

Government and Industry Cooperation in Export Assurance

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History of Federal-State-industry cooperation

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



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Industry partners

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



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APHIS-industry cooperation

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



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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



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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



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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



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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...”



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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



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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%)



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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”



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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



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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

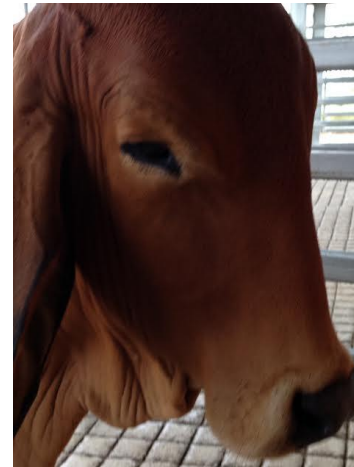


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Key needs

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



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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



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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



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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



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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



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Moving towards the middle

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



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APHIS changes

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



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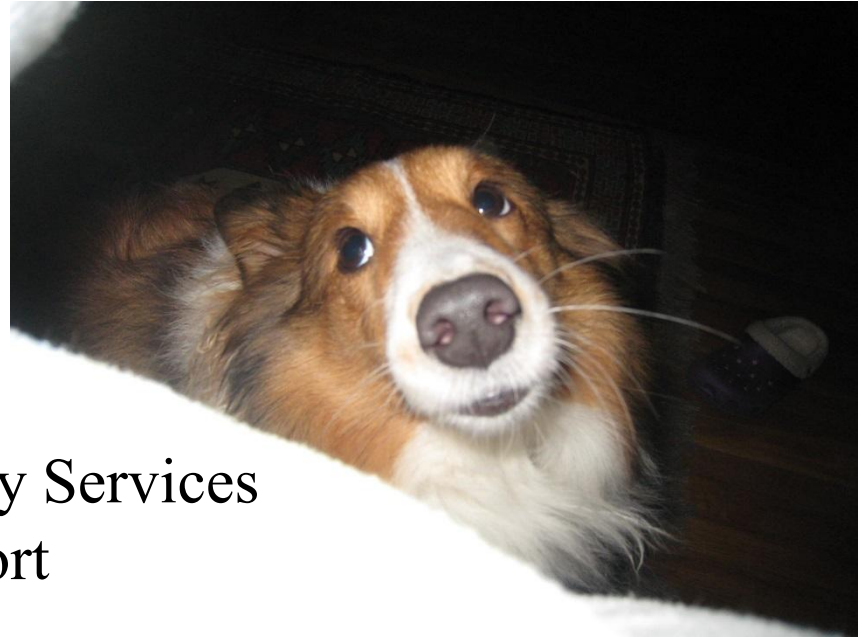




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QUESTIONS?



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