International Regulatory Requirements for *Leptospira* Vaccine Potency Testing

Hans Draayer

October 19-21, 2012
Session Objectives

- Gain an understanding of the impact on the global movement of Lepto vaccines on animal usage and other resources (e.g. product cost, supply, resources etc.)
- Conduct roundtable discussion to review current situation and evaluate potential paths forward
  - USA — Geetha Srinivas, DVM, PhD, CVB, USDA
  - Europe — Lukas Bruckner, DVM, IVI, Switzerland
  - Mexico — Alejandro de la Peña-Moctezuma, PhD, Universidad Nacional Autónoma de México
- Call in participants
- Propose system for gathering a complete database of current global Lepto vaccines and requirements (time permitting)
Impact of Global Markets
Trade Scenarios

1. Companies trade domestically only, no international trade
2. The importing country recognizes the country of origins testing and batch release data with no additional testing.
3. The importing country requires a specific potency assay be conducted by the exporting firm based on the current importing markets regulations in addition to the current country of origin serial release assay
   1. Exporting firm could manufacture batches specific to import market specs under country requirements if allowed by domestic agency, however small batch size and dating can be issue
4. The importing country requires retesting of the product in country by either a local laboratory and/or a local government-testing lab prior to distribution.
Potency Testing Scenario – global manufacturer

Domestic (10/group, Challenge, SC)

Lepto 5

Firm testing 100+ hamsters

Random Gov. confirm Testing

Serial Release 120+ hamsters

Market A
(5 Hamster/group, With challenge, in country testing)

Yes, example 1 serovar selected

Firm testing 50+ hamsters

Country Serial Release 50+

Market B
(7 Hamster/group, Serology, MAT IM)

Firm testing 35+ hamsters

Required Gov. confirm testing

Serial Release 70+

Gov testing 35+ hamsters

Gourdneck View Consulting, LLC

Totals
120+ hamsters
170+ hamsters
240+ hamsters
Round Table Discussion

Participants
- Moderator – Hans Draayer, MS
- USA — Geetha Srinivas, DVM, PhD, CVB, USDA
- Europe — Lukas Bruckner, DVM, IVI, Switzerland
- Mexico — Alejandro de la Peña-Moctezuma, PhD, Universidad Nacional Autónoma de México
- Any call in participants

- Current import requirements for major markets
- Potential next steps, open discussion
- Time permitting – proposal for global Lepto vaccine database
Information Gathering: General Overview

- Country/Region________________________________________

  - Are the Leptospira Vaccines/Bacterins currently manufactured in your country/region? Yes___, No_____ (If yes, please complete the tables on the following slides)

  - Are the Leptospira Vaccines/Bacterins currently being Imported in your country/region? Yes___, No_____ If yes:
    - Are the exporting countries currently registered potency assays recognized as proof of potency? Yes___ No_____  
    - Is re-testing by an in-country laboratory required? Yes___ No_____  
    - Is confirmatory testing routinely conducted by a Government Laboratory? Yes___ No_____  

- Are there any on-going initiatives in your country/region to replace reduce or refine Leptospira potency assays? Yes___ No_____ (if Yes please provide a brief description of these efforts)
Currently Registered Veterinary Leptospira Vaccines and Bacterins

(Use “M for Manufactured, “I” for Imported or “MI” for both, mark all serovars that apply)

<table>
<thead>
<tr>
<th>Serovar</th>
<th>Bovine</th>
<th>Porcine</th>
<th>Canine</th>
<th>Other______</th>
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<tr>
<td><em>L. ictero.</em></td>
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<td><em>L. canicola</em></td>
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Are there emerging Leptospira serovars of concern in your country/Region: If Yes, please list:
Currently Allowed Veterinary Leptospira Vaccines and Bacterins Potency Assays
(check all apply, use “SRA” if an assay is a Standard Required Assay)

<table>
<thead>
<tr>
<th>Serovar</th>
<th>Lab Animal vaccination/Challenge (list L.A. species)</th>
<th>Lab Animal vaccination/serology* (list L.A. species)</th>
<th>In-vitro*</th>
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<tbody>
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* If possible provide brief description of serologic methods or *in-vitro* assays on the following slide