CervidTB Stat Pak® and DPP Testing in 2013

Lee Ann Thomas, DVM, MS
Director, Ruminant Health Programs
U.S. Department of Agriculture
Animal and Plant Health Inspection Service
Veterinary Services

Date
2013 Stat-Pak® and DPP Testing

- Testing began on 4 February 2013
- Blood drawn by accredited veterinarians
- Testing performed by National Veterinary Services Laboratory (NVSL)
- Testing use detailed in VS Guidance Document (VSG 6701.1)
2013 Stat-Pak® and DPP Testing

• Animals testing positive to first Stat-Pak and DPP tests retested after 30 days with the DPP

• If second DPP is positive, animals are classified as reactors and may be indemnified and submitted for necropsy and sample collection for TB testing
2013 Stat-Pak® and DPP Testing

• The secondary DPP test results were being read visually as negative or positive per test kit instructions.

• A colorimetric reader was also being used to obtain a numerical value (optical density) for future use.
2013 Stat-Pak® and DPP Testing

- 5214 animals tested
  - 25 States represented

<table>
<thead>
<tr>
<th>Species</th>
<th>Number Tested</th>
<th>Percentage of tested</th>
</tr>
</thead>
<tbody>
<tr>
<td>White tailed deer</td>
<td>3170</td>
<td>60.8%</td>
</tr>
<tr>
<td>Elk</td>
<td>1482</td>
<td>28.4%</td>
</tr>
<tr>
<td>Fallow deer</td>
<td>391</td>
<td>7.5%</td>
</tr>
<tr>
<td>Red deer</td>
<td>146</td>
<td>2.8%</td>
</tr>
<tr>
<td>Reindeer</td>
<td>25</td>
<td>0.48%</td>
</tr>
</tbody>
</table>

Through August 31, 2013
2013 Stat-Pak® and DPP Testing

• Specificity for the Stat-Pak was 83.9% and 97.74% for the first DPP test
• Number of cervids classified as reactors based on positive Stat-Pak and DPP tests

<table>
<thead>
<tr>
<th>Species</th>
<th>Number of Reactors</th>
</tr>
</thead>
<tbody>
<tr>
<td>White tailed deer</td>
<td>37</td>
</tr>
<tr>
<td>Elk</td>
<td>12</td>
</tr>
<tr>
<td>Fallow deer</td>
<td>2</td>
</tr>
</tbody>
</table>
2013 Stat-Pak® and DPP Testing

- 44 Necropsies have been conducted with lab testing of appropriate tissues

<table>
<thead>
<tr>
<th>Species</th>
<th>Number Tested</th>
<th>M. Bovis (TB) infection found</th>
</tr>
</thead>
<tbody>
<tr>
<td>White tailed deer</td>
<td>31</td>
<td>None</td>
</tr>
<tr>
<td>Elk</td>
<td>10</td>
<td>None</td>
</tr>
<tr>
<td>Fallow deer</td>
<td>3</td>
<td>None</td>
</tr>
</tbody>
</table>
2013 Stat-Pak® and DPP Testing

There have been a larger number of false positive tests than expected based on data from test validation studies and previously published scientific literature.
2013 Stat-Pak® and DPP Testing

• Statistical analysis of the Stat-Pak and DPP testing data after 41 negative necropsies indicates:

• With a specificity of 97.7% and a sensitivity value of 77%, we can be 95% sure that the population prevalence is less than 0.29 percent (.0029)*.

*CEAH analysis
2013 Stat-Pak® and DPP Testing

- DPP reader optical density values obtained for:
  - Retrospectively tested infected animals
  - Recently tested negative animals

- Determination of cutoff points for optical density values
2013 Stat-Pak® and DPP Testing

• A new protocol for using OD values was developed.
• Review the USAHA TB SAS
• The TB SAS accepted our statistical analysis and concurred with our proposed testing protocol changes
• New DPP reader cutoff values were applied to previous tests
• NVSL sent out amended lab reports in September
2013 Stat-Pak® and DPP Testing

- 10 reactors were reclassified as negative and 2 remained positive
- 22 suspects were reclassified as negative and 1 remained a suspect
Questions?
Chronic Wasting Disease Herd Certification Program

Lee Ann Thomas, DVM, MS
Director, Ruminant Health Services
U.S. Department of Agriculture
Animal and Plant Health Inspection Service
Veterinary Services

2013 USAHA – CWAL Committee
22 October 2013
Goals for CWD HCP Program
http://www.aphis.usda.gov/animal_health/animal_diseases/cwd

• Established a voluntary national CWD herd certification program for farmed deer, elk, and moose.

• Established minimum standards for interstate movement of cervids
FY2013 Funding Overview

• FY2012 - APHIS/VS “ECSR” Commodity Health Line
  – Equine, cervids, small ruminants
  – Funds essential activities for surveillance & program operations with flexibility to respond to new and emerging health concerns.

• FY2013 CWD Program Activities - $1M
  – Basic CWD program staff support

• Proposed FY2014 CWD Program Activities - $1M
FY 13/14 Program Activities
APHIS VS

• Federal oversight of voluntary national CWD HCP

• Principle activities conducted by APHIS
  ➢ Approval of State CWD HCP in participating States
  ➢ Review of Approved States’ annual reports
  ➢ NVSL oversight of approved CWD laboratories to conduct and report CWD test results.
  ➢ Confirmatory testing of all CWD presumptive positive samples in farmed and wild cervids.
• Based on available resources, APHIS will serve in an advisory capacity to Approved States for:
  ➢ Epidemiological investigations of positive findings
  ➢ Development of herd plans (newly infected herds)
  ➢ Quarantine, depopulations, cleaning & disinfection
  ➢ Assistance with annual herd inspections and tri-annual physical herd inventories
FY 13/14 Program Activities
Approved States

• Compliance with CWD rule
  ➢ CWD Program Standards guidance

• Submit annual reports to APHIS (FY14)
• Manage HCP data (state database/ VS “Core One”)
• Report positive cervid herds to APHIS
• Respond, investigate, and manage any positive, suspect, and exposed animals/herds.
• Develop herd plans for positive/exposed herds
CWD Interim Final Rule

- CWD Herd Certification Program and Interstate Movement of Farmed or Captive Deer, Elk, and Moose.

- Published in the FR - June 13, 2012 (Docket No.00-108-8) with public comment period.

- Effective date was 8/13/2012
  - Part 81 delayed enforcement until 12/10/2012

- Public comments have been considered.

- Affirmation of final rule is in development
Cervid Species Affected by Rule

• Revised federal rule applies only to the following genera known to be susceptible to CWD by natural infection:
  ➢ Cervus (elk, red deer, sika deer)
  ➢ Odocoileus (WTD, MD, BTD)
  ➢ Alces (moose)

• States may have requirements for other cervid species.

Photo courtesy Leslie Kent- 2010
Objectives of the CWD Rule

• Provide uniform minimum requirements for state CWD herd certification programs (HCPs).

• Provide uniform minimum requirements for interstate movement of CWD susceptible species.

• Provide a regulatory framework to support domestic and international markets for farmed cervids and cervid products.

• Provide consistent approach towards minimizing risk of introduction and transmission of CWD in cervid populations.
CWD Rule Provisions

• Part 55 (Subpart A): Indemnity, Laboratory Approval, Official Laboratory Testing

• Part 55 (Subpart B): Voluntary national Approved State CWD HCP for farmed cervids (deer and elk)
  ➢ Fencing requirements
  ➢ Animal ID and herd inventory requirements
  ➢ Surveillance - testing mortalities >12 months
  ➢ Herd status – based on years of surveillance and participation in HCP

• Part 81: Interstate movement minimum requirements
Interstate Movement

• CWD rule (Part 81) establishes minimum requirements for interstate movement of cervids
  - Farmed cervids from certified herds
  - Captive (wild) cervids
  - Movement directly to recognized slaughter facility
  - Research purposes

• CWD rule does not include international movement regulations.
  - National Center for Import and Export (NCIE) oversees international import and export issues pertaining to cervids.
  - APHIS VS NCIE Protocol for the Importation of Farmed Cervids from Canada (August 2013).
Approval of State CWD HCP

- States having a CWD HCP may request federal approval of their State program

- APHIS will approve a State CWD HCP in accordance with CWD rule (9 CFR 55.23)

Photo courtesy Leslie Kent 2010
29 Approved State HCPs
October 2013

• 19 Approved States –
  – AK, CO, ID, IN, KS, LA, MN, MO, MT, NE, NY, NC, ND, OH, OK, SD, TN, VT, WI

• 10 Provisional Approved –
  – IL, IA, KY, ME, MI, NM, PA, TX, UT, WV

• Cervids may not move interstate from States not listed, in accordance with 9 CFR 81.3

http://www.aphis.usda.gov/animal_health/animal_diseases/cwd
Approved State Responsibilities

• Signed MOU w/ APHIS
• Authority to restrict animal movement
• Enforces and monitors quarantines
• CWD reportable disease
• Surveillance & disease reporting capability
• Animal identification
Approved State Responsibilities

- Designated CWD HCP coordinator
- Mortality surveillance
- Recordkeeping and data management
- Ability to conduct epi investigations
- Education/ outreach for producers
- Herd plans (CWD positive/exposed herds)
- Annual reports to renew Approved status
Herd Owner Enrollment

- Herd owners already participating in State CWD program – will keep initial State enrollment date (first date of participation) when State is designated an Approved State CWD HCP.

- No available funding projected for FY2014 to support direct herd owner enrollment in the national program.

  ➢ For herd owners in states that permit cervid farming but do not have State CWD HCP
Herd Owner Responsibilities

• Animal identification
  ➢ 2 forms
    o One must be USDA official ID
    o Second must be unique to animal in the herd (State/local IDs are acceptable)
  ➢ By 12 months of age
  ➢ Before movement from premises

• Fencing requirements

• Reporting escapes & mortalities

• Mortality testing for certified status
  – On-farm (all mortalities) and animals sent to slaughter facilities and hunting operations (in enrolled herd inventory)
Herd Owner Responsibilities

• Herd records & inventories
  ➢ Annual visual herd /record inspection
  ➢ Tri-annual physical herd inventory

• Separation from other herds
  ➢ 30 feet buffer zone between perimeter fencing
  ➢ No commingling

• Status of herd additions (same or greater)
CWD Program Standards

- **Purpose** – to provide clarification and guidance on how to comply with and meet requirements of the CWD rule.

- **Part A – Herd Certification Program**
  - Assist State agencies in maintaining CWD-certified herds
  - Provide guidance on procedures to certify herds as low risk for CWD by compliance with requirements in 9 CFR 55.
  - Provide guidance on compliance with minimum requirements for interstate movement in 9 CFR 81.

- **Part B – Guidance on Response to CWD-affected herds**
  - Provides guidance on suggested best management practices that may be used by State and herd owner to manage CWD-affected herds.
CWD Working Group

• Formed to review and provide input on revisions to the CWD Program Standards (2012 USAHA Resolution).

• Members: Cervid Industry, State Animal Health Officials, State Wildlife Agencies/AFWA, Labs (AAVLD/NAHLN), and APHIS VS.

• Weekly teleconferences Nov 2012 – June 2013

• Topics discussed included – physical inventory, sample collection, missing samples, reporting mortalities and escapes, transiting, herd plans, trace outs, animal identification, fencing, interstate movement.

• Revised Program Standards in clearance and will be posted in FR for public comment.
Current CWD Status 2013

- **22 states** have reported CWD in farmed and/or wild cervids.

- **Wild cervids:** CWD has been detected in **18 states**
  - CO, IL, KS, MD, MN, MO, ND, NE, NY,
  - NM, PA, SD, TX, UT, VA, WI, WV, WY

- **Farmed cervid herds:** CWD has been detected in **13 states** in **60 farmed cervid herds** (40 elk herds, 19 WTD herds, 1 red deer herd)
  - CO, KS, IA, MI, MN, MO, MT, NE, NY, OK, PA, SD, WI

- No new CWD positive farmed cervid herds in FY2013

- **12 CWD positive farmed herds** remain in quarantine
  - 7 Elk herds (CO); 3 Elk herds (NE)
  - 1 WTD herd (IA)
  - 1 Red deer herd – partial depopulation (MN)
Chronic Wasting Disease
CWD-Positive Farmed Cervid Herds and Wildlife

October 2013

- Positive Captive Elk Herds
- Positive Captive WTD or Red Deer Herds
- Depopulated Positive Captive Cervid Herds
- Game Management Units with Positive Deer
- Game Management Units with Positive Elk
- Game Management Units with Positive Moose
Surveillance in Farmed Deer and Elk

July 2013

Number of Animals Sampled

<table>
<thead>
<tr>
<th>Fiscal Year</th>
<th>Number of Animals Sampled</th>
</tr>
</thead>
<tbody>
<tr>
<td>FY 2002</td>
<td>6243</td>
</tr>
<tr>
<td>FY 2003</td>
<td>12,045</td>
</tr>
<tr>
<td>FY 2004</td>
<td>15,172</td>
</tr>
<tr>
<td>FY 2005</td>
<td>15,628</td>
</tr>
<tr>
<td>FY 2006</td>
<td>14,913</td>
</tr>
<tr>
<td>FY 2007</td>
<td>17,189</td>
</tr>
<tr>
<td>FY 2008</td>
<td>20,777</td>
</tr>
<tr>
<td>FY 2009</td>
<td>23,642</td>
</tr>
<tr>
<td>FY 2010</td>
<td>20,000</td>
</tr>
<tr>
<td>FY 2011</td>
<td>20,430</td>
</tr>
<tr>
<td>FY 2012</td>
<td>22,585</td>
</tr>
<tr>
<td>FY 2013</td>
<td>18,147</td>
</tr>
</tbody>
</table>
Diagnostic Updates

• CWD Approved Labs
  – NAHLN Approval
  – NVSL Proficiency Test (IHC and/or ELISA)

• CWD HCP Official Tests
  – Immunohistochemistry (IHC)
  – Histopathology and Western Blot
  – **Bio-Rad CWD ELISA (MRPLN, Obex)** - Added

• Live animal test – (experimental)
  – RAMALT (rectal biopsy) - WTD *(Thomsen, et.al, 2012)*
  – RAMALT – RMNP Elk *(Monello, et.al, JWD 2013)*
Laboratories Approved to Conduct CWD and Scrapie Testing

September 2013
Research Updates

• Vaccination – “R&D” experimental studies (collaborations between U. Saskatchewan, Wyoming, Colorado)

• Experimental oral transmission study in reindeer (Mitchell, O’Rourke, Spraker, Balachandran - 2012)

• Role of genetics in chronic wasting disease of North American cervids (Robinson, O’Rourke, et al - 2012)

• Prion gene polymorphisms and role in inter-species transmission of prion diseases (Cortez, Sim, et al - 2013)

• Prion uptake by plants (Johnson, et al, USGS study - 2013)

Important to consider interpretation of experimental findings for relevance to natural disease events
APHIS – Cervid Industry Meeting
September 18, 2013

• Outreach/education on CWD
• FY14 Proposed Budget
• Research Needs
  – Vaccines (CWD, EHD/BT)
  – Live animal test
  – Genotyping
• CWD Rule and Program Standards
• Trade /marketing opportunities

Upcoming 2014 NAHMS Cervid Industry Study
Questions?

Patrice.N.Klein@aphis.usda.gov