

Veterinary Services Webinar



Brucellosis and Bovine Tuberculosis Proposed Rule and Program Standards

August 2012



Safeguarding Animal Health



Today's Webinar

- **Review development process**
- **Describe content of proposed rule and Program Standards**
- **Discuss next steps**
- **Take participants' questions and feedback**





Vision for the Regulations

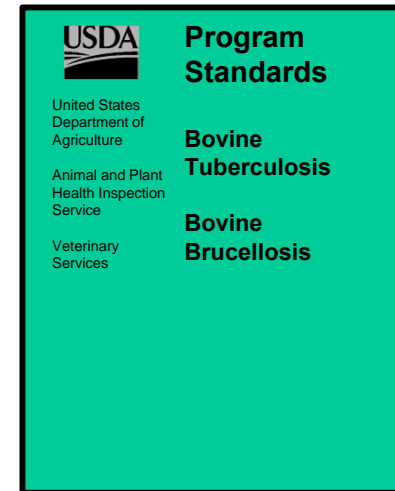
- **Single rule for both the brucellosis and TB programs**
 - Ensures consistency
 - Increases flexibility
 - Reduces administrative burden

Regulatory Approach



CFR

- Provides regulatory authority
- Use of performance standards when possible



Program standards

- Details of how performance standards can be met
- Replaces UM&R

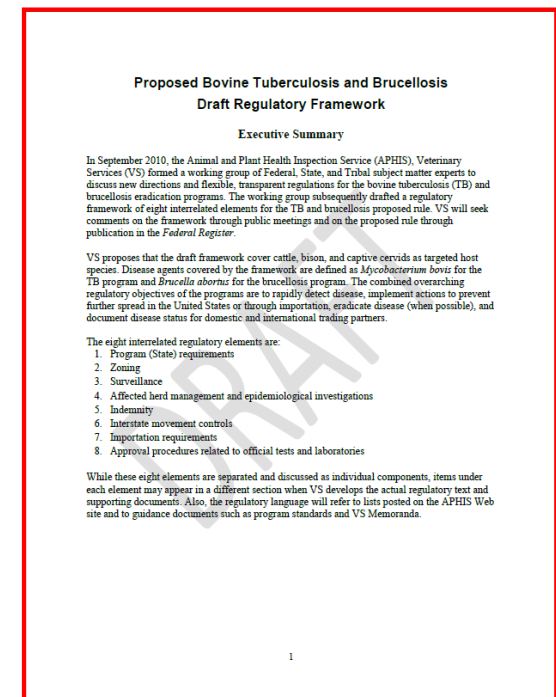


History

- **TB Listening Sessions in December 2008**
- **Concept papers in October 2009**
- **Working group established September 2010**
- **Published a draft regulatory framework for public comment in May 2011**
- **Held public meetings in May and June 2011**

The Draft Regulatory Framework described eight interrelated elements:

1. Program (State) requirements
2. Zoning
3. Surveillance
4. Affected herd management and epidemiological investigations
5. Indemnity
6. Interstate movement controls
7. Importation requirements
8. Approval procedures related to official tests and laboratories



Description of Each Element

- **Fundamental Concepts**
- **Content of Proposed Rule**
- **Content of Program Standards**
- **Key Differences from Draft Regulatory Framework**

Scope of Regulations

- **Agent species**
 - *Brucella abortus* and *Mycobacterium bovis*
- **Program (host) species**
 - **Cattle, bison, and captive cervids**

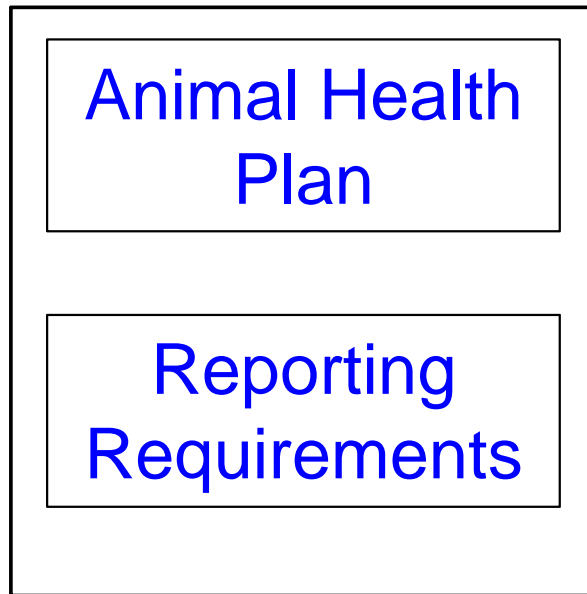


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Element 1: Program Requirements and State Status: Concepts

Determinants of Status



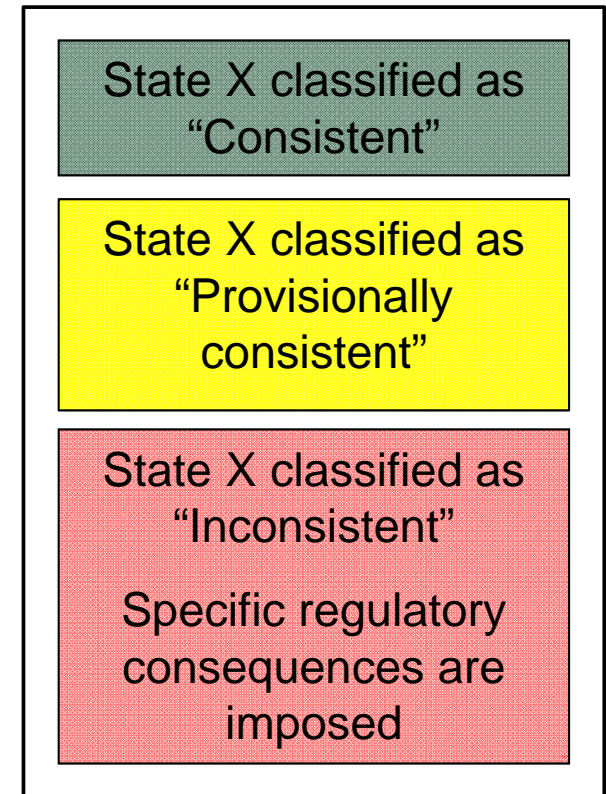
VS approves and State implements



State submits and VS makes available



Three-tiered status system



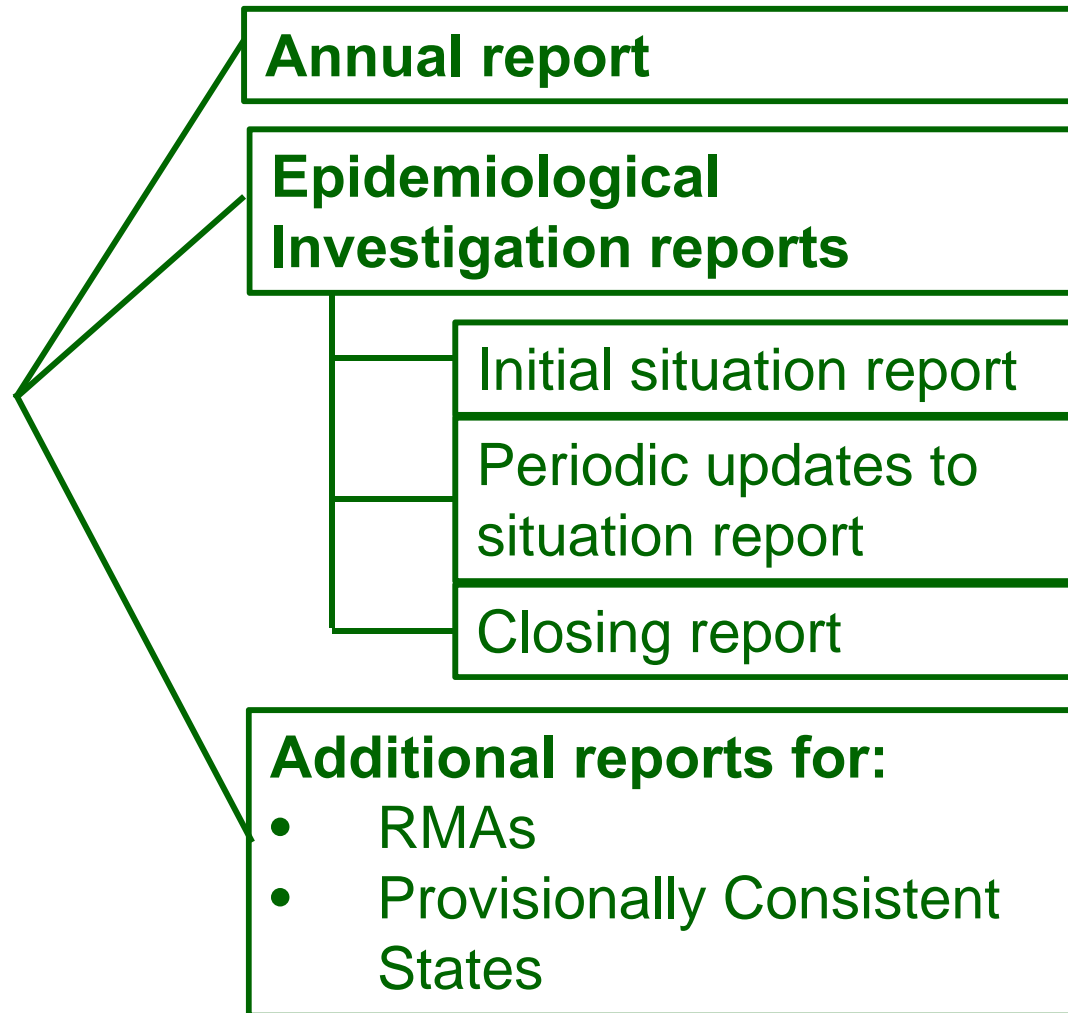
States and Tribes develop, submit, and implement **animal health plans (AHP)**

Animal Health Plan

1. Laws and regulations
2. Organization and infrastructure
3. Responsible persons
4. Program animal demographics
5. Surveillance
6. Sources of brucellosis and bovine tuberculosis
7. Risk mitigation activities
8. Disease investigation, management, and response
9. Recognized management area (optional)

States and Tribes complete **required reports**

- **Transparency is a foundation of success**
- **Reports also document compliance**



States and Tribes will be classified according to a **three-tiered status system**

State X classified as “Consistent”

- APHIS approves AHP
- State implements AHP and submits reports

State X classified as “Provisionally Consistent”

- Probationary status
- Conditional AHP approval
- State lapses from AHP or does not submit reports
 - No disease risk
- Specified time for remedial action
- Specific regulatory consequences imposed

State X classified as “Inconsistent”

- AHP not approved
- State lapses from AHP or fails to submit reports
 - risk of disease transmission (or unknown risk)
- Specific regulatory consequences imposed

A **notice-based process** will make animal health plans and reports publicly available and designate status

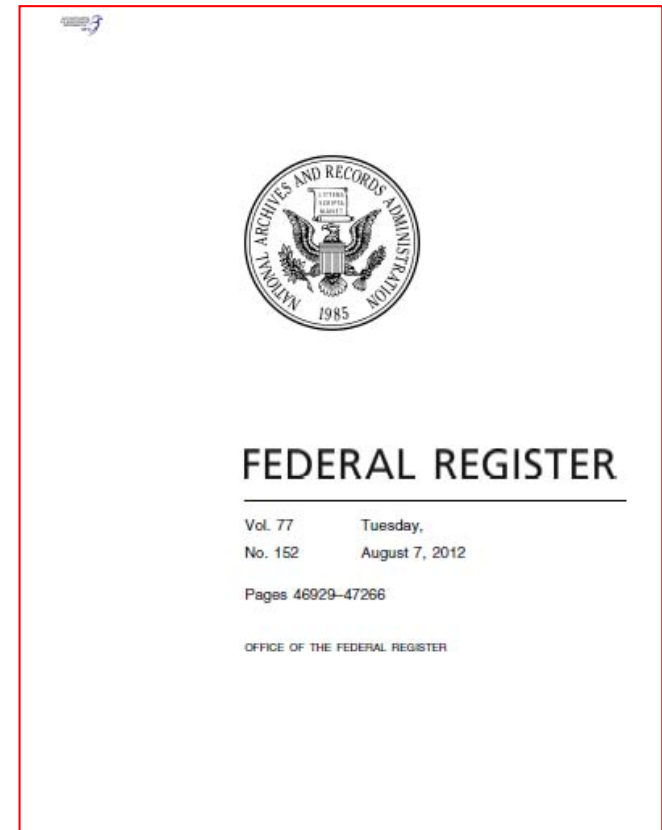
Animal Health Plans

- Make available for public review and comment
- Approval

Status

- Initial status
- Redesignations
 - Reason
 - Remedial measures and timeframe
 - Specify restrictions

Changes to Program Standards



Animal Health Plan

Proposed Rule

Program Standards

Establish submission process

- Detailed description of submission process
- Process for joint submissions for certain categories

Define categories of information

- Detailed submission requirements
- Evaluation criteria
- Template

Establish process for APHIS review and approval

- Detailed description of review/approval process



Animal Health Plan

Proposed Rule	Program Standards
Notice-based process	<ul style="list-style-type: none"> • Detailed description of process • Requirement for making AHP publicly available
Allow for amendments	<ul style="list-style-type: none"> • Situations which initiate amendments • Process to submit amendments
Allow for compliance reviews and audits	<ul style="list-style-type: none"> • Situations which may initiate reviews or audits • Review team membership • Review reports

State and Tribal Classifications

Proposed Rule	Program Standards
Establish 3-tiered system	<ul style="list-style-type: none"> Describe Tribal classifications
Establish process for initial status designation	<ul style="list-style-type: none"> Integrate status with AHP approval process

State and Tribal Classifications

Proposed Rule	Program Standards
<p>Define conditions for redesignation</p>	<ul style="list-style-type: none"> • Detailed description of circumstances that may result in redesignation to a lower status • Actions to re-establish consistent status
<p>Establish a notice-based process for announcing statuses</p>	<ul style="list-style-type: none"> • Detailed description of process • Describe how additional requirements for provisionally consistent status will be established via notice • Link to list of State statuses on the APHIS Web site

Technical Advisory Board

Key Differences from Regulatory Framework

- Reduced the role of an advisory board to provide counsel on specific technical issues



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Required Reports

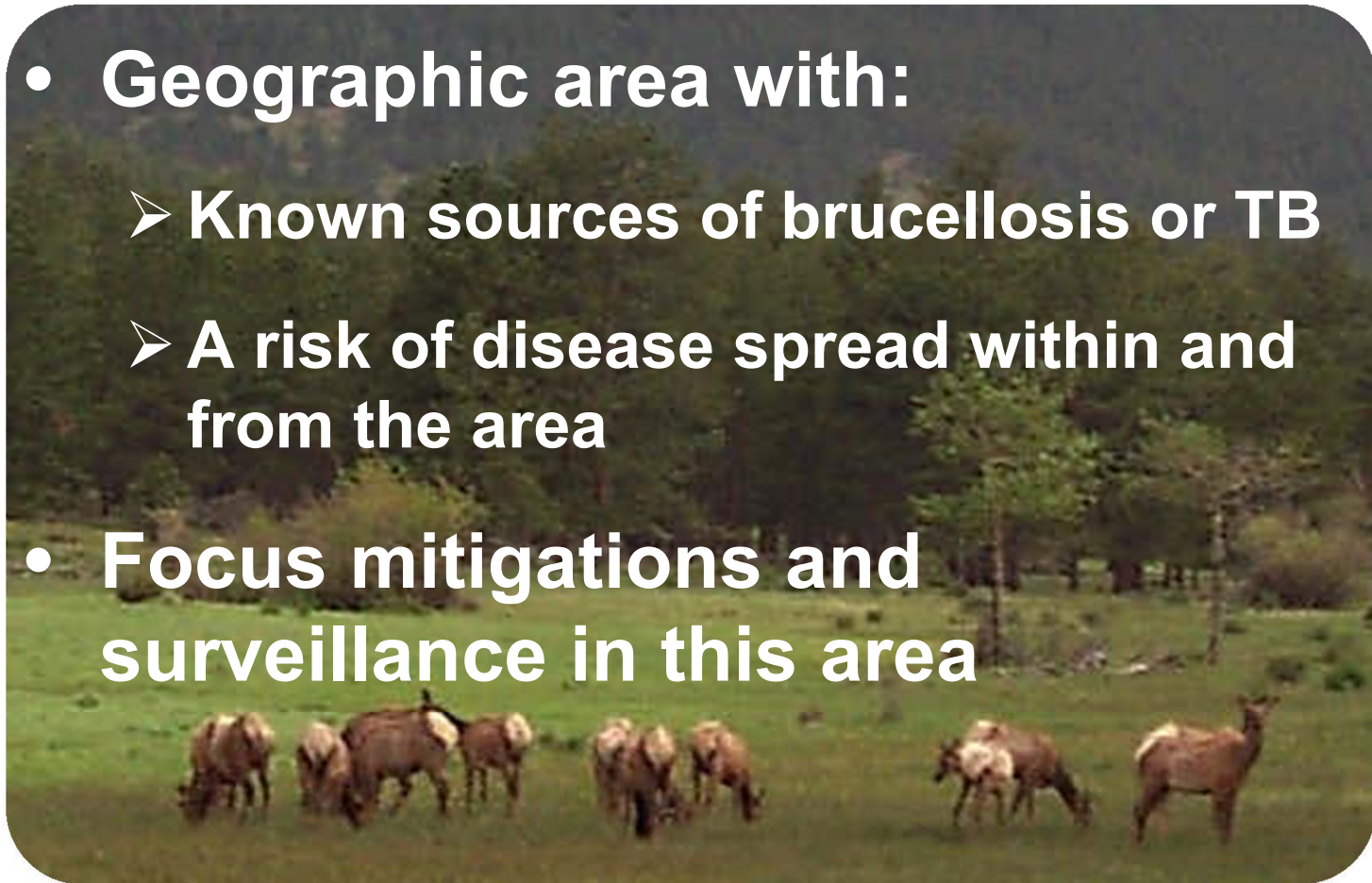
Proposed Rule	Program Standards
<p>Defines required reports and specifies timelines for submission</p>	<ul style="list-style-type: none"> • Template for annual report • Submission process

Key Differences from Regulatory Framework

- Eliminated options for reduced frequency of reporting
- Annual reports as a minimum

Element 2: Recognized Management Areas: Concepts

- **Geographic area with:**
 - **Known sources of brucellosis or TB**
 - **A risk of disease spread within and from the area**
- **Focus mitigations and surveillance in this area**



States and Tribes amend their AHP to include description of **recognized management areas (RMA)**

Animal Health Plan

9. Recognized management area (optional)
 - a. Geographical description
 - b. Determination of boundaries
 - c. Sources of disease and assessment of disease spread
 - d. Risk mitigation activities
 - e. Laws and regulations
 - f. Personnel
 - g. Official identification

Recognized Management Areas

Proposed Rule	Program Standards
Establish process to recognize a management area	<ul style="list-style-type: none"> • Detailed description
Define categories of information	<ul style="list-style-type: none"> • Detailed submission requirements • Evaluation criteria • Template
	<ul style="list-style-type: none"> • Official brucellosis vaccination program
Establish approval process	<ul style="list-style-type: none"> • Detailed description

Recognized Management Areas

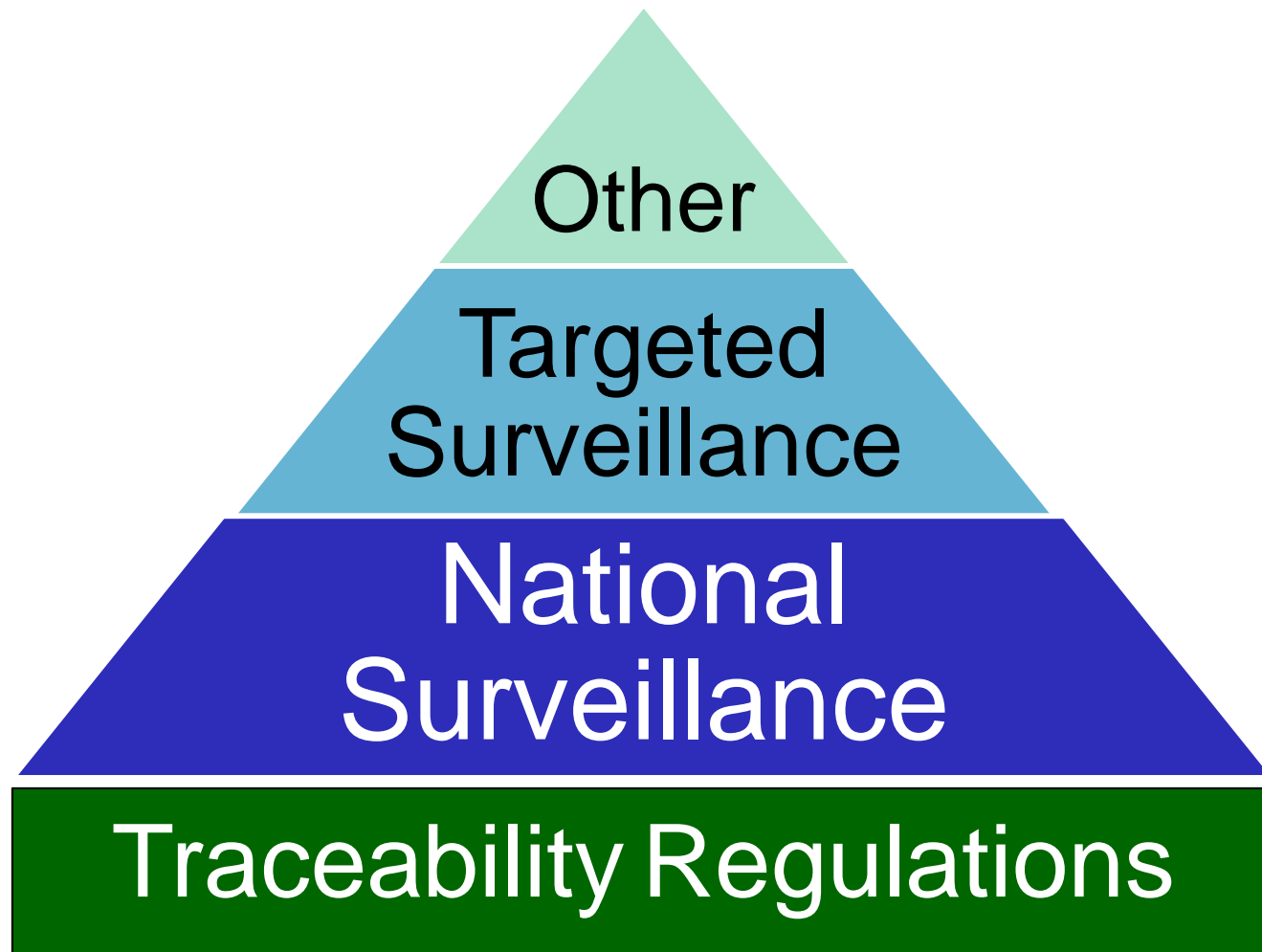
Proposed Rule	Program Standards
Establish notice-based process	<ul style="list-style-type: none"> • Detailed description
Allow for amendments	<ul style="list-style-type: none"> • Situations which initiate amendments • Process to submit amendments
Reporting requirements	
Process to terminate	<ul style="list-style-type: none"> • Situations which may initiate termination
	<ul style="list-style-type: none"> • Situations which may initiate reviews or audits

Recognized Management Areas

Key Differences from Regulatory Framework

Regulatory Framework	Proposed Rule and Program Standards
Zones are not limited by geopolitical boundaries	RMAs defined <u>within</u> a State or Tribe
Zones could be established when disease is discovered in wildlife, but no program animals are at risk	Definition of RMA <u>requires</u> risk of disease transmission to livestock
All zoning efforts should be eradication-based	RMAs <u>mitigate the risk</u> of disease introduction to livestock and disease spread from the area and <u>may</u> include a goal of eradication

Element 3: Surveillance: Concepts



National Surveillance Plans



- Describe objectives
- Define detection levels
- Describe sampling streams
- Identify sampling goals
- State performance standards
- List required activities

Surveillance in Captive Cervids



- No routine slaughter surveillance standards
 - Encourage collection and submission
 - May consider pilot projects

- Surveillance will consist of testing for interstate movement

Targeted Surveillance

- Required in:
 - Source populations
 - At-risk populations
 - Recognized Management Areas (and “buffer” zones)
 - Provisionally consistent State or Tribe
- Details included in Animal Health Plans
- Failure to conduct may result in status redesignation

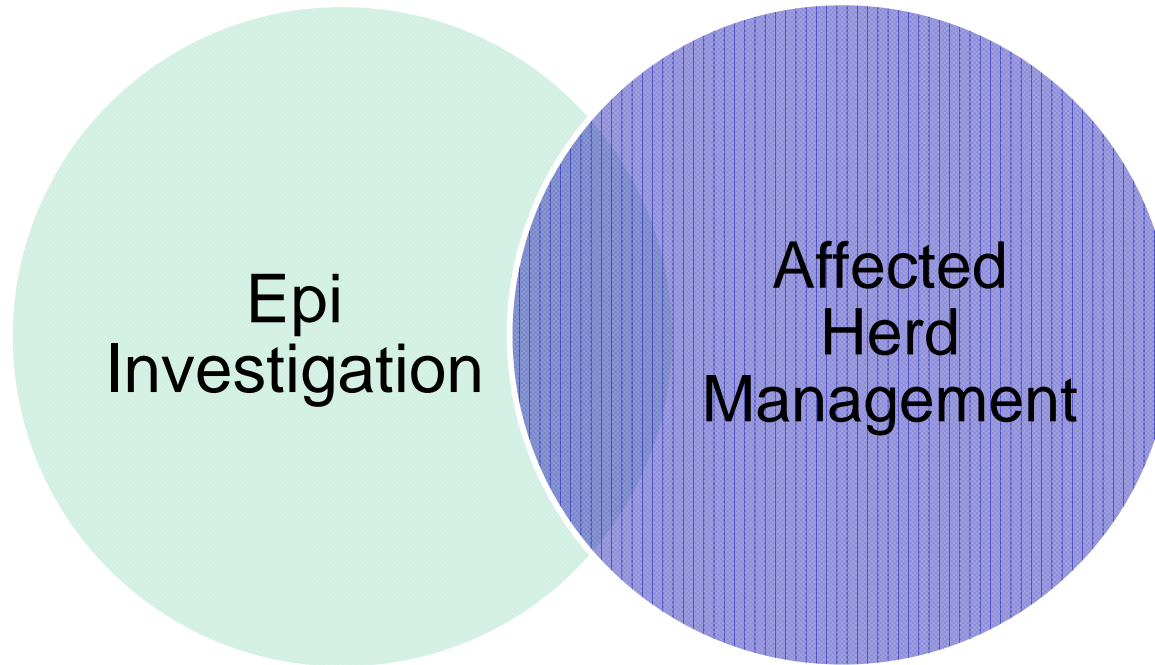


Surveillance

Proposed Rule	Program Standards
Requires participation in National Surveillance Plans (or approved alternate plan)	<ul style="list-style-type: none"> • Defers to surveillance plans for details • Detailed requirements, evaluation criteria, submission, approval, and reporting processes for alternative plans
Requires targeted surveillance	<ul style="list-style-type: none"> • Recommended approaches for targeted surveillance
Identifies consequences for failure to conduct surveillance	

Element 4: Epidemiological Investigations and Affected Herd Management: Concepts

- Describes investigation requirements
- Timeframes for conducting
- Reporting requirements



- Defines affected herd
- Standards for herd management
- Requires movement restrictions

- Consequences if standards are not met
- Provides conditions for approved variances from program requirements

Epidemiological Investigations

Proposed Rule	Program Standards
<p>Requires investigation (including herd testing) to be initiated and movement restrictions in place within 15 days of notification</p>	<ul style="list-style-type: none"> • Describes epidemiological investigation testing, including: <ul style="list-style-type: none"> ○ Test-eligible program animals ○ Situations when animals should be removed for diagnostic purposes • Recommendations for other testing as part of an epidemiological investigation <ul style="list-style-type: none"> ○ Wildlife ○ Other non-program animals
<p>Reporting requirements</p>	<ul style="list-style-type: none"> • Timelines for submission • Report templates
<p>Consequences for failure to investigate</p>	

Affected Herd Management

Proposed Rule	Program Standards
<p>Defines when herds are to be classified as affected</p>	
<p>Establishes that affected herds may be managed through depopulation or a test-and-remove protocol</p>	<ul style="list-style-type: none"> • Describes criteria to: <ul style="list-style-type: none"> ○ See if Federal funds will support depopulation or test-and-remove ○ Develop testing protocols (including assurance testing) ○ Include in herd management plans ○ Release of quarantine
<p>Requires movement restrictions</p>	<ul style="list-style-type: none"> • Identifies permissible animal movements from affected herds
<p>Consequences for failure to manage affected herds</p>	

Element 5: Indemnity

No longer included in this rulemaking!

- **Indemnity component will be a separate comprehensive regulation**
- **Rule will cover indemnity for multiple disease programs in swine, cattle, cervids, and animals depopulated due to a declared emergency of a foreign animal disease**

Element 6: Interstate Movement Controls: Concepts

- Sets movement controls for animals that pose a risk of disease spread
- Defines the types and classifications of animals and herds subject to movement controls (example: rodeo and event cattle)



Interstate Movement of Reactor, Suspect, and Exposed Program Animals

Requirements:

- Official identification
- Accompanied by a permit
- Restricted purposes and destinations for movement
- Shipment is sealed or authorized individual accompanies
- Destination and cleaning & disinfection verified

Interstate Movement of Rodeo, Event, and Exhibited Cattle and Bison

Requirements:

- Official identification
- Accompanied by an ICVI
- Individual test no more than 60 days before initial movement

AND

- Individual test no more than 180 days before any subsequent interstate movement



Interstate Movement of Captive Cervids

Requirements:

- Official identification
- Accompanied by an ICVI
- Originate from an accredited herd

OR

- Herd test completed 120 days to 1 year before movement

AND

- Individual test no more than 60 days before movement



State Status and Interstate Movement of Cattle and Bison

State Status	Requirements and Restrictions
Consistent	<ul style="list-style-type: none"> • Rodeo, event, and exhibited cattle as described • Recognized management area described in Animal Health Plan • Otherwise no restrictions
Provisionally Consistent	<ul style="list-style-type: none"> • Same as for Consistent <u>unless</u> Federal Register specifies restrictions
Inconsistent	<ul style="list-style-type: none"> • Immediate slaughter with official ID and ICVI • Otherwise: <ul style="list-style-type: none"> ○ Official ID and ICVI ○ Brucellosis and/or TB testing – herd <u>and</u> individual tests

Interstate Movement Controls

Proposed Rule

Program Standards

Restricts interstate movement of reactor, suspect, and exposed program animals

- Describes criteria for APHIS approval of quarantined feedlots and pens

Establishes interstate movement requirements for cattle and bison according to State status

- Rodeo and event cattle
- Recognized Management Areas

- Establishes criteria for accredited herds

Establishes interstate movement requirements for captive cervids

- Establishes criteria for accredited herds



Element 7: Import Requirements



Criteria to Evaluate Region for TB or Brucellosis

- **Region has:**
 - **Policy that TB and brucellosis are notifiable diseases**
 - **Documented prevalence**
 - **Veterinary infrastructure able to manage disease**

Criteria to Evaluate Region for TB or Brucellosis — Continued

Veterinary infrastructure includes:

- **Appropriate epidemiological investigations**
- **Management of affected herds**
- **Regulatory controls on livestock movements**
- **Oversight and quality controls of diagnostic testing**

Criteria to Evaluate Region for TB and Brucellosis — Continued

- **APHIS must approve vaccination scheme**
- **Region must have surveillance equivalent to or exceeding U.S. standards**
- **Prevalence as determined by this surveillance will help determine disease status**

Bovine Tuberculosis — 4 Levels

- Level 1 – herd prevalence less than 0.01% in region (similar to current MAA status)
- Level 2 – herd prevalence equal to or greater than 0.01%, but less than 0.1% (similar to MA status)
- Level 3 – herd prevalence equal to or greater than 0.1%, but less than 0.5% (similar to AP status)
- Level 4 – herd prevalence equal to or greater than 0.5%, or not assessed by APHIS (similar to nonaccredited status)

Brucellosis —2 Levels

- Level 1 – Herd prevalence of less than 0.01%
- Level 2 – Herd prevalence equal to or greater than 0.01%, or unassessed by APHIS

Import Requirements for TB Level 1 and Brucellosis Level 1

- No testing required, only certification that the animal originates from the Level 1 region
 - Steers and spayed heifers may be imported from any brucellosis region without testing
 - Cattle from any TB or brucellosis region may be imported for immediate slaughter without testing

Import Requirements for TB Level 2 and Brucellosis Level 2

- Steers and spayed heifers must have a negative individual TB test within 60 days of export
- Sexually intact cattle must have a negative whole-herd TB test conducted between 1 year and 60 days before entry. Animals are retested at the port of entry and may enter if negative.
- For brucellosis, a negative whole-herd test is required between 1 year and 30 days before entry. Animals over 6 months must be retested at the port of entry.

Import Requirements for TB Level 3

- Steers and spayed heifers must have:
 - Negative whole-herd test between 1 year and 120 days before export
 - Negative individual TB test within 60 days before export
- Sexually intact cattle must have:
 - Negative whole-herd test between 1 year and 120 days before export
 - Negative individual TB test a minimum of 60 days before export
- Animals are retested at the port of entry and may enter if negative

Import Requirements for TB Level 4

- APHIS veterinarian must administer a whole-herd test between 1 year and 120 days before export, and an individual test at least 60 days before export
- Another individual animal test will be performed at the port of entry or during import quarantine
- Importer must enter into Cooperative Trust Fund Agreement with APHIS to cover APHIS costs

Import Requirements

Proposed Rule	Program Standards
<ul style="list-style-type: none"> Heifers must be spayed according to APHIS requirements 	<ul style="list-style-type: none"> Process for spaying a heifer, which can be applied to any entity that meets requirements to send spayed heifers to the United States

Import Requirements

Clarifications and Key Differences from Regulatory Framework

Regulatory Framework	Proposed Rule and Program Standards
Determining risk in the region of origin	Expanded on in proposed rule
Increasing import requirements for exporting entities	Overall measure is prevalence levels coupled with veterinary infrastructure to address those levels
Notification of destination when imported animals moved from first point of concentration	Not in proposed rule

Import Requirements

Clarifications and Key Differences from Regulatory Framework

Regulatory Framework	Proposed Rule and Program Standards
Movement controls for imported animals after first point of concentration	Not in proposed rule
Post-entry restricted movements and long-term follow-up testing	Not in proposed rule

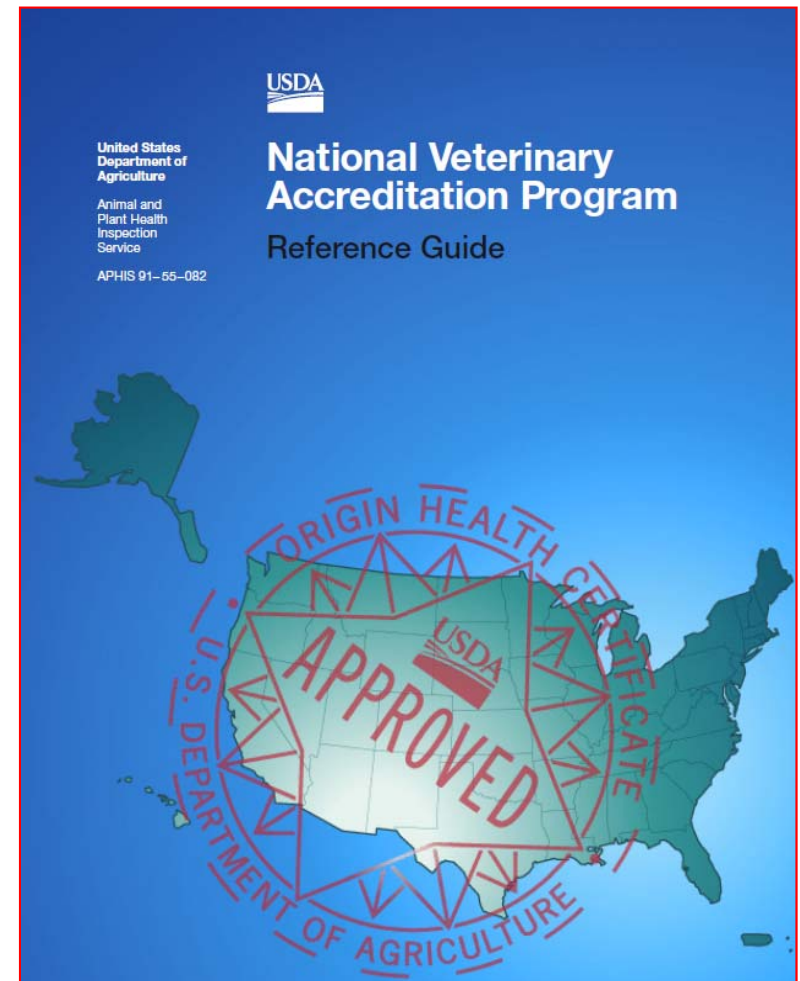
Element 8: Official Tests, Laboratories, and Testers: **Concepts**



- APHIS approves all tests, laboratories, and testers
- Process for requesting, granting, recertifying, and withdrawing approvals

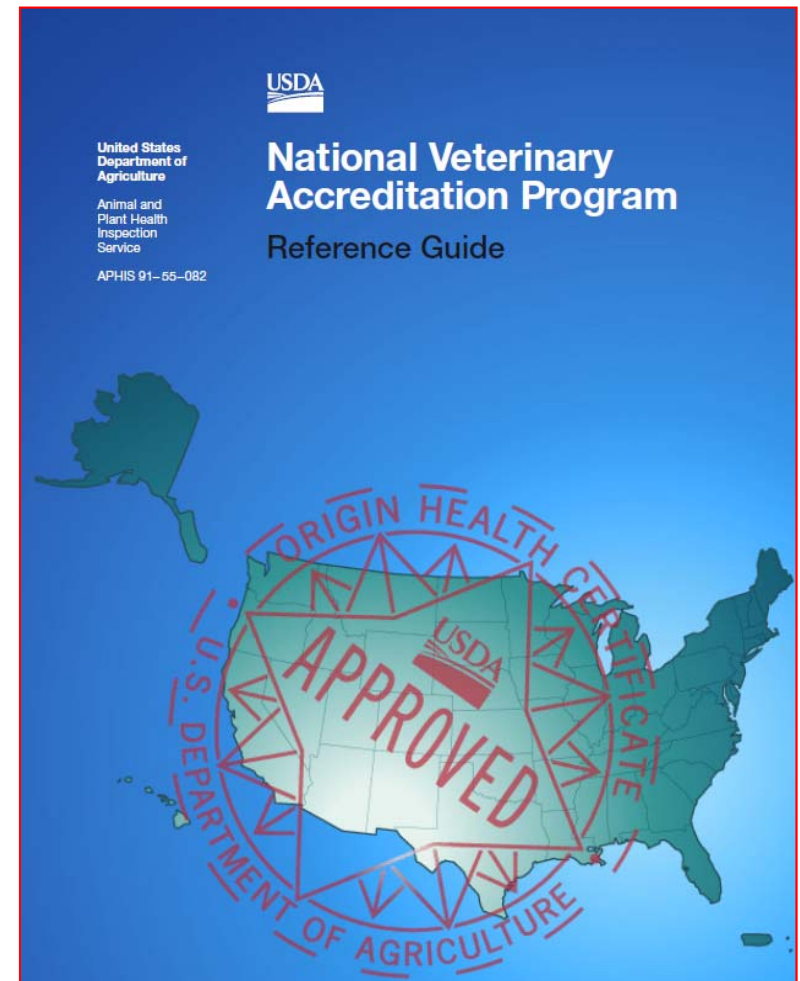
Qualified Accredited Veterinarians (QAV)

- A “program certification” under the National Veterinary Accreditation Program (NVAP)
- Only QAVs conduct official tests for TB



Qualified Accredited Veterinarians (QAV)

- Requirements will include:
 - Complete training modules
 - Demonstrate ability to conduct tests
 - Meet performance standards for the caudal fold tuberculin test
 - Meet reporting standards



Official Tests, Laboratories, and Testers

Proposed Rule

Program Standards

Require approval for program testing

For each approved test:

- Use of test
- Specimen collection instructions
- Testing instructions
- Test interpretation instructions

Establishes processes to grant and withdrawal approval

- QAVs as official testers for TB

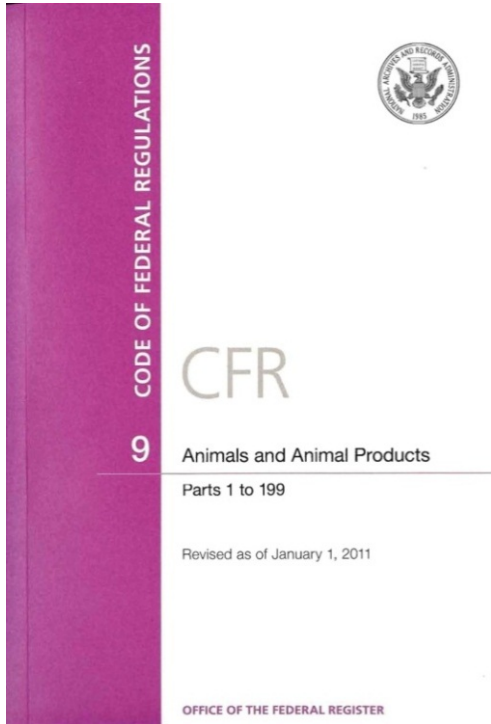
- Detailed descriptions of each process
- Submission requirements for laboratory applications

- QAV standards will be published in separate document

Establishes notice-based process and lists on APHIS Web site



Timeline



May–June 2011: Complete

- Public meetings to obtain stakeholder feedback on regulatory framework

Early 2012: Complete

- Draft proposed rule and Program Standards

Late 2012: Pending

- Publish proposed rule and Program Standards after Departmental/OMB clearance



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We Want your Feedback!!

- Comment period after publication (90 days)
- Submit written comments through www.regulations.gov





Questions?
Use “chat” box
or
“Raise your hand” icon.



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Thank you!

PowerPoint and recording will
be posted online.