



Veterinary Services



CervidTB Stat Pak® and DPP Testing in 2013

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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

Species	Number Tested	Percentage of tested
White tailed deer	3170	60.8%
Elk	1482	28.4%
Fallow deer	391	7.5%
Red deer	146	2.8%
Reindeer	25	0.48%

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

Species	Number of Reactors
White tailed deer	37
Elk	12
Fallow deer	2

2013 Stat-Pak® and DPP Testing

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

Species	Number Tested	<i>M. Bovis</i> (TB) infection found
White tailed deer	31	None
Elk	10	None
Fallow deer	3	None

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 to 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?





United States Department of Agriculture

Chronic Wasting Disease Herd Certification Program



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**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.

FY 13/14 Program Activities

APHIS VS

- 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
 - One must be USDA official ID
 - 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.

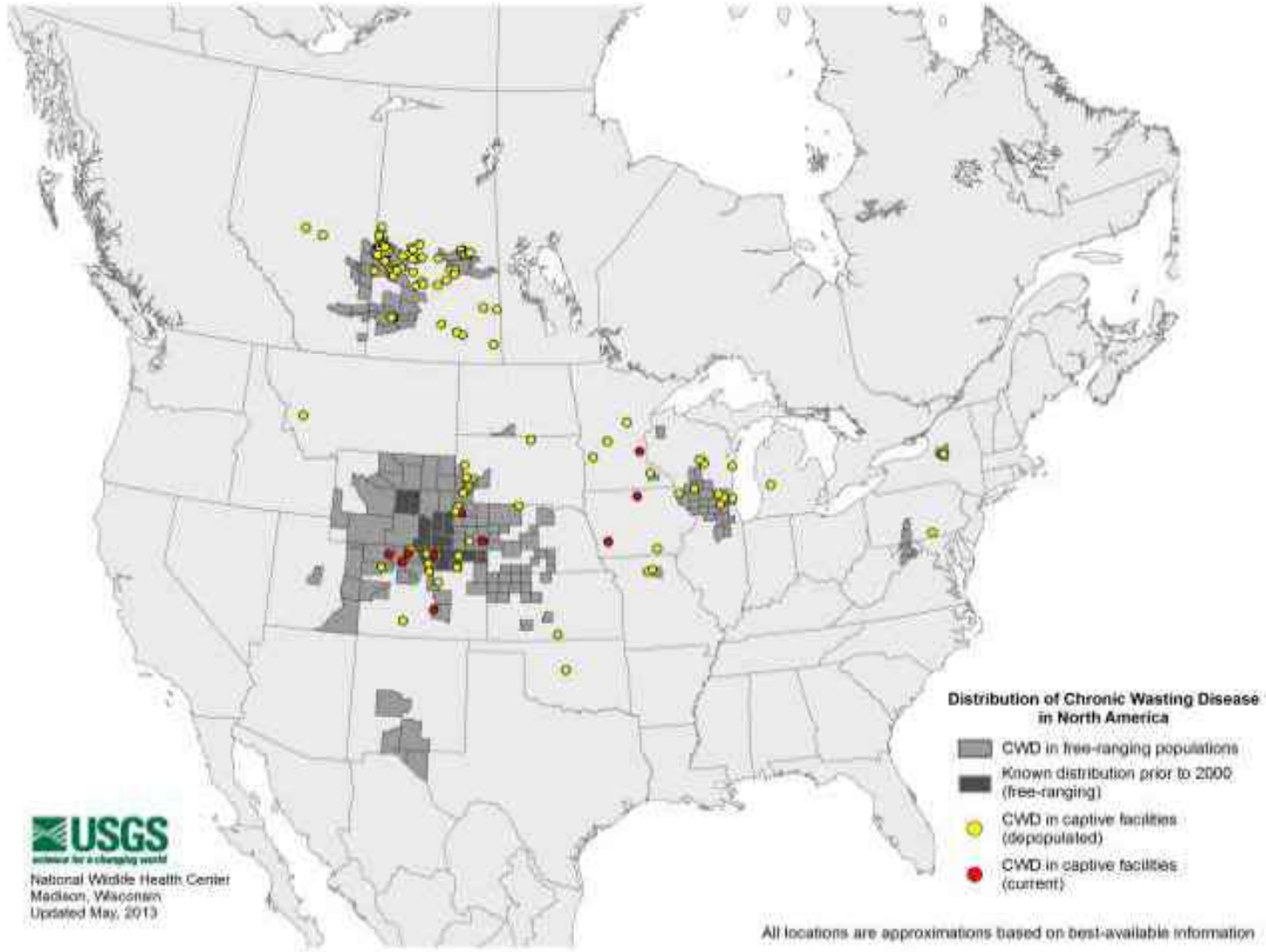
CWD Working Group

- 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

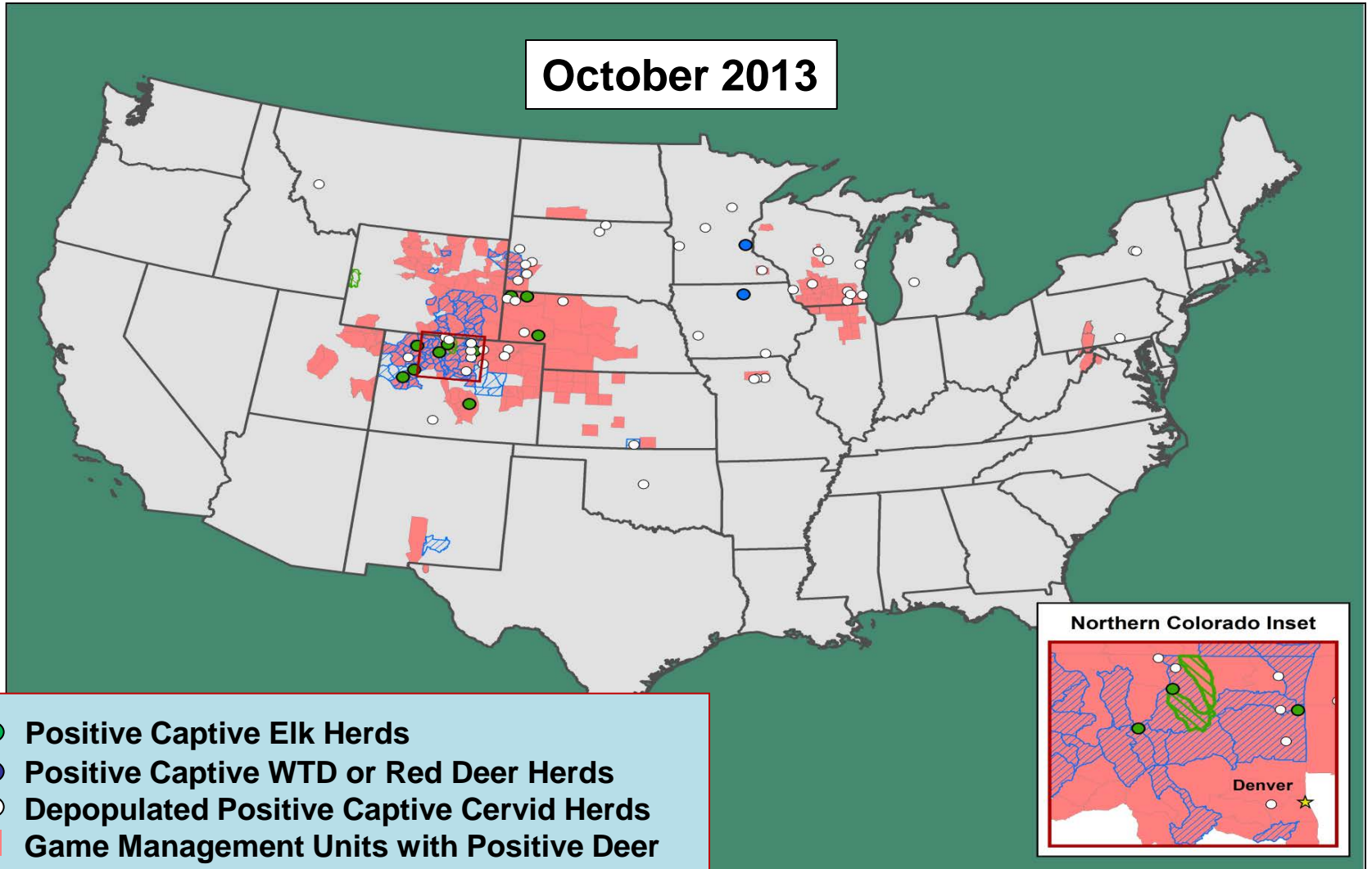
- **22 states** have reported CWD in farmed and/or wild cervids.
- Wild cervids: CWD has been detected in **18** states
 - CO, IL, KS, MD, MN, MO, ND, NE, NY,
 - NM, PA, SD, TX, UT, VA, WI, WV, WY
- Farmed cervid herds: CWD has been detected in **13** states in **60** farmed cervid herds (40 elk herds, 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

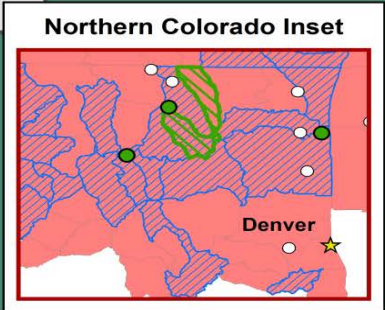


CWD-Positive Farmed Cervid Herds and Wildlife

October 2013

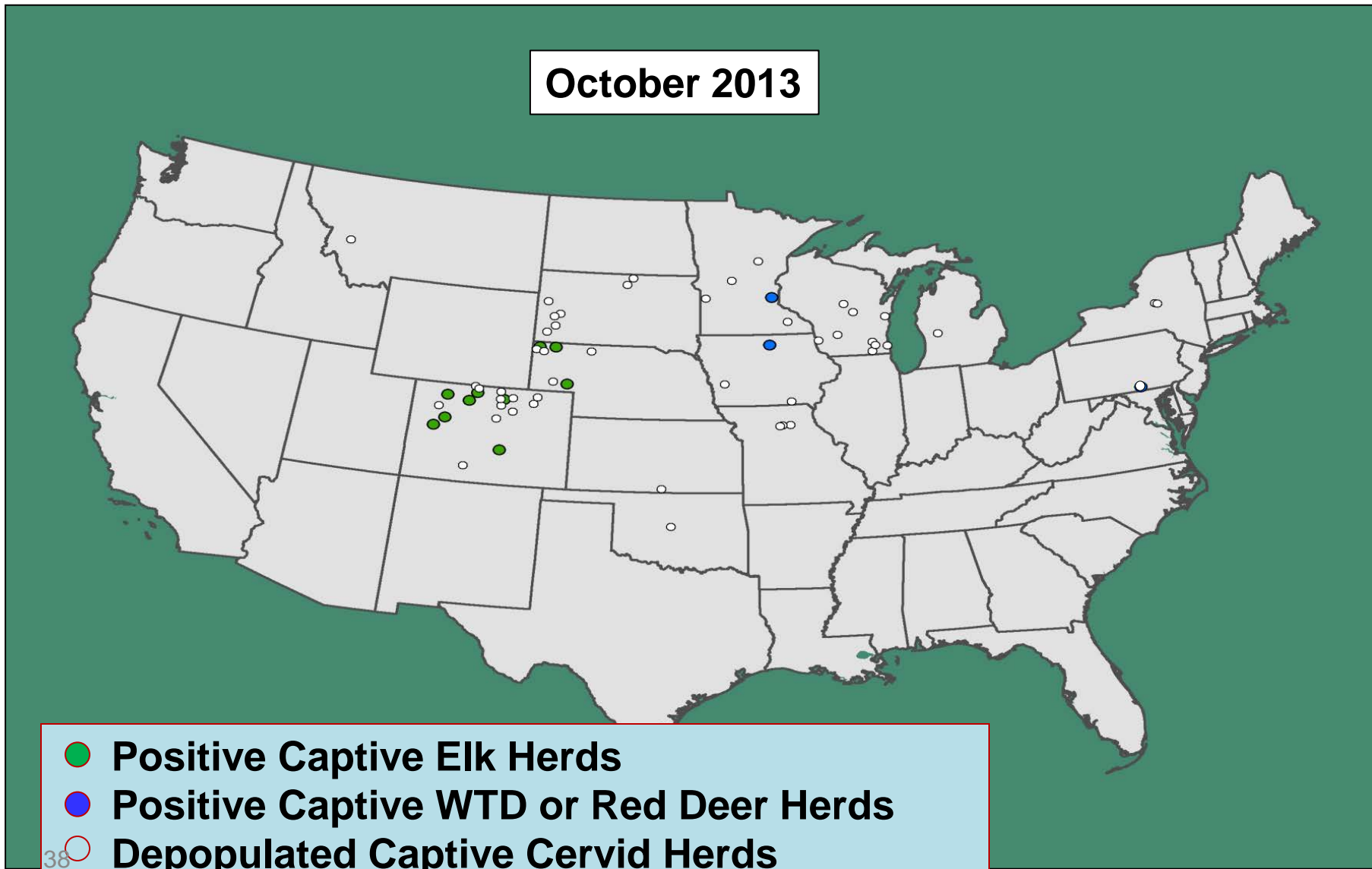


- Positive Captive Elk Herds
- Positive Captive WTD or Red Deer Herds
- Depopulated Positive Captive Cervid Herds
- Game Management Units with Positive Deer
- Game Management Units with Positive Elk
- Game Management Units with Positive Moose



Remaining CWD-Positive Captive Cervid Herds

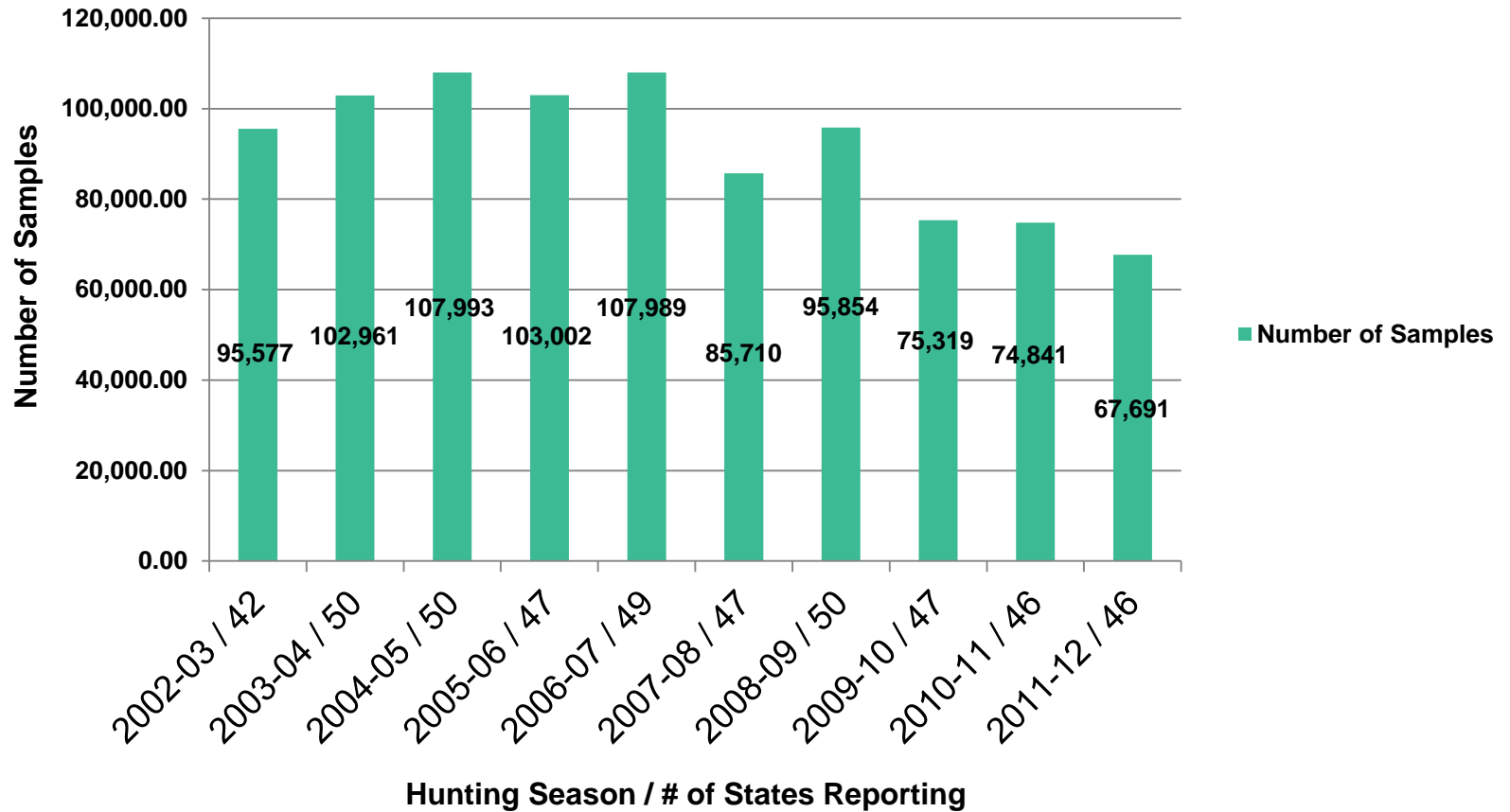
October 2013



- Positive Captive Elk Herds
- Positive Captive WTD or Red Deer Herds
- Depopulated Captive Cervid Herds

Surveillance in Wild Cervids

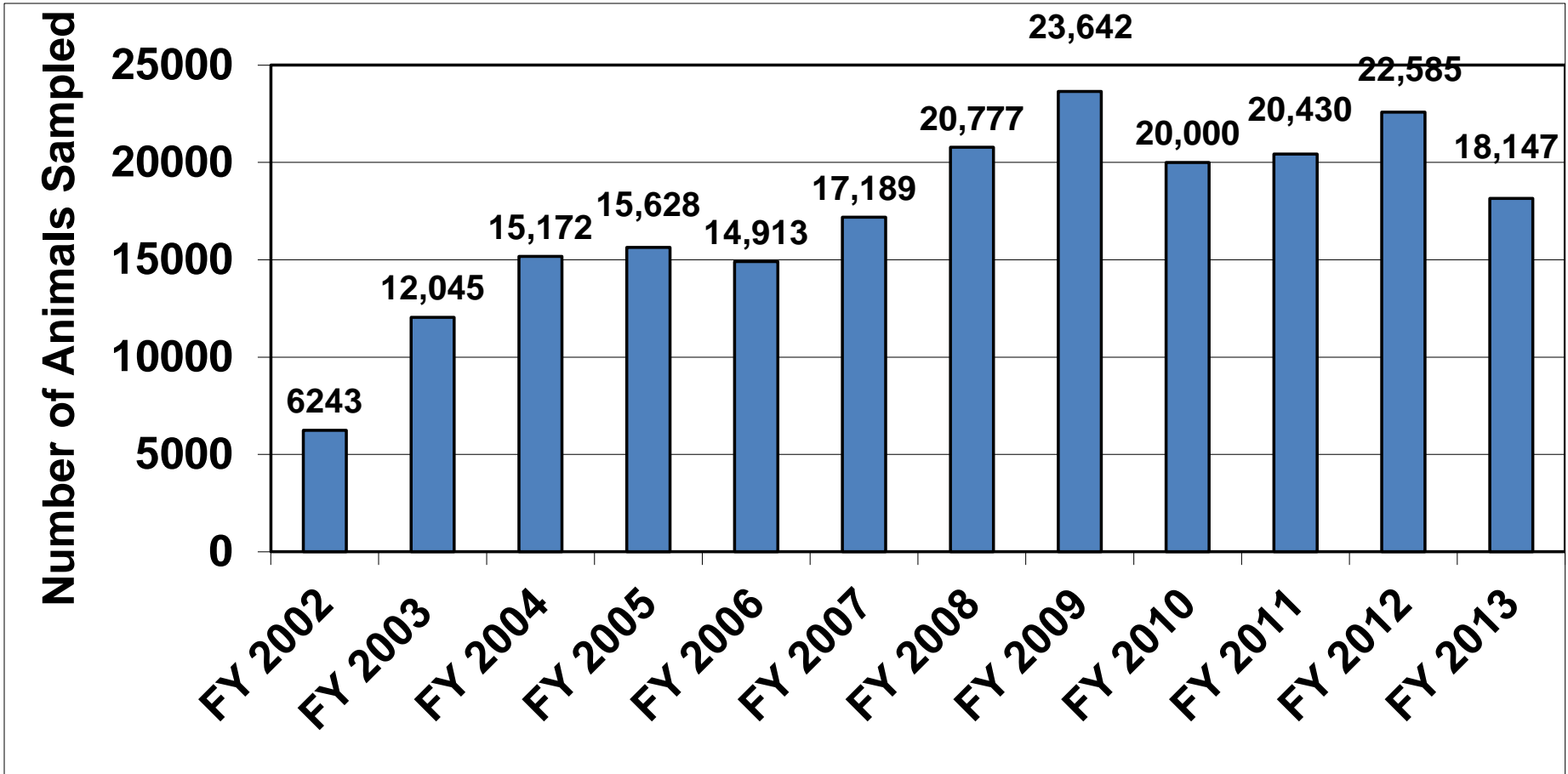
July 2013





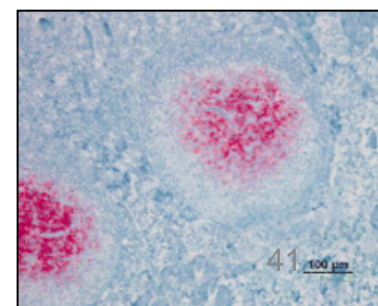
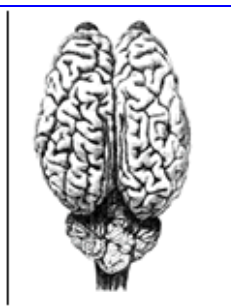
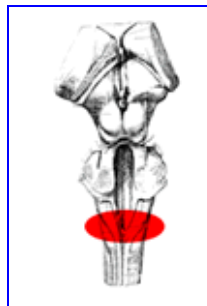
Surveillance in Farmed Deer and Elk

July 2013

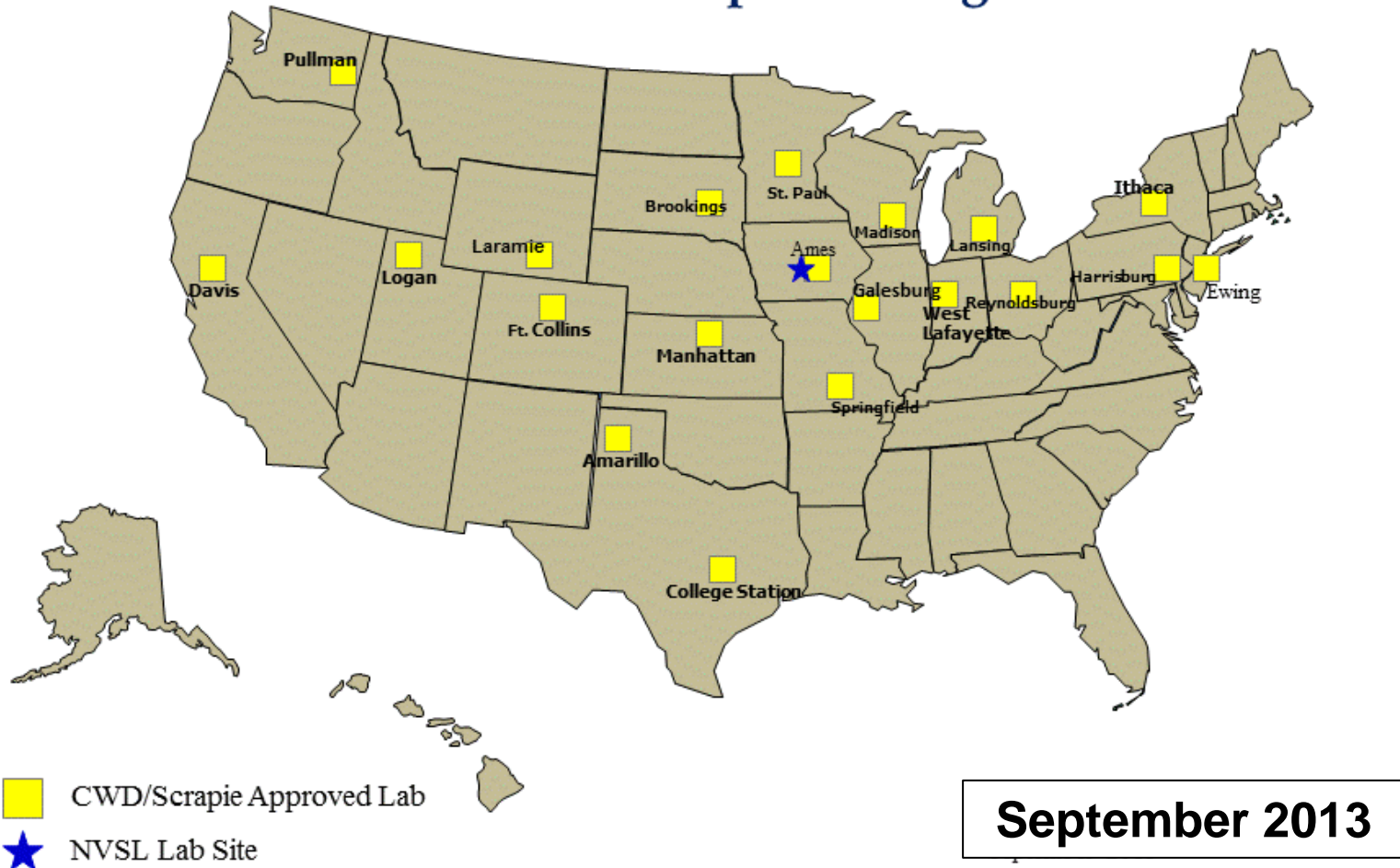


Diagnostic Updates

- 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



Research Updates

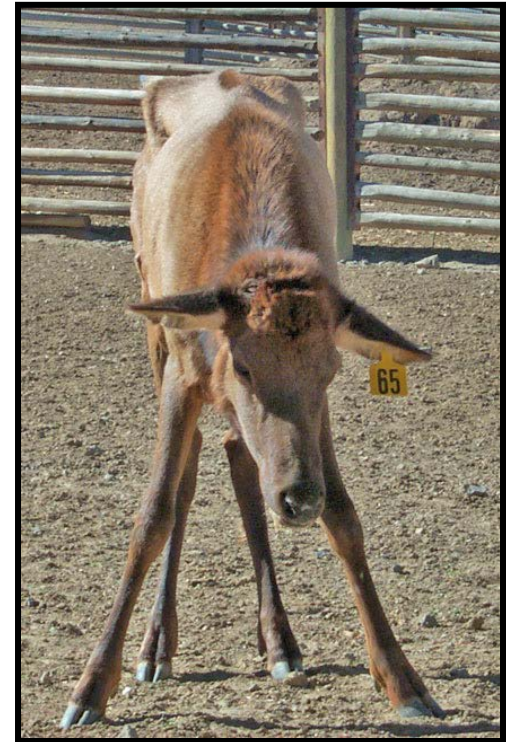
- Vaccination – “R&D” experimental studies (collaborations between U. Saskatchewan, Wyoming, Colorado)
- Experimental oral transmission study in reindeer (Mitchell, O’Rourke, Spraker, Balachandran - 2012)
- Role of genetics in chronic wasting disease of North American cervids (Robinson, O’Rourke, et 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?



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http://www.aphis.usda.gov/animal_health/animal_diseases/cwd/