USDA Animal and Plant Health Inspection Service
U.S. DEPARTMENT OF AGRICULTURE

USDA National Tuberculosis Eradication Program Update

USDA APHIS Veterinary Services
USAHA Subcommittee on Tuberculosis
October 2023

Cattle Health Updates

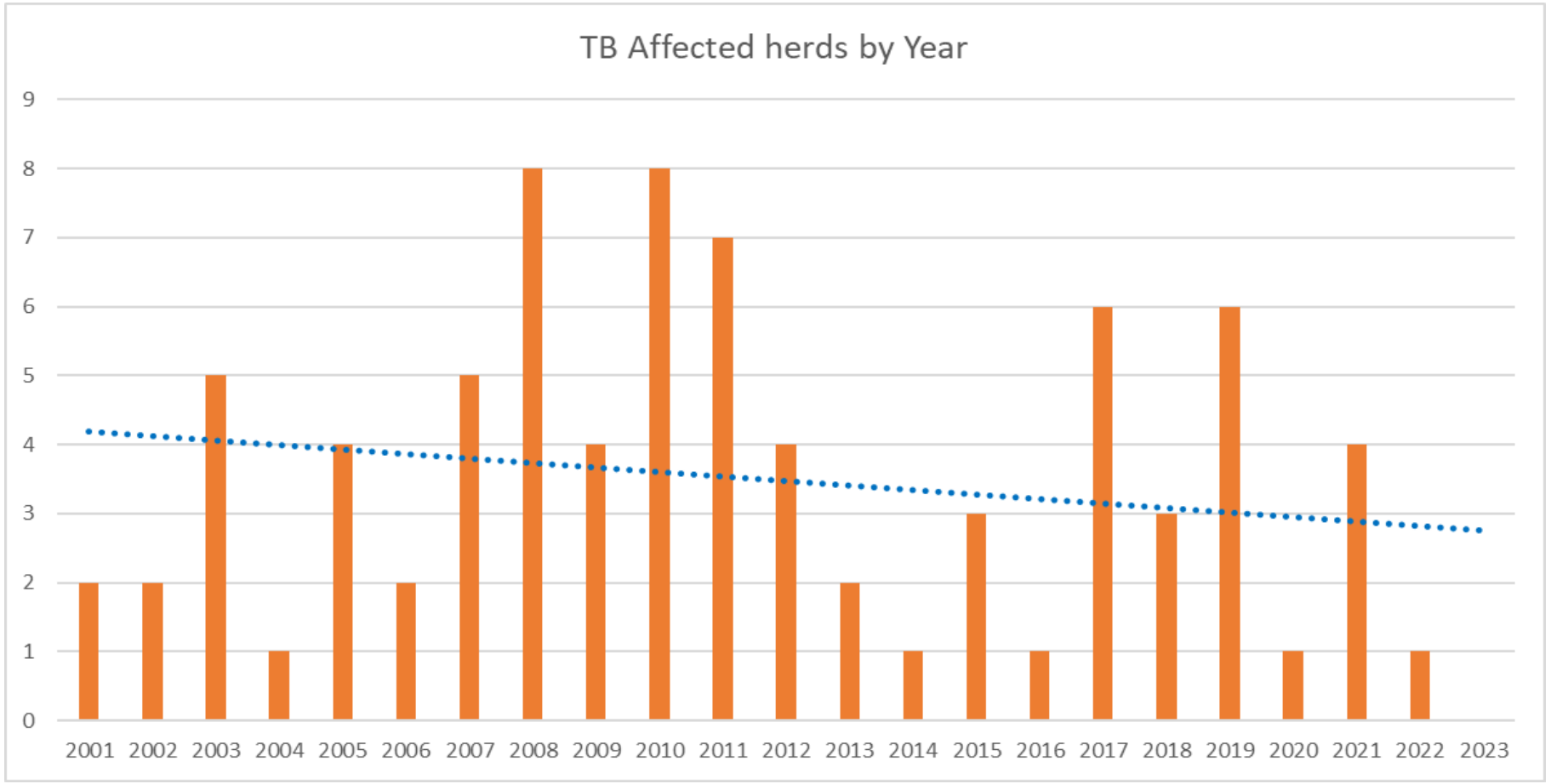
Mark Lyons
Ruminant Health Center
Strategy and Policy

National Tuberculosis Eradication Program Update

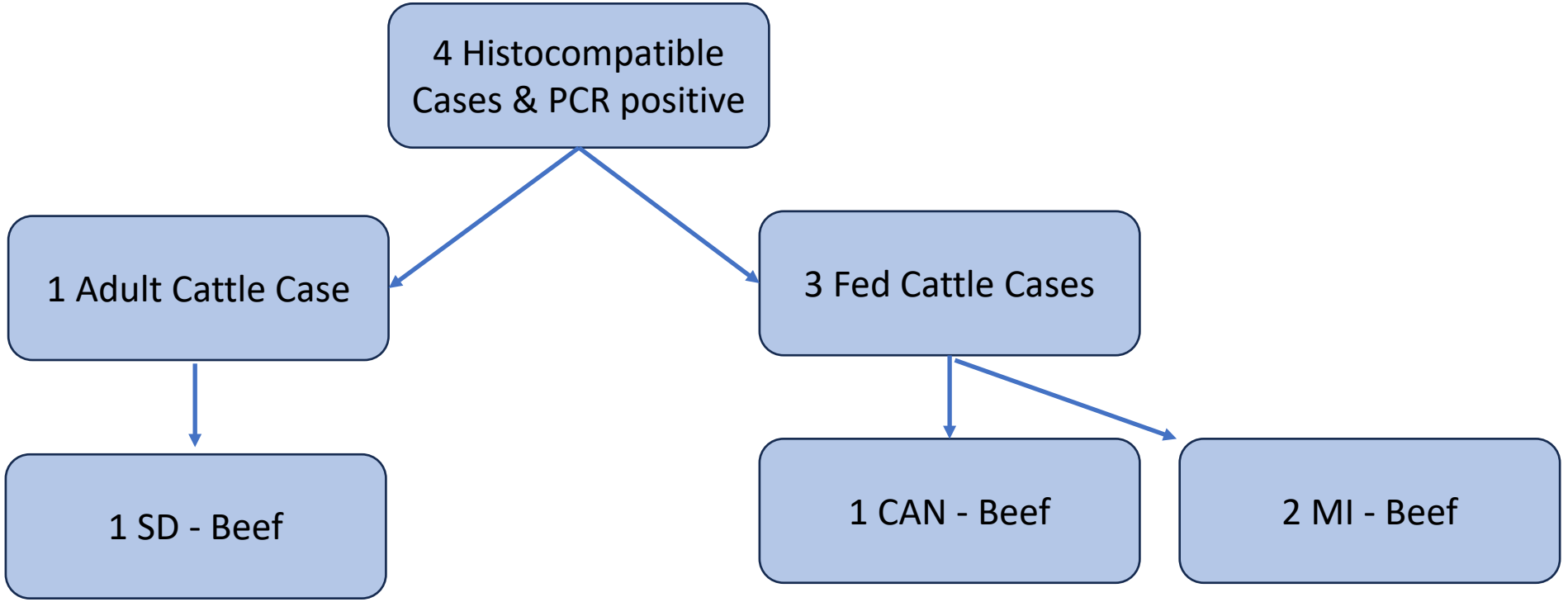
FY 2023 TB Infected Animals

By State	FY 23 6-35 cases	FY23 affected herds identified	Beef	Dairy	Cervids	Domestic Swine	Total Animals
SD	1	0	1				**1**
NM	0	0		2			**2**
MI	2	0	2				**2**
HI			1				**1**
NE/CAN	1		1				**1**
FY23 Total	**4**	**0**	**5**	**2**	**0**	**0**	**7**
FY22 Total	***3***	***7***	***6***	***11***	***3***	*9*	***29***
FY21 Total	***11***	***7***	***43***	***21***	***0***	*0*	***64***

TB-Affected Cattle & Bison Herds FY 2001-Present (excluding MI & HI)



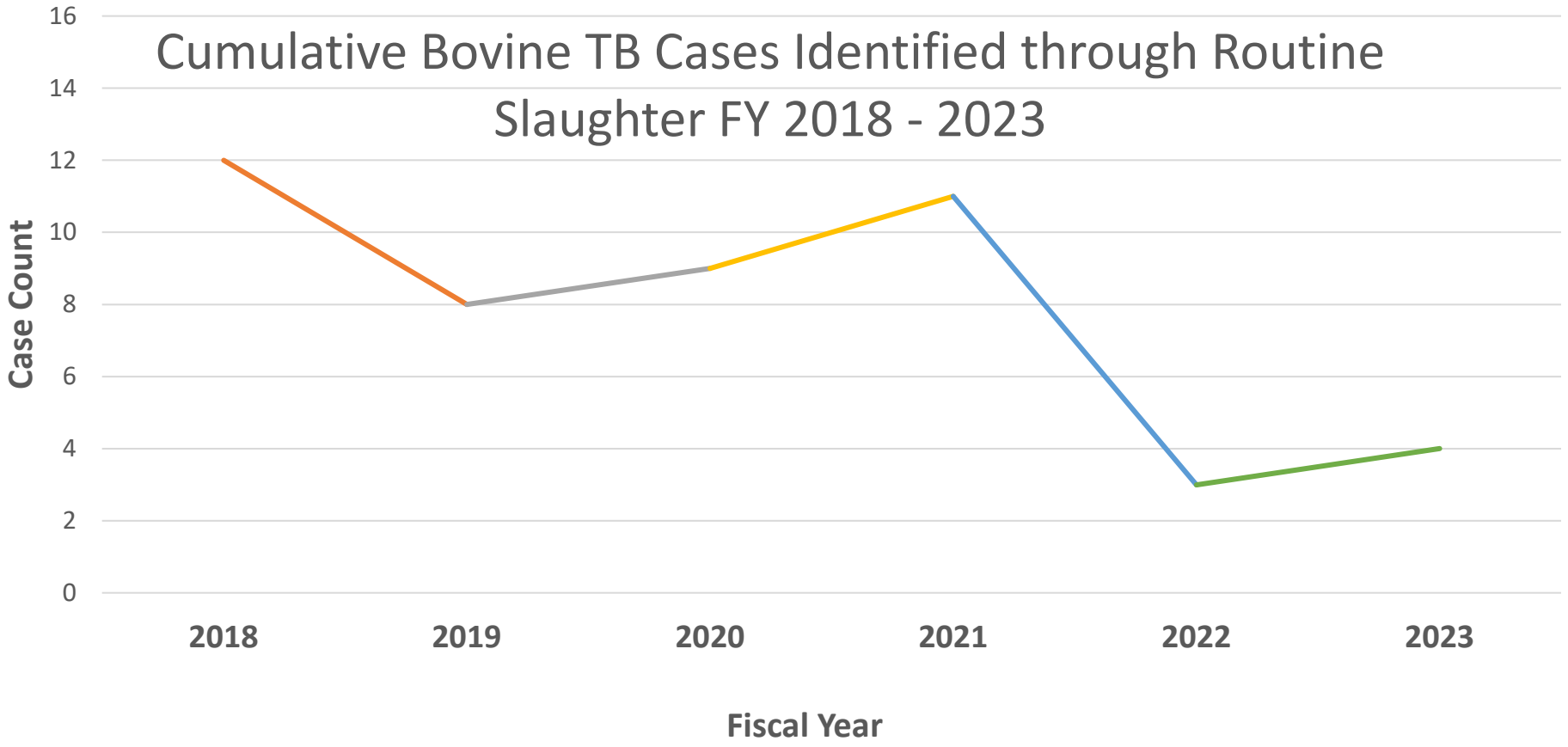
TB Slaughter Surveillance Cases (6-35) FY 2023



FY2023 New TB Animal Detections

Location[1]	Date Detected	Method of Detection	Herd Type	Herd Management Status	Next Test Tentative Start Date
SD 23	July 2023	6-35 Slaughter	Beef	1st whole herd test negative, verification test pending	TBD
NE/CAN 23	February 2023	6-35 Slaughter	Beef	Traced to Canada through a NE feedlot (Lot of CAN steers)	Found an affected beef herd in Saskatchewan
MI 23-B	February 2023	6-35 Slaughter	Beef – same MI feedlot	Traced to MAZ border county herd. No infection found	Source Herd undergoing annual assurance testing
MI 23-A	December 2022	6-35 Slaughter	Beef – same MI feedlot	Traced to MAZ border county herd. No infection found	Source Herd undergoing annual assurance testing

1. Herds are named with the last 2 digits of the **calendar** year and in order of occurrence within a state during that year, with Michigan's numbers being cumulative across years.
* These herds are under the same ownership



Cattle Type/Class	Month confirmed	Slaughter Plant State	Slaughter Origin State	Outcome/current status
Beef	December 2022	MI	MI	Trace Completed - Assessment Testing Fall 2023
Beef	February 2023	MI	MI	Trace completed
Beef	February 2023	NE	CAN	CAN Officials conducting investigation
Beef	July 2023	SD	SD	Verification Testing Fall 2023

FY2023 TB affected/High-risk herds

Location[1]	Date Detected	Method of Detection	Herd Type	Herd Management Status	Next Test Tentative Start Date
HI 22A	January 2022	Epi Investigation	Beef	Depopulation Completed	N/A
MI 22-82	January 2022	Surveillance	Dairy	Test and Remove Phase	Assurance Test Feb. 2024
TX 19A	February 2019	Epi Investigation	Dairy	Test and Remove Phase	Pending Culture Results
NM 19	May 2019	Slaughter Trace	Dairy	Test and Remove Phase	Pending Verification Test Results
TX 20B	Sept. 2020	Slaughter Trace	Beef	Test and Remove Phase	Assurance Test July 2023
NM 20A	October 2020	Assurance Test	Dairy	Test and Remove Phase	Assurance Test August 2023
NM 22B*	July 2022	Epi Investigation	Dairy	Test and Remove Phase	Sept. 2023
TX 22A*	July 2022	Movement Testing	Dairy	Test and Remove Phase	Sept. 2023

1. Herds are named with the last 2 digits of the **calendar** year and in order of occurrence within a state during that year, with Michigan's numbers being cumulative across years.

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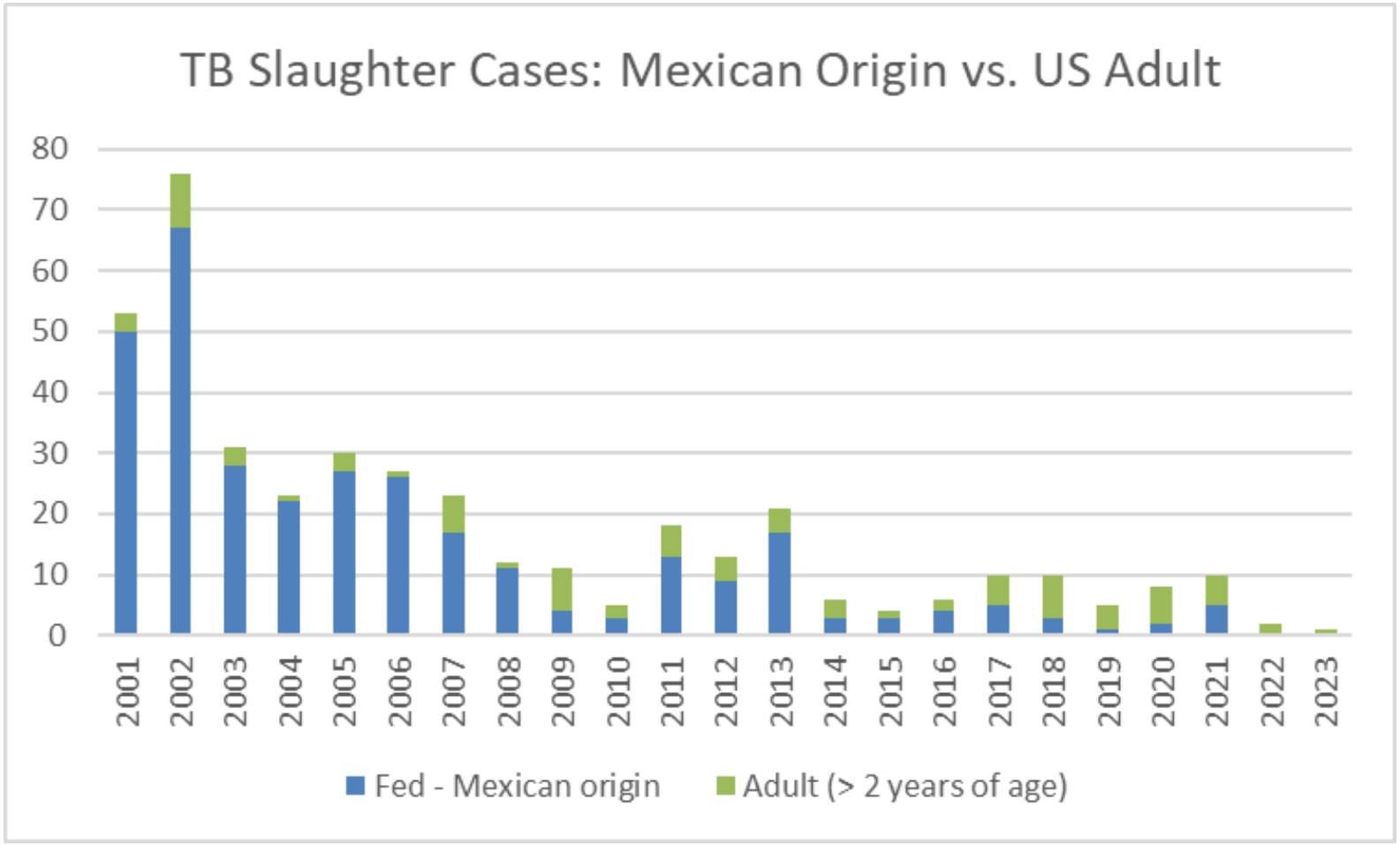
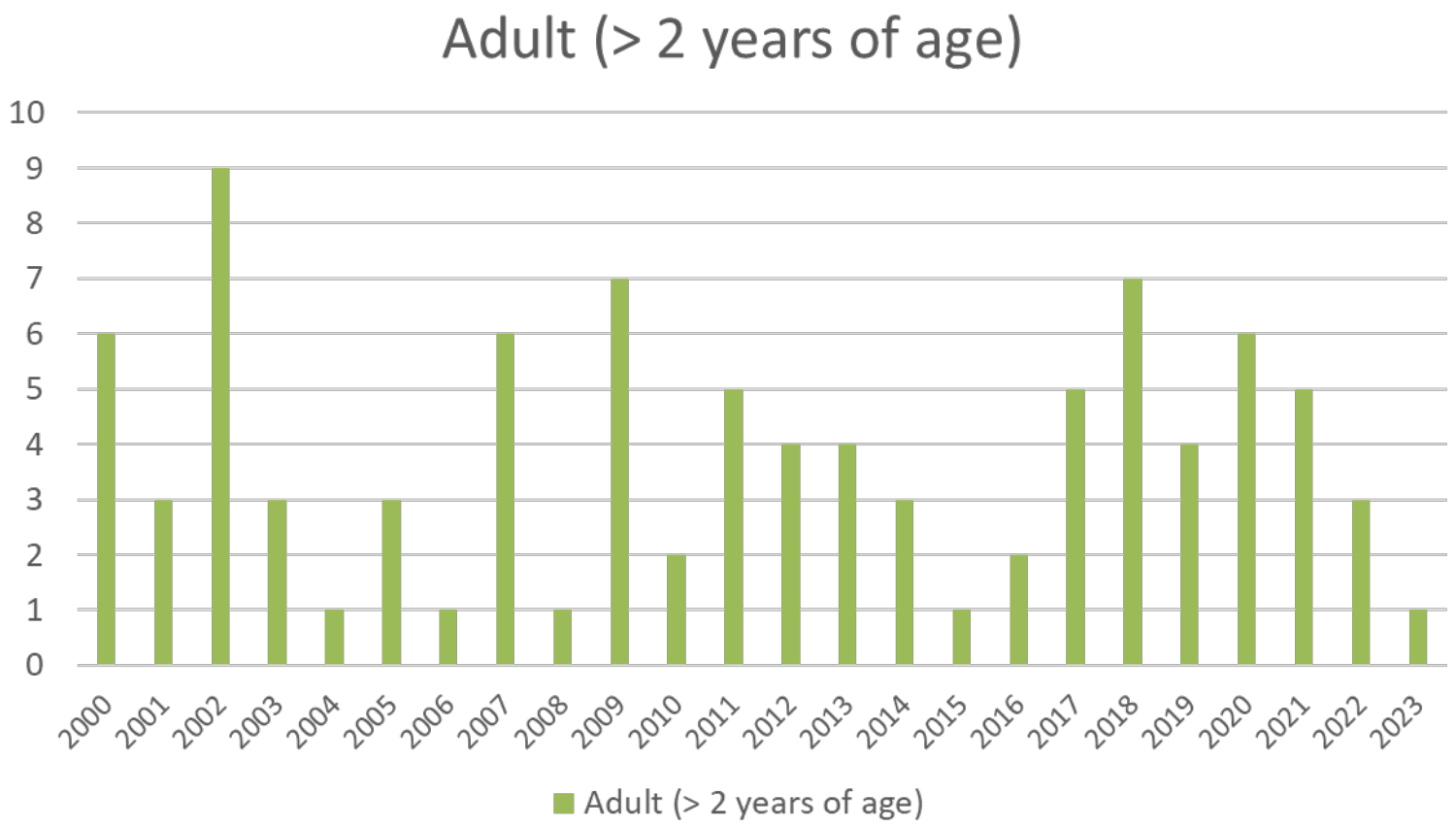
2001 - 2023 Slaughter Surveillance Comparison

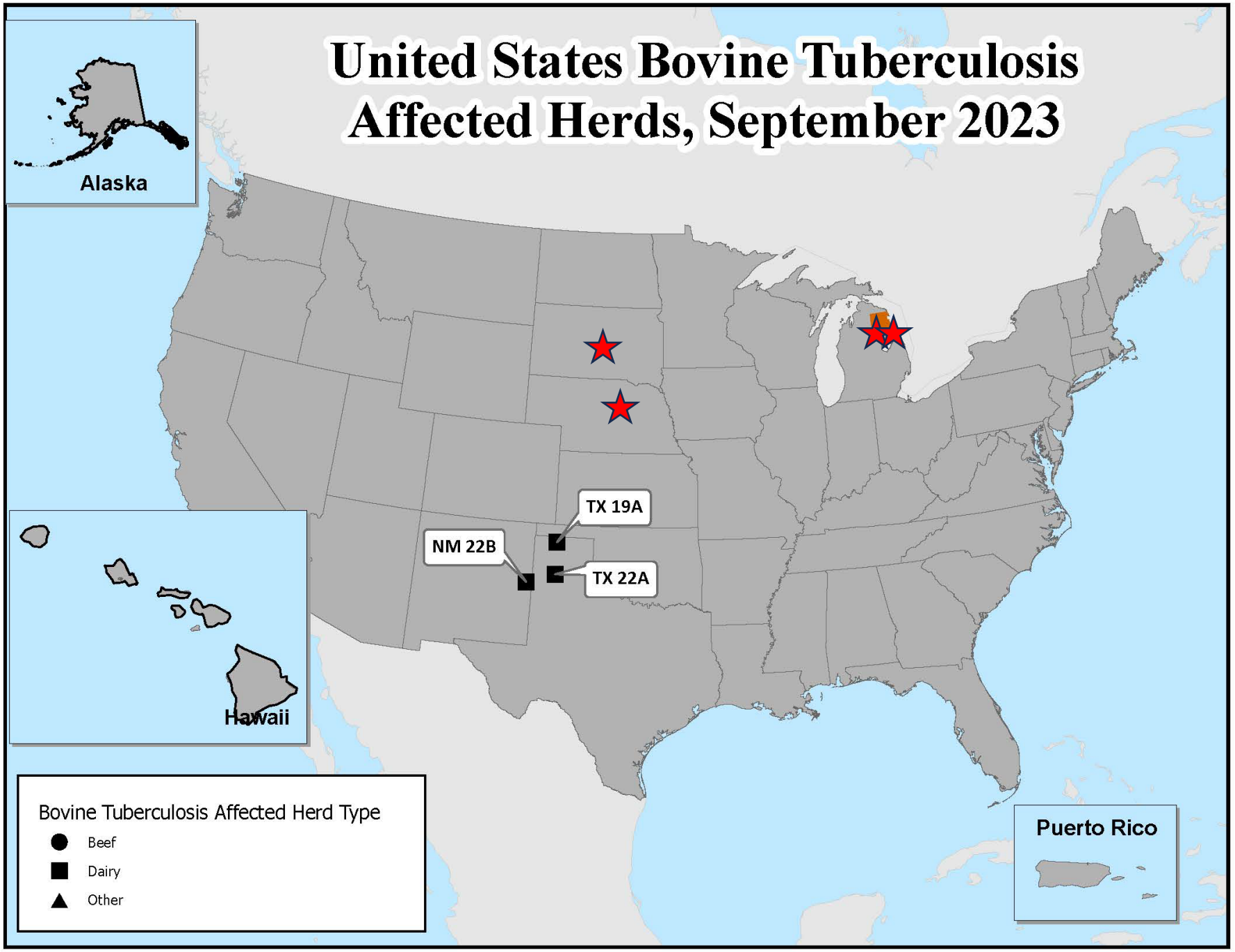
Comparison of Mexican vs. US Adult *M. bovis* slaughter cases, FY 2001–2023[1]



2000 - 2023 Slaughter Surveillance: Focus on US Adult cases

M. bovis Positive Adult Cattle from Slaughter Surveillance, FY 2000–2023[1]





★ = VS 6-35 detections

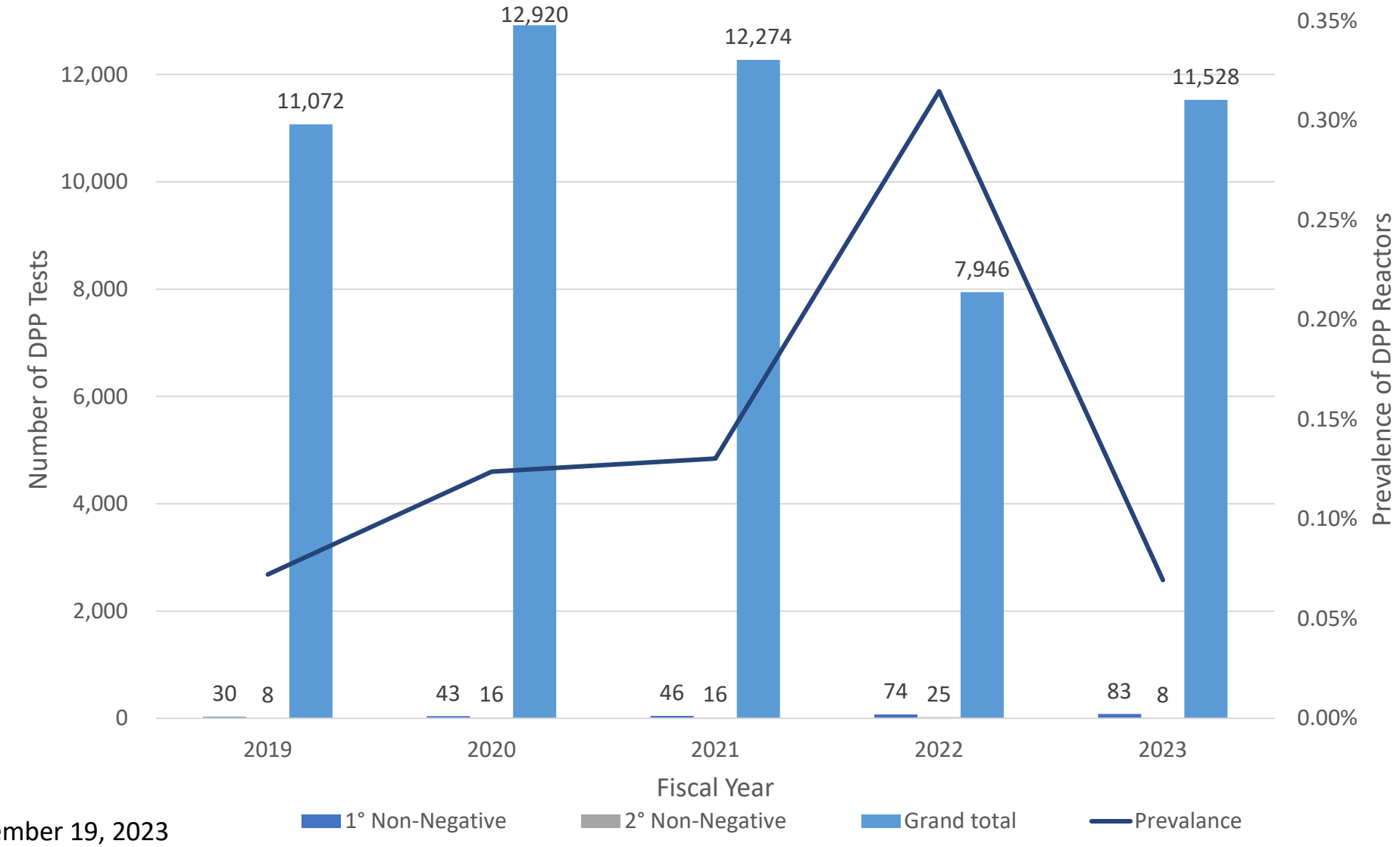
Cervid DPP Testing

Cervid TB Surveillance FY 2023 Dual Path Platform (DPP) Results

Cervid Species	Number of DPP tests	Number of 1^0 DPP tests non-negative	Number of 2^0 DPP Tests Non-Negative	Culture Positive
Fallow Deer	586	6	1	NA
Red Deer	372	0	NA	NA
White-tailed Deer	7,627	53	3	NA
Elk	2,752	22	3	NA
Reindeer	98	2	1	NA
Total	**11,435**	**83 (0.7%)**	**8 (0.07%)**	**0**

Results as of September 19, 2023

Cervid TB Surveillance FY 2023 Five-year trend in DPP



Results as of September 19, 2023

Cervid TB Surveillance FY 2023 Single Cervical Test (SCT) Results

Cervid Species	Number of SCT	Number of SCT suspects	Number of CCT negative	Number of CCT suspect/reactor
Total	1,030	4	4	0

Results as of September 19, 2023

Proposed TB Rule: Status Update

Why is the TB rule being updated?

- Modernization
  - Adapt to changes in the cattle, farmed cervid, and bison industries
  - Changes in disease dynamics, including wildlife and human introduction pathways
  - Depopulation of affected herds no longer feasible due to herd size, public perception and indemnity funding availability
- Science-based decisions
  - Testing and management strategies based on data and science (i.e., Test and Remove Plans)
- Consistency
  - Bring TB regulations into uniformity with other Federal Disease Program rules (i.e., 2019 Scrapie Rule)
- Consolidate Guidance
  - Consolidate existing guidance into single program standards document
- 2010 Federal Order

USDA Rulemaking Process

Workplan

- Need Identified
- Risk, environmental and other analysis as needed
- Working group
- Work plan prepared

Proposal

- Workplan submitted to USDA /APHIS Regulatory Analysis and Development (RAD) for review
- OMB Designation
  - *Not Significant*
  - *Significant*
  - *Economically Significant*
- Proposal drafted

Review and Clearance

- Review by USDA attorneys and policy officials
- Depth of review based on OMB designation
- ***Major impact on rulemaking timeline***

Comment Period

- Proposed rule published in Federal Register
- 60-day public comment period

Revision

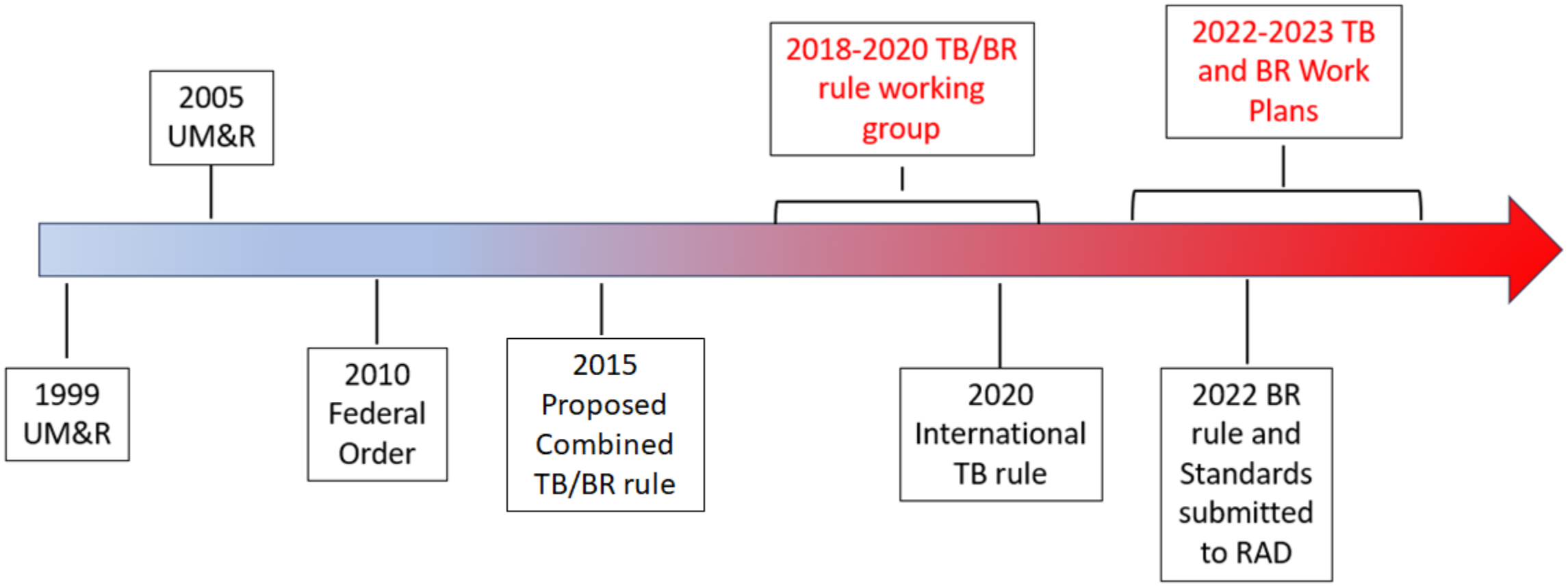
- Repeat 1-3 based on public comment

Publish Final Rule

- Final Rule Published in Federal Register
- Effective date 30 days after publication*

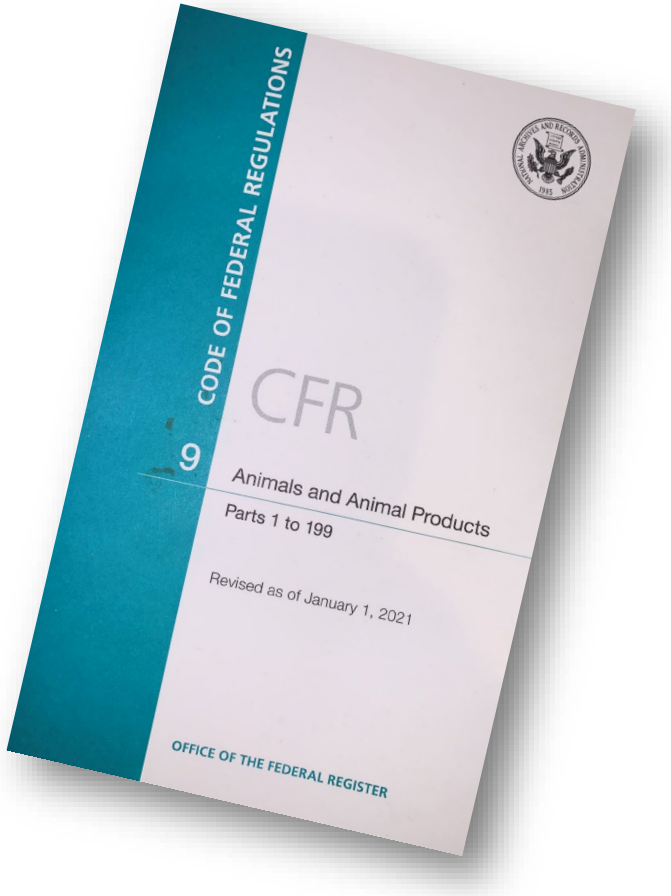
** Can become effective earlier if rule relieves restrictions or there is good cause for making the rule effective earlier.*

USDA TB Rulemaking Timeline



Components of Rule Updates

- Separate Brucellosis and TB rules
- 9 CFR 77 with preamble
- TB Program Standards (replacing UM&R)
- Major elements
  - Consistent vs Inconsistent state status
  - Wildlife
  - Tribal authority to develop own TB plans
  - Non-program species



TB Rule Timeline

Workplan

TB Rule

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Proposal

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ADT Rule

Publish Final Rule

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Mexico TB Updates

Regionalization Update

Kari Coulson
Regionalization Evaluation Services
Strategy and Policy

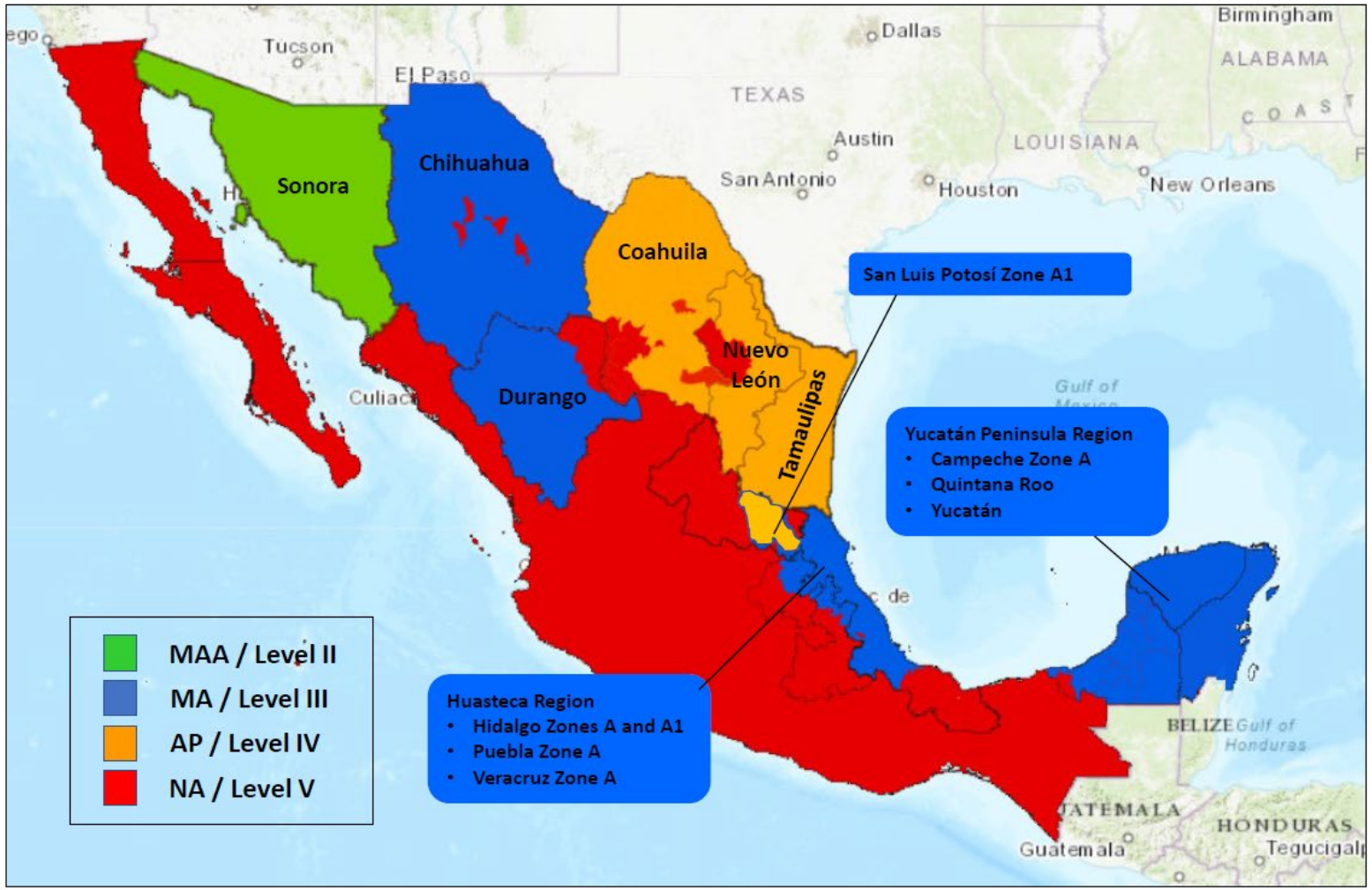
APHIS Import TB and Brucellosis Final Rule (9 CFR 93)

- Rule effective October 19, 2020
- Bovine TB and brucellosis classified separately
- Final rule establishes:
  - A system for evaluating and classifying the bovine TB and brucellosis statuses of foreign regions
  - Risk-based import testing requirements for bovine animals from regions of each classification level
  - A notice-based process for making proposed classifications and the supporting evaluations available for public comment

APHIS Recognition of TB Status

- Five classification levels for TB (Level I-V)
- Classified regions must meet minimum TB program criteria:
  - Veterinary control and oversight
  - Epidemiology
  - Affected herd management
  - Surveillance
  - Movement control
  - Vaccination (for brucellosis)
- March 2023
  - APHIS published the final notice classifying 8 Mexican regions for TB status under the new rule
- Ongoing APHIS review of Mexican regions classified for TB (each region reviewed every 2-3 years)

APHIS Recognition of TB Status of Mexican Regions



APHIS FY 23 TB Reviews

- Coahuila- November 2022
- Yucatán Peninsula Region- February 2023
- Nuevo León- March 2023

Coahuila- November 2022

- Routine status review-Zone A; review of Zone B1
- Strengths
  - Surveillance
  - Epidemiological investigations and TB-affected herd management
  - Staffing
- Recommendations
  - Zone B1
  - Oversight
  - Export gathering centers
  - Movement control
- **Conclusion:** Zone A- retain Level IV status; Zone B1- review September 2023 (APHIS determination pending)

Yucatán Peninsula- February 2023

- Routine review status review
- Strengths
  - Vary based on state
  - Slaughter inspection
  - Animal identification and traceability
- Recommendations
  - Area test
  - Harmonize cattle entry requirements
  - Ensure 95% slaughter surveillance
  - Improve epidemiological investigations
  - Enforce Certified TB-free herd protocol
- **Conclusion:** Retain Level III status; contingent on completion of area test

Nuevo León- March 2023

- Routine review status review
- Strengths
  - Export gathering centers
  - Slaughter inspection
  - Recordkeeping (PVIs, EGCs, feedlots)
  - Laboratory- histology/culture correlation rates
- Recommendations
  - Enforce animal identification and traceability requirements
  - Enforce approved feedlot protocol
  - Full area test of Zone A
  - Routine supervision- slaughter inspection
  - Improve epidemiological investigations
  - Enforce Certified TB-free herd protocol

Nuevo León- March 2023

- Conclusion: Nuevo León will be reclassified from Level IV to Level V status for TB, effective December 1st
- APHIS is also suspending cattle inspection at the Colombia Bridge facility in Nuevo León, effective December 1, 2023
- APHIS will receive cattle for inspection at other Southern Border port facilities—including the nearby port of entry at Laredo, Texas

FY24 APHIS TB reviews

- Huasteca Region (Veracruz, Hidalgo, Puebla)
  - November 27- December 8, 2023
- Chihuahua
  - February 19-23, 2024
- Sonora
  - April 8-12, 2024

National TB Initiative Updates

TB Initiative Updates

Tyler Thacker
NVSL – Mycobacteria and Brucella Section
Diagnostics and Biologics

Overview of Projects

- BCG Vaccination Project in Baja California, Mexico
- Modernizing bTB Antemortem Diagnostics
- bTB Biosecurity and Source Attribution
- Wildlife Survey and bTB Surveillance, Moloka’i, HI
- TB Lesion Flipbooks (FSIS)
- Mexican-Origin Cattle Slaughter Surveillance

BCG Vaccination Project in Baja California, Mexico

- Objective
  - Determine the efficacy of vaccination with the BCG TB vaccine to reduce bTB in infected commercial dairies

- Accomplishments
  - Calves are vaccinated within 2 weeks of birth
    - Total = 2,247 as of July 31, 2023, with an overall goal of 6,000
  - Antemortem testing – CFT/CCT testing, blood for in-tube IFN-gamma test (QFT)
    - 2nd Testing Campaign in progress (3 Dairies completed)
  - Revaccination of animals 9-12 months of age
  - Sampling of enrolled animals at slaughter is underway

Modernizing bTB Antemortem Diagnostics

- Goal
  - Evaluate modernized tests
  - Identify and evaluate tests that can differentiate infected from vaccinated animals (DIVA)
- Accomplishments
  - Completed ruggedness sampling and testing of the QFT
  - Completed negative animal sampling to evaluate specificity using cattle from the United States
  - Continue to sample potential positive animals for sensitivity using cattle enrolled in BCG Project
- Plan going forward
  - Continue discussions with states to apply QFT testing on US animals - targeting positives
  - Continue data collection and analyze test specificity/sensitivity

bTB Biosecurity and Source Attribution

- Objectives
  - Develop standardized biosecurity assessment survey
  - Conduct in-depth affected herd investigations and develop a standardized database/plan for the results
  - Improve awareness and best practices to prevent zoonotic TB transmission of *M. bovis*
- Accomplishments
  - Completed in-depth dairy herd investigations, Texas & New Mexico. Currently working with MI
  - Conducted in-depth, retrospective investigations in South Dakota
  - Human-to-cattle transmission manuscript published in Frontiers of Veterinary Science
  - Participation in the National Milk Producers Federation multi-sector bovine TB working group
  - Received agreement from three states to share human *M. bovis* isolate WGS

Wildlife Survey and bTB Surveillance, Moloka'i, HI

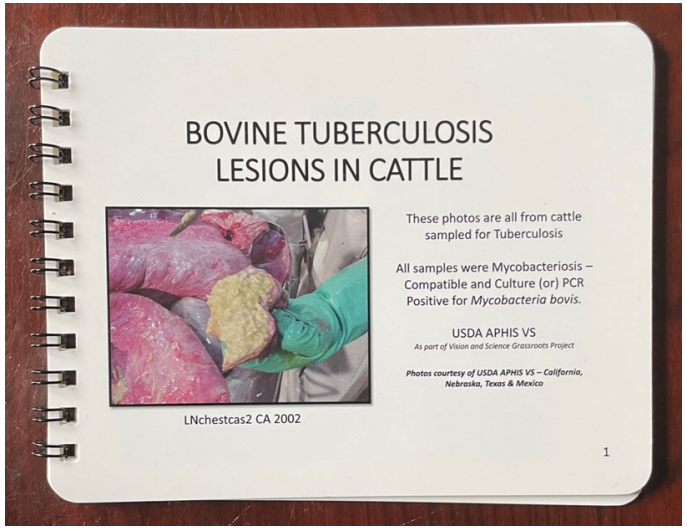
- Objectives
  - Establish baseline information necessary for conducting risk assessments and development of control measures for bTB on Moloka'i island

- Accomplishments
  - 1-year camera trap program to estimate population densities of free-ranging swine/axis deer and capture wildlife-livestock interactions
    - 57 cameras across 3 camera grids will monitor wildlife and ~20 cameras on cattle pastures will capture wildlife-livestock contacts
    - Private land permission for access has been requested from 12 landowners (deploy October)
    - On-island WS staff is getting onboarded
  - Communication
    - Developed materials for distribution on Moloka'i

TB Lesion Flipbooks (FSIS)

- Objectives
  - Provide reference materials (flip book) and training to FSIS inspectors to improve granuloma recognition
  - Most veterinarians and technicians working in abattoirs have not seen a real TB granuloma
  - Flip books provide readily available visual information to aid identification

- Accomplishments
  - To date: 675 distributed to 25 states
  - 325 available



Mexican-Origin Cattle Slaughter Surveillance

- Objectives
  - Evaluate the risk of bovine tuberculosis (bTB) in Mexican Origin Cattle
    - Estimate the prevalence of bTB in Mexican origin cattle
    - Evaluate MX origin cattle movements from importation to slaughter in the U.S.

- Accomplishments
  - Newly hired staff are currently being trained in Texas
  - ORISE Fellow
    - Funding has been allocated for hiring an ORISE Fellow to help with data management (start in Dec. 2023)

Questions?

Thank you