



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-Jejuni ~ 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.
 - Animal welfare/public perception impacts on California & U.S. sheep/lamb industry.
 - 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