Government and Industry Cooperation in Export Assurance

Sara Kaman, DVM
National Institute for Animal Agriculture
April 5, 2016
History of Federal-State-industry cooperation

- Disease eradication programs: TB, brucellosis, scrapie, pseudorabies
- Secretary’s Advisory Committees
- US Animal Health Association
- NIAA

Safeguarding Animal Health
Industry partners

- Certified Semen Services (CSS)
- American Embryo Transfer Association (AETA)
- Livestock Exporters Association (LEA)
- US Livestock Genetics Export (USLGE)
APHIS-industry cooperation

• Annual APHIS-industry meetings
• Training courses
  – June 2015 Texas: American Embryo Transfer Association (AETA), Select Breeders
  – May 2016 Wisconsin: AETA, CSS
American Embryo Transfer Association (AETA)

- Australian site visit – IVF embryos
- Requirement for AETA-certified embryo collection team veterinarian
- Accompanied by AETA government liaison veterinarians and practitioners
Certified Semen Services (CSS)

- APHIS-CSS Memorandum of Understanding (MOU)
- Originally developed to authorize CSS semen to produce embryos for export to the EU
- Renegotiated every 5 years
- Latest renegotiation started in 2012
Renegotiating the MOU

- Reviewed scope of CSS authority to inspect on behalf of APHIS
- APHIS vs. CSS inspection
- Interpretation of wording of health certificate and/or protocol statements
Interpretation

- “approved by the competent authority”
- “USDA-approved”
- “under the supervision of”
- “inspected by APHIS”
- “...collected, processed and stored in accordance with the OIE Code...”
Challenge: finding the balance

• APHIS
  – Expectations of and obligations to trading partners
  – Legal/regulatory accountability?
  – International standards

• CSS
  – Maintaining status quo?
  – Government “over reach”? 
  – Business
APHIS vs. CSS: 4 options

1. APHIS only (12%)
2. Initial APHIS inspection, then CSS annual audit (22%)
3. CSS only (48%)
4. No inspection (18%)
Quads Germplasm Comparison Project

• Compared 4 countries against OIE Code
• Australia, NZ, Canada – OIE focused, prescriptive inspection programs
• US – CSS, less prescribed overall
• NZ – also uses 3rd party verifier
  – ISO 17020 trained auditors
  – “Audit the auditors”
Domestic vs. international standards

- CSS: sets US domestic bovine semen industry standards
- OIE Code: sets international guidelines for semen and embryo collection/processing
- Similar, but not identical
Recommended areas for improvement

- Define scope of CSS role in inspection on behalf of APHIS
- Define APHIS’s role when issues identified that affect export certification
- Define scope of APHIS oversight of CSS inspection program
Key needs

- Provide training to APHIS VMO’s
- Develop training materials/modules
- Consistency – checklist!
- Follow-up, consequences

Safeguarding Animal Health
Generic checklist

- Developed cooperatively
- Compromise
- Practical
- Implementable
Light-bulb moment

- Site visit to CSS headquarters, October 2015
- Overview, history, background of CSS
- Building trust/understanding
- Paperwork review
  - Common themes
  - Perspective
Understanding differences in perspectives

- CSS perspective
  - Focused on semen quality, semen identification, sire health
  - AI Center Practices Evaluation secondary
  - Voluntary
  - Keep SCC in the program to help improve rather than remove for non-compliance
APHIS (regulatory) perspective

- Focuses on biosecurity, infrastructure, facility management/operations, separation of animals of different health status
- The need for a red line!
- Inspections need to be auditable, defensible, documented
- Follow-up clearly documented
The cost of doing (export) business

- Compliance is NOT voluntary
- Judgment calls are appropriate, up to a point.
- Maintain APHIS credibility as the competent authority and international reputation
- Maintain market access for all commodities
Moving towards the middle

- CSS amended Participation Agreement
- CSS incorporates generic checklist for export purposes
- AI Center Animal Management Evaluation no longer voluntary
APHIS changes

- Training
  - May 2016 training course: Madison, WI
  - BOEM training modules
  - Checklists
- More direct involvement (co-inspections, headquarters reviews, etc.)
Safeguarding Animal Health
QUESTIONS?

Sara Kaman, DVM
USDA, APHIS, Veterinary Services
National Import and Export Services
sara.kaman@aphis.usda.gov
301-851-3354