry lacks infrastructure for sheep health products
  • Vaccines, Antibiotics, Nutritional products – minerals, etc.

• Limited supply of sheep vaccines available - ongoing issue.

• Limited supply of sheep vaccine manufacturers.
  • Cost – Benefit impedes development of sheep health products.

• Current animal antibiotic environment supports need for greater vaccine availability.

• Sustainability of industry depends on infrastructure.
Background…California Wool Growers Assn.

- **Mission Statement:** *Delivering lasting value to support all segments of the California Sheep industry.*
  - *Advocacy, Education, & Investment in Markets & Infrastructure*

- **Infrastructure:**
  - Animal Health & Nutritional Products…Minerals, Supplements, **Vaccines**

- **Past efforts (1990s)**
  - Campylobacter Fetur-Je juni ~ Vibrio (Hygieia)
  - Blue Tongue – Type 10, 11, 17 (Poultry Health Laboratories)
Effort #1 ~ Footrot Vaccine

- Top priority for many California producers…more so than predators at times.
- Direct & Indirect Costs in the thousands of dollars:
  - Overall animal health
  - Reproduction efficiency
  - Feed efficiency
  - Treatment – Footbaths, hoof trimming, Zactran (antibiotic – vet script required)
  - Labor Hours
- Animal Welfare Issue & Public Image Concerns
Approach #1…Develop a Vaccine

• 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.

• To date, samples have been inconclusive.
  • Timing, overtreatment, comprised samples, potential sampling error.
  • Swabs, tissue, aerobic, anaerobic – no luck.

• Sampling challenges impeding vaccine development efforts.

• May no longer be feasible.
Approach #2…Import Footvax

- In 2017, granted a USDA-APHIS Veterinary Biological Permit for Research & Evaluation to import Footvax
  - Footvax already proven to be an efficacious for treating footrot.
  - Viewed as short-term approach to long-term strategy.
  - Support from American Sheep Industry Assn. (ASI) & State Veterinarians.
- Renewed in 2018 for additional year.
- Looking at potential long-term option.
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.
- Approval from State Veterinarians
  - California, Idaho, Nevada, Oregon, Utah, Washington, & Wyoming
- Quarterly sales reports to appropriate State Veterinarians
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 & USDA-APHIS 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.
Footvax Survey Results

• All producers required to complete a survey.
• Survey questions focus on footrot pre- & post footvax.
  • Treatment protocols, herd management, costs, etc.
• All producers indicated multiple treatment protocols – antibiotics, footbaths, trimming, culling, segregation.
• Economic impacts of footrot very expensive ($5 to $25 per ewe).
• No adverse reactions.
• High success rate for eliminating/preventing footrot with Footvax.
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.
Effort #2 ~ Blue Tongue

• Only 1 vaccine currently on the market – Colorado Serum Type 10
  • Live vaccine
  • Restrictions i.e. can’t vaccinate bred ewes

• Many blue tongue vaccines approved for sale
  • Example – Poultry Health Laboratories

• But **none** are on the market

• Multiple Strains
  • California – Types 10, 11, & 17
Approach – Develop New Vaccine

• 2015 – Began effort to develop an autogenous vaccine for types 10, 11, & 17.
  • No restrictions – vaccinate bred ewes.
• CWGA collaborated with local biologics company & USDA-APHIS Center for Veterinary Biologics.
• Assisted in obtaining needed isolates & member producers for trials.
• Strong industry support – ASI, State Veterinarians.
• Goal – Conditional license, distributed by CWGA to CWGA members.
• Vaccine was ready for trials in early 2018, but did not occur.
Lessons Learned

• Lost two years of vaccine availability due to lack of communication from manufacturer.
• Open & honest communication is vital.
  • Two different explanations.
  • Neither are the same or address the problem.
• Limitations as a third party in development process.
• USDA-APHIS supports sheep industry efforts.
• Vaccine manufacturers need to work with USDA-APHIS on these efforts.
Next Steps

• Effort continues – working with new vaccine manufacturer.
  • Communication issues will not be an issue.

• Challenge – Obtaining isolates
  • Obtaining isolates provided in 2016 not feasible – start from scratch.
  • Asking members with blue tongue cases for permission for CWGA to submit isolates to manufacturer.
  • Offering members cost-share option for lab test fees.
  • Difficult as were not told trials did not happen until end of blue tongue season.
  • Difficult as most producers self-diagnose blue tongue.
Effort #3 ~ Campylobacter Fetus-Jejuni (Vibrio)

- Only 2 Vibrio vaccines on the market
  - California/Hygieia vaccine is the only tetracycline resistant vaccine
  - Colorado Serum
- Hygieia Vibrio subject to supply issues since 2016
  - Demand larger than supply?
  - Production issues?
- As of September 2018 – Hygieia product is unavailable, status is unknown.
  - Producer flock health program determines if they can use &/or how long can use the Colorado Serum product.
Next Steps

• Beginning the process to develop a new Vibrio vaccine.

• Have identified a vaccine manufacturer & in early discussions.

• Fall lambing is underway.
  • Asking members with any abortions for permission for CWGA to submit isolates to manufacturer.
  • Offering members cost-share option for lab test fees.
  • Challenge – Getting producers to submit aborted fetus/placentas.

• Goal – Conditional license for California/all sheep producers.
Vaccine Availability Issues in 2018

• Vaccines unavailable during peak demand season.
  • Blue Tongue Type 10: Unavailable April – mid-October
  • Chlamydia: Unavailable May/June – mid-October
  • Hygieia Vibrio: Out of Stock, Unavailable, Status Unknown
  • Tetanus Antitoxin: Limited supply
• Producers who planned ahead were okay.
• Producers that didn’t know until diagnosed struggled & many did not vaccinate.
• Impacts on flock health, production efficiency, lamb crops?
Other Issues

- Limited number of companies manufacturing sheep vaccines.
- Distributors limited on inventory capacity.
  - If sheep vaccines are a small percentage of portfolio many will often direct order or carry only enough supply for season.
- Carrying inventory has costs for all parties (i.e. lost sales, state taxed)
- Difficult to plan ahead for 2019 – Order for supply shortages?
- Australia sheep industry advantage in number & types of vaccines available.
Comments

• Sheep health infrastructure is vital for industry sustainability.

• USDA-APHIS Center for Veterinary Biologics supports sheep industry.
  • Two way street – parties need to work together.

• Australian vaccines may not be available now, but there are means to offer those vaccines to U.S. producers.

• Current animal antibiotic environment supports need for greater vaccine availability.

• *Industry needs to be proactive vs. reactive*
Thank you…Questions