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EXECUTIVE SUMMARY

Surveillance is a key activity in the eradication of bovine tuberculosis (TB). The objectives for TB surveillance activities include detection of the disease in program species of animals (cattle, bison, and cervids), estimating the magnitude of Mycobacterium bovis infection (prevalence/incidence), measuring progress toward regulatory goals, providing metrics to help evaluate compliance with program standards, and giving stakeholders and decisionmakers timely and relevant actionable information.

This plan outlines national surveillance activities. These activities will be conducted using Federal and cooperating State resources. States may elect to supplement this national surveillance, or APHIS may require States to do so.

The intent is to implement this national surveillance plan at the beginning of FY 2016 (October 2015). However, certain elements of the plan referred to in this document will not be implemented immediately; they will be phased in pending finalization of the tuberculosis and brucellosis rule or official program approval of new diagnostic tests. These include:

- Requirements for Qualified Accredited Veterinarians (QAVs) – until full implementation, caudal fold test (CFT) performance standards will be in effect as per the 2005 Bovine Tuberculosis Eradication Uniform Methods and Rules (UM&R), Appendix C.
- Federal testing requirements as specified in 9 CFR 76 will be in effect upon finalization of the rule. Until then, current Federal testing requirements in 9 CFR 77 will remain in effect.

Slaughter inspection is the foundation of adult cattle and bison national TB surveillance in the United States. All adult cattle and bison slaughtered in the United States for wholesale or retail purposes are individually inspected for evidence of tuberculosis by State meat inspection or Food Safety and Inspection Service (FSIS) personnel. The total number of adult cattle and bison slaughtered under Federal inspection in U.S. establishments should be sufficient to detect a TB prevalence level of 0.0003 percent or higher among the U.S. adult cattle and bison population with 95 percent confidence.

To validate that carcass inspection is sufficient to detect cases of TB at this level, APHIS has established a granuloma submission standard: Each slaughter establishment should submit suspicious granulomatous lesion(s) from at least one animal in every 2,000 adult cattle or bison slaughtered at the facility for laboratory evaluation for TB.

All fed cattle (steers and heifers managed for slaughter and meat production) slaughtered in the United States for wholesale or retail purposes are individually inspected for evidence of tuberculosis by State meat inspection or FSIS personnel as described for adult cattle above. APHIS has not established a national TB granuloma submission performance standard for fed-cattle establishments. However, APHIS strongly encourages submission of any suspicious granulomatous lesion(s) for laboratory evaluation for TB.
APHIS has not established a national TB granuloma submission standard for establishments slaughtering cervids. However, VS encourages submission of granulomas from these establishments. VS may initiate a pilot project to explore the feasibility of this surveillance stream in the future.

In addition to slaughter surveillance, tuberculin skin testing and serologic testing of program animals, if officially approved for program use in the future, also contribute to national TB surveillance. Live animal testing is the primary means of surveillance for TB in captive cervids as there are no granuloma submission standards for establishments that slaughter cervids. Federal testing requirements include testing for interstate movement (9 CFR 77), testing for export from the United States (CFR 91.5), and testing for herd accreditation (UM&R). Testing program species for these purposes contributes to national TB surveillance and enhances the detection of bovine tuberculosis. In addition to the Federal testing requirements, State or Tribes may impose additional TB testing requirements. This testing may include, but is not limited to, testing for entry of program animals into the State or Tribe, testing of program animals for movements within the State or Tribe, and milk ordinance testing for dairy cattle.

In addition to national surveillance activities, targeted or risk-based surveillance will be required by 9 CFR 77.7, 77.9, 77.11, and 77.13 and the UM&R. Targeted surveillance may incorporate slaughter surveillance streams and/or live animal testing that exceeds the national surveillance described in this plan. Targeted surveillance will be required when a known source of TB in livestock or wildlife poses a risk of transmission to program animals, a State/zone status less than accredited free has been established, or an epidemiologic investigation is being conducted. These targeted surveillance efforts are critical to overall tuberculosis national surveillance. Inadequate approaches to targeted surveillance requirements over time could potentially weaken overall surveillance and require adjustments to the national standards and assumptions described in this plan.
### Summary of Performance Metrics (Standards) for the Tuberculosis National Surveillance Plan

**Performance Metrics (Performance Standards) - Adult cattle and bison slaughter surveillance stream:**

- The total number of adult cattle and bison slaughtered under inspection in U.S. establishments should be sufficient to detect a 0.0003 percent or higher prevalence level among the U.S. cattle and bison population with 95 percent confidence.

- Each cattle and bison slaughter establishment must submit suspicious granulomatous lesion(s) from at least one animal in every 2,000 adult cattle or bison slaughtered at the facility.

**Performance Standard - Adult cattle and bison live animal testing surveillance stream:**

- Each State must implement a system to monitor the response rate reported by each accredited veterinarian authorized to conduct official tuberculin tests. A response rate of less than one responder for each progressive specified range of CFT tests conducted as outlined in the 2005 UM&R, after 300 animals have been tested, must be addressed and appropriate action taken and documented.
INTRODUCTORY INFORMATION

1. Disease Description

Tuberculosis (TB) is an infectious, granulomatous, zoonotic disease caused by the acid-fast bacilli bacteria from the genus *Mycobacterium*. TB occurs worldwide and affects all species of warm-blooded vertebrates; clinical signs and lesions are typically similar in the various species.

Tuberculosis is caused by bacteria that are part of the *Mycobacterium* group: *M. bovis*, *M. avium*, and *M. tuberculosis*. The three bacterial types differ in cultural characteristics and pathogenicity. All three types can also produce infection in multiple species. *M. bovis* can survive for several months in the environment, particularly in cold, dark, and moist conditions.

Though distributed worldwide, the disease in cattle has been successfully controlled in many developed countries. It is difficult to eradicate, however, and efforts to eliminate the disease are costly. In the United States, the herd prevalence of bovine TB has dropped from 5 percent to less than 0.001 percent since eradication efforts began in 1917. Although bovine TB has not been detected for many years in the majority of U.S. States, TB affected herds continue to be detected periodically.

TB is usually a subclinical disease. Infections can remain dormant for years and reactivate during periods of stress or in advanced age. In cattle, clinical signs, when present, usually take months to develop. Clinical signs of TB reflect the extent and location of the lesions. Generalized signs include progressive emaciation, lethargy, weakness, anorexia, and fever. Superficial lymph node enlargement may be a useful diagnostic sign when present. The severity of the disease varies with the dose of infectious organisms and individual immunity. Mortality from TB is rare.

Inhalation of infected droplets expelled from the lungs of infected cattle is the most common route of infection. Infection can also be transmitted via direct contact or ingestion of contaminated milk or feed. The main reservoirs of infection are humans and cattle. However, other animals have been found to be reservoirs in some countries, including badgers and red deer (England, Ireland); opossums and ferrets (New Zealand); mule deer, white-tailed deer, and bison (North America); buffalo (South Africa); and water buffalo (Australia). The prevalence of infection in such reservoirs influences the incidence of infection in other species.

Diagnosis of TB may be made via slaughter inspection of cattle and bison or diagnostic necropsy. Granulomatous lesions are submitted to the National Veterinary Services Laboratory (NVSL). Histopathology is useful in identifying the presence of consistent pathologic tissue changes and acid-fast bacteria (TB compatible). Polymerase chain reaction (PCR) can demonstrate the presence of *Mycobacterium tuberculosis*-complex genetic material. Isolation of the organism from bacterial culture remains the gold standard for identification of *M. bovis*. Genotyping using whole genome sequencing is
a high resolution method for determining the relatedness of isolates, understanding TB transmission and prioritizing investigations.

The caudal fold tuberculin (CFT) test in cattle and bison and single cervical tuberculin test (SCT) or DPP serological test in cervids are the primary official screening tests currently used in live animal TB surveillance. The intradermal tuberculin skin tests use a purified protein derivative (PPD) to elicit a cell-mediated immunity response. Generally, the CFT, the SCT or the DPP are used to test an entire herd or group of animals. Responders (any animal that has a visible or palpable reaction to the skin test) or serologic positive animals are usually classified as TB suspects. TB suspects are retested using the comparative cervical test (CCT) or the interferon gamma test (interferon \( \gamma \)) in cattle; the CCT or DPP is used as a secondary test in cervids.

The CCT is used to evaluate whether a CFT responder is predominantly sensitized to \( M. \ bovis \) or \( M. \ avium \) antigens. Cattle sensitized to \( M. \ avium \) only are not likely to be infected with \( M. \ bovis \), and usually are not euthanized for diagnostic necropsy or culled to slaughter for further diagnostic evaluation. This method, therefore, results in removing fewer uninfected cattle. This is an example of using tests in series. This method is used when cattle are judged to be of low risk for TB infection, and the highest possible test specificity is desired.

The interferon \( \gamma \) test is a method of identifying cell-mediated sensitization in vitro by measuring the response of lymphocytes to \( M. \ bovis \) antigens. The interferon \( \gamma \) test can replace the CCT and be used to test cattle in series. It can also be used alongside the CFT for whole-herd testing in known TB-affected herds or other high-risk herds, where any cattle responding to either test are removed. This is an example of using tests in parallel. This method is used when cattle are judged to be of high risk of TB infection, and the highest possible test sensitivity is desired.

The cervical tuberculin test (CT) is sometimes used to test cattle exposed to tuberculosis. It is sometimes referred to as “double strength” tuberculin. It provides an increase in sensitivity for testing of high-risk animals.

Herds confirmed as infected with TB (affected herds) are either depopulated or managed with a test-and-removal (TRP) protocol. Details on managing TB affected herds can be found in the 2005 Bovine Tuberculosis Eradication Uniform Methods and Rules and VS Memorandum 552.47.

2. Purpose and Rationale for Surveillance

Tuberculosis has an important worldwide impact on animal industries and human health. Control measures are based on prevention and eradication. Surveillance is a key element for prevention and control programs.
Surveillance for TB serves as an important case-finding tool, critical to the initiation of investigations, particularly given the currently low prevalence of TB in U.S. livestock populations.

3. Surveillance Objectives

Surveillance is a key activity in the eradication of bovine TB. The objectives for TB surveillance activities include:

- Detection of bovine tuberculosis in program species of animals (i.e., case-finding),
- Estimating the magnitude of *Mycobacterium bovis* infection (prevalence/incidence),
- Measuring progress toward regulatory goals,
- Providing metrics to aid in evaluation of compliance with program standards, and
- Giving stakeholders and decisionmakers timely and relevant actionable information.

This plan outlines national surveillance activities. These activities will be conducted using Federal and cooperating State resources. States may elect to supplement this national surveillance, or APHIS may require States to do so.

In addition to national surveillance activities, targeted or risk-based surveillance are required by 9 CFR 77. Additional details are described in the 1999 and 2005 UM&R. Targeted surveillance may incorporate slaughter surveillance streams and/or live animal testing that go beyond the national surveillance focused on in this plan. Targeted surveillance will be required when:

- A known source of TB in livestock or wildlife poses a risk of transmission to program animals.
- An epidemiologic investigation is being conducted.
- A State or part of a State has been downgraded to modified accredited advanced or lower status for TB, and APHIS specifies additional surveillance for the State to regain accredited free status.

These targeted surveillance efforts are critical to overall national tuberculosis surveillance. Inadequate approaches to targeted surveillance over time could potentially weaken overall surveillance and require adjustments to national standards and assumptions described in this plan.

4. Expected Outcomes

National tuberculosis surveillance will be used to monitor the incidence of TB in the United States. Given the low prevalence of TB here, surveillance is a valuable case-finding tool.

Surveillance results will also be used for decisionmaking and policy development regarding design and implementation of future TB surveillance programs and control efforts.
The results of the surveillance program will be an important component of documenting the TB status of U.S. cattle. The USDA has designed this national surveillance plan to meet or exceed the internationally accepted surveillance practices recommended by the OIE. Compliance with OIE guidelines is an important component of assuring trading partners of the quality of our surveillance efforts. USDA expects that this robust surveillance program will continue to provide the foundation for market confidence in the health of U.S. cattle.

5. Stakeholders and Responsible Parties

Benefits and costs of tuberculosis eradication accrue to its stakeholders. Stakeholders include:

- All sectors of the cattle, bison, and captive cervid industries including producers and producer organizations, market operators and marketing organizations, and processors and processor organizations
- Animal health officials and organizations including the United States Animal Health Association (USAHA)
- State government entities including Departments of Agriculture (or equivalent), Departments of Natural Resources (or equivalent), and Divisions of Wildlife
- Veterinary diagnostic laboratories (State, Federal, or privately funded) responsible for testing samples and reporting results
- Federal government, primarily United States Department of Agriculture (USDA) Animal and Plant Health Inspection Service (APHIS), FSIS, and the Food and Drug Administration (FDA) via the Pasteurized Milk Ordinance (PMO)
- Taxpayers who ultimately fund tuberculosis surveillance and benefit from disease freedom
- International trading partners

Responsible parties include all stakeholders, specifically:

- Producers who support and participate in surveillance despite the absence of overt evidence of disease
- Accredited veterinarians who conduct TB testing
- Slaughter plant workers who collect surveillance samples
- Federal and State animal health officials who collect surveillance samples
- Veterinary diagnostic laboratory personnel who test samples
- Federal and State program officials who manage tuberculosis surveillance
- Federal and State governments that approve funding for tuberculosis surveillance
- Taxpayers who provide funding for surveillance activities

POPULATION DESCRIPTION AND SAMPLING METHODS

6. Population Description and Characteristics

Adult Cattle Population
There are approximately 39 million adult cattle in the United States. This includes approximately 30 million adult beef cattle and approximately 9 million adult dairy cattle (NASS 2012). Annually, there are between 5-6 million adult cattle slaughtered under Federal and State slaughter inspection. All adult cattle and bison slaughtered in the United States for wholesale or retail purposes are individually inspected for evidence of tuberculosis by State meat inspection or FSIS personnel. The “Top 40” federally inspected adult cattle and bison slaughter establishments, by volume, slaughter more than 95 percent of cattle and bison annually, and represent animals from all regions of the country.

**Fed-Cattle Population**

Approximately 27 million cattle on feed are slaughtered annually. Each animal is individually inspected for evidence of tuberculosis by State meat inspection or FSIS personnel.

**Captive Cervid Population**

According to the latest NASS data from 2007, there are an estimated 5,600 captive deer farms in the United States with an estimated 270,000 deer. There are approximately 1,900 captive elk farms with an estimate 68,000 elk in the United States. Currently there are interstate movement testing requirements for captive cervids not destined for immediate slaughter.

### Case Definition

**Clinical Case Definition**

Animals infected with *M. bovis* are difficult to diagnose on clinical signs alone, even in advanced cases. Clinical signs may mirror the extent and location of lesions in the animal, plus any underlying toxemia, and may include progressive emaciation; lethargy; weakness; anorexia; and a low-grade, fluctuating fever. A respiratory form may be manifested as a bronchopneumonia with a chronic intermittent, moist cough with dyspnea and tachypnea. Also, superficial lymph node enlargement may be present.

An animal may be suspected for *M. bovis* based on

- positive response to an official tuberculin screening test (suspect or reactor)
- positive response to an official tuberculin secondary test (suspect or reactor)
- identification of granulomatous lesions at slaughter inspection or necropsy

**Case Classifications**

**Exposed**

Any livestock that have been exposed to bovine tuberculosis by reason of associating with other livestock in which *M. bovis* has been diagnosed.
**Suspect**

Any animal (bovine, bison, or cervid) that shows a response to an official tuberculosis screening test (CFT in cattle or SCT/DPP in cervids) and is not classified a reactor, or is classified suspect by an official tuberculosis secondary test (CCT or γ interferon in cattle).

**Reactor**

Any animal (bovine, bison, goat, or cervid) classified as a reactor by a State or Federal regulatory veterinarian or regional epidemiology officer (REO) following a positive official tuberculosis screening or secondary test.

**NGL: No Gross Lesion (NGL)**

Any animal that has no visible lesion(s) of bovine tuberculosis detected upon necropsy or slaughter inspection. An animal with a skin lesion(s) alone will be considered in the same category as an NGL animal.

**Laboratory Criteria for Diagnosis**

A combination of histopathology, mycobacterial culture, and/or polymerase chain reaction (PCR) testing is used to further evaluate tissues collected during necropsy or at the time of slaughter for the presence of *M. bovis*. These are used as the final stage of testing for bovine tuberculosis and permit the final classification of suspect, reactor, and exposed animals as infected or negative.

- **Histopathology** is a rapid method of identifying structural changes in tissues associated with mycobacterial infections.
- **PCR** testing is used to determine the presence of genetic material from the *Mycobacterium tuberculosis* complex (which includes *M. bovis*, *M. tuberculosis*, and several other species), *M. avium* and *M. a. paratuberculosis* in tissue.
- **Mycobacteriologic culture** isolates mycobacteria from the tissue and permits the definitive identification of *M. bovis*.

**TB Presumptive Positive Case**

- **Mycobacteriosis compatible on histopathology.** This diagnosis means that the lesion is consistent with tuberculosis and the granuloma contains acid-fast bacteria. Because the species of acid-fast bacteria causing this lesion cannot be determined using histopathology alone, a diagnosis of mycobacteriosis compatible is not a diagnosis of infection with *M. bovis*.
- **Positive PCR.** Indicates that the DNA for the mycobacterial species was present. A positive result for the IS6110 primer is presumably positive for *M. bovis*. It does not necessarily mean the animal was infectious or shedding.

**TB Confirmed Positive Case**
Animals that have acid fast bacteria recovered on culture that are speciated as *Mycobacterium bovis* are considered to be TB-infected.

Animals that have mycobacteriosis compatible lesions or are epidemiologically linked to *M. bovis* cases and are also PCR positive for *Mycobacterium tuberculosis* complex will be considered to be TB infected.

Bovine TB is a reportable disease. State animal health officials and the APHIS-VS Assistant District Director (ADD) should be notified and consulted.

8. Data Sources

Slaughter Data

Adult cattle, bison, and fed-cattle slaughter and granuloma submission data come from a variety of sources and are compiled by Cattle Health Center and NSU staff. FSIS provides slaughter volume data by plant from its Public Health Information System (PHIS) database. Granuloma submission data are provided by the National Veterinary Service Laboratories (NVSL), the California Animal Health and Food Safety Laboratory System (CAHFS), and the FSIS pathology laboratory. These data are collated in Excel spreadsheets and used to evaluate whether slaughter plants meet granuloma submission performance metrics (performance standards).

Live Animal Testing Data

In addition to slaughter surveillance, routine tuberculin skin testing of cattle, bison, and cervids as required by national or State regulations (and serologic testing if officially approved for program use in the future) also contributes to national TB surveillance. Live animal testing is the primary means of surveillance for TB in captive cervids; there are no standards for granuloma submissions from establishments that slaughter cervids. Skin testing data are entered into State databases. VS has transitioned from State generic databases (GDBs) to Surveillance Collaboration Services (SCS) State databases. Data from test charts are entered into State databases either manually or via mobile information management (MIM) hand-held devices. Data from live animal testing by accredited veterinarians contribute to national TB surveillance and increase the level of detection over slaughter surveillance alone.

9. Sampling Methods

Adult Cattle and Bison Slaughter Surveillance Stream

Slaughter inspection is the foundation of adult cattle and bison national TB surveillance in the United States. All adult cattle and bison slaughtered for wholesale or retail purposes are individually inspected for evidence of tuberculosis by State meat inspection or FSIS personnel. The normal (routine) slaughter postmortem inspection procedure consists of visual observation, palpation, and the incision of lymph
nodes of each slaughtered animal to detect granulomatous lesions that may be caused by TB (FSIS Directive 6100.2). Additional postmortem procedures are performed on specific classes of high-risk animals. Expanded postmortem inspection procedures are performed as outlined in Guideline #4 for TB reactors. Modified expanded procedures are performed on TB Suspect or TB Exposed animals (FSIS Directive 6240.1 Rev 1). VS rewards FSIS’ inspection program personnel (IPP) and public health veterinarians (PHV) for the submission of granulomatous lesions, along with corresponding animal identification (ID) devices, to the National Veterinary Services Laboratories (NVSL) and other approved laboratories, that result in the detection of cases of bovine TB, and the identification of previously unrecognized TB-affected cattle, bovine, or captive cervid herds.

Performance Standard:

- The total number of adult cattle and bison slaughtered under Federal inspection in U.S. establishments should be sufficient to detect a TB prevalence level of 0.0003 percent or higher among the U.S. adult cattle and bison population with 95 percent confidence.

Basis for Establishing a New National TB Slaughter Surveillance Performance Standard for Adult Slaughter Detection Levels

Background
The routine surveillance standard as outlined in the 2005 Bovine Tuberculosis Eradication Uniform Methods and Rules (UM&R) established State requirements for routine surveillance and included both slaughter surveillance and skin testing. The required number of adult cattle and bison inspected at slaughter or tuberculin tested to meet the established detection level of 0.05 percent or higher was calculated based on an assumption that both slaughter inspection and skin testing provided 100 percent sensitivity in detecting disease.

A New National Slaughter Surveillance Performance Standard:
The National TB Surveillance Plan outlines changes to national surveillance requirements. These include:

- Assessment of slaughter surveillance will be at the national level, with a new performance standard that will have a national scope.
- The performance standard for national surveillance applies to slaughter surveillance only, and will no longer consider tuberculin testing.
- The new performance standard for the level of detection will take into account that slaughter sensitivity (SSE) is less than 100 percent in determining the number of samples required to meet slaughter surveillance goals.

Methods
Slaughter SSE for bovine TB is less than 100 percent. A 2003 study estimated SSE at 28.5 percent. In 2009, the National Surveillance Unit (NSU) completed an “Analysis of Bovine Tuberculosis Surveillance in Accredited Free States.” In that analysis, animal-level SSE was calculated for various beef and dairy cattle herd sizes (Table 1). In addition to the factors assessed in the 2003 study, the 2009 NSU analysis included other factors such as within-herd prevalence, probability of an infected animal being culled to slaughter, the probability that an inspector would submit a lesion to a testing laboratory, and probability that an animal was slaughtered under validated inspection. Each of these factors increases the precision of SSE estimates. SSEs vary by herd size and production types. In general, SSE tends to increase as herd size increases due to more animals going to slaughter. Dairy herds have higher SSEs largely because they have higher rates of culling to slaughter than do beef herds.

Table 1 – Animal-Level Slaughter Sensitivity (SSE) by herd size

<table>
<thead>
<tr>
<th>Dairy Herd Size</th>
<th># adult dairy</th>
<th>% of adult dairy</th>
<th>SSE (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1-49</td>
<td>974,727</td>
<td>10.7</td>
<td>7.4</td>
</tr>
<tr>
<td>50-99</td>
<td>1,903,907</td>
<td>20.9</td>
<td>7.8</td>
</tr>
<tr>
<td>100-499</td>
<td>3,079,044</td>
<td>33.8</td>
<td>19.1</td>
</tr>
<tr>
<td>≥500</td>
<td>3,151,922</td>
<td>34.6</td>
<td>65.3</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Beef Herd Size</th>
<th># adult beef</th>
<th>% of adult beef</th>
<th>SSE (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1-49</td>
<td>9,565,813</td>
<td>28.9</td>
<td>5.3</td>
</tr>
<tr>
<td>50-99</td>
<td>6,322,043</td>
<td>19.1</td>
<td>13.4</td>
</tr>
<tr>
<td>100-499</td>
<td>12,279,989</td>
<td>37.1</td>
<td>11.6</td>
</tr>
<tr>
<td>≥500</td>
<td>4,931,855</td>
<td>14.9</td>
<td>13.0</td>
</tr>
</tbody>
</table>

From “Analysis of Bovine Tuberculosis Surveillance in Accredited Free States,” 2009

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1 The probability of detecting an animal infected with TB at slaughter (slaughter sensitivity) is the probability of an infected animal having a visible lesion times the probability of the lesion being detected by slaughter inspectors times the probability of the lesion being submitted to the laboratory times the probability of the laboratory tests the sample and finds it to be positive. For slaughter surveillance, the combined slaughter sensitivity is 0.285 (28.5%). (Chioino 2003).
**Overall estimate of animal-level slaughter sensitivity (SSE)**

From the information in Table 1 above, a single overall estimate of animal-level slaughter SSE was developed. Overall SSE was calculated from a weighted average of SSEs for all dairy and beef herd size groups. The calculated result was an overall animal-level slaughter sensitivity of 20.9 percent.

In addition, the simulation model used to estimate SSE by various beef and dairy herd sizes (Table 1) was used to estimate overall animal-level SSE. The result was a SSE estimate of 21.5 percent. Therefore, a 20.9 percent animal-level SSE is a reasonable and conservative estimate.

There are approximately 39 million adult cattle in the United States (~30 million beef, ~9 million dairy), and between 5 and 6 million adult cattle and bison slaughtered annually under validated inspection (validated slaughter inspection is performed at establishments that meet the granuloma submission performance standard of one granuloma submission for each 2,000 adult cattle/bison slaughtered).

Using estimates of the overall SSE and total adult cattle population, the slaughter detection level with 95 percent confidence can be determined, given that the number sampled (number of adult cattle and bison slaughtered under validated inspection) is between 5 and 6 million adult cattle and bison annually.

<table>
<thead>
<tr>
<th>Number of Validated Slaughter Samples Required</th>
<th>Resulting Detection Level with 95% confidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>3,551,651</td>
<td>0.0004%</td>
</tr>
<tr>
<td>4,721,530</td>
<td>0.0003%</td>
</tr>
<tr>
<td>7,040,532</td>
<td>0.0002%</td>
</tr>
</tbody>
</table>

Table 2 shows the number of validated slaughter samples required to reach three different detection levels with 95 percent confidence, assuming a SSE of 20.9 percent.

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2 U.S. adult beef and dairy cows: ~39,000,000 (~30,000,000 beef; ~9,000,000 dairy); January 1, 2012 inventory: Beef cows—29,882,900 head Milk cows—9,229,500 head NASS Cattle report, January 27, 2012.

3 In FY 2007 6,194,594 adult cattle slaughtered; Validated slaughter = 5,892,252 (95.12%) e.g., had adequate granuloma submissions to meet 1 per 2,000 standard
Conclusion
The total number of adult cattle and bison slaughtered under inspection in U.S. establishments should be sufficient to detect a 0.0003 percent or higher animal-prevalence level among the U.S. adult cattle and bison population with 95 percent confidence. This compares to the current OIE guideline of having the ability to detect TB animal-level prevalence at 0.1 percent⁴.

Validation of Adult Cattle and Bison Slaughter Inspection

To validate that carcass inspection is sufficient to detect cases of TB at this level, APHIS-VS has established a granuloma submission standard:

**Performance Standard:**
- Each slaughter establishment should submit suspicious granulomatous lesion(s) from at least one animal in every 2,000 adult cattle or bison slaughtered at the facility for laboratory evaluation for TB.
- See Appendix 1 for background on the derivation of the granuloma submission standard.

Failure of one or more establishments within a State or zone to meet this granuloma submission rate may compromise the effectiveness of national tuberculosis surveillance.

Fed-Cattle Slaughter Surveillance Stream

All fed cattle slaughtered in the United States for wholesale or retail purposes are individually inspected for evidence of tuberculosis by State meat inspection or FSIS personnel as described for adult cattle above.

Validation of Fed-Cattle Slaughter Inspection

APHIS-VS has not established a national TB granuloma submission performance standard for fed-cattle establishments.

APHIS-VS conducted a pilot study in 2011 to evaluate the effectiveness and feasibility of establishing a national performance standard for TB granuloma submissions in fed-cattle slaughter plants. The results of this project did not support establishing a national performance standard for granuloma submissions in this class of cattle. However, APHIS-VS strongly encourages submission of any suspicious granulomatous lesion(s) for laboratory evaluation for TB. We recommend a voluntary submission rate of one or more lesions for every 20,000 fed cattle slaughtered per slaughter establishment.

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APHIS-VS and States/Tribes may collaborate in the evaluation of data and identification of specific establishments for “targeted slaughter surveillance.” Considerations may include identification of known source populations, types of cattle received, locations where infected animals/herds have been identified, future use of a cattle movement model to identify establishments through a more quantitative approach, or others. Where targeted slaughter surveillance is warranted, APHIS-VS will work with FSIS and State/Tribal officials to develop an appropriate granuloma submission standard and to monitor compliance with the standard.

Captive Cervid Slaughter Surveillance Stream

APHIS-VS has not established a national TB granuloma submission standard for establishments slaughtering cervids. However, VS encourages submission of granulomas from these plants. VS may initiate a pilot project to explore the feasibility of this surveillance stream in the future.

Monitoring Adult Cattle and Bison Slaughter Surveillance

Monitoring National Adult Cattle and Bison Slaughter Surveillance in Federally-Inspected Establishments

APHIS-VS will:

- Monitor TB granuloma submissions for all federally inspected slaughter establishments in the U.S. (Staff from multiple VS units including: Cattle Health Center [CHC], NVSL; Centers for Epidemiology and Animal Health [CEAH]; and VS field offices)
- Collaborate with FSIS to assure that all federally-inspected adult cattle and bison slaughter establishments comply with the granuloma submission standard and ensure appropriate corrective actions are taken in cases when establishments are not in compliance. (Staff from CHC and CEAH)
- Conduct a minimum of one visit per calendar quarter to each federally-inspected adult cattle and bison slaughter establishment. The purpose of the periodic visits is to monitor surveillance activities for tuberculosis and to provide assistance to the attending meat inspection personnel, to recognize any slaughter surveillance awards, and to establish management in resolving any surveillance issues that may arise. (VS field offices)
- Report TB granuloma submission rates quarterly for the 40 largest by volume U.S. adult cattle and bison slaughter establishments to FSIS and the AD and State Veterinarian in each State. (Staff from CHC and CEAH)

Monitoring Adult Cattle and Bison Slaughter Surveillance in State-Inspected Establishments
Each State or Tribe will:

- Monitor TB granuloma submissions for all State-inspected adult cattle and bison slaughter establishments. Ensure that each establishment submits suspicious granulomatous lesions for laboratory examination at a rate of one or more for every 2,000 adult animals slaughtered.
- Collaborate with State meat inspection officials to assure that all State-inspected adult cattle and bison slaughter establishments are aware of and, if applicable, comply with the granuloma submission standard, and ensure appropriate corrective actions are taken in cases when plants are not in compliance.
- Conduct a minimum of one visit per calendar quarter to each State-inspected adult cattle and bison slaughter establishment by State and/or Federal animal health officials. The purpose of the periodic visits is to monitor surveillance activities for tuberculosis and assist the attending meat inspection personnel and establishment management in resolving any surveillance issues that may arise.
- While not required, VS recommends that States conduct similar activities for custom-exempt slaughter establishments.

**Live Animal Testing Surveillance Stream**

In addition to slaughter surveillance, tuberculin skin testing of program animals (and serologic testing if officially approved for program use in the future) also contributes to national TB surveillance. Live animal testing is the primary means of surveillance for TB in captive cervids as there are no standards for granuloma submissions from establishments that slaughter cervids.

The following are reasons for which live animal testing may be performed. Testing program species for these purposes contributes to national TB surveillance and enhances the detection of bovine tuberculosis.

**Testing for Interstate Movement**

9 CFR 77 describes specific TB testing requirements for certain classes of animals that move in interstate commerce. These requirements include:

**Cattle or bison:**
- Interstate movement testing for cattle from States or zones with MAA (except as exempted by the 2010 Federal Order), modified accredited or accreditation preparatory status.

**Captive Cervids:**
- Interstate movement testing for captive cervids not destined for immediate slaughter

**Testing for Export**
In addition to meeting testing requirements for interstate movement, program animals are required to be tested for TB prior to export from the U.S (CFR 91.5). Importing countries may also establish additional TB testing requirements for these animals.

**Testing for Herd Accreditation**

The 2005 UM&R describes testing requirements for bovine herds to become accredited for TB. 9 CFR 77.35 and VS Memo 552.46 describes testing requirements for captive cervid herds to become accredited for TB.

**State or Tribal Testing Requirements**

In addition to the Federal testing requirements for interstate movements, State or Tribes may impose additional TB testing requirements. This testing may include (but is not limited to):

- Testing for entry of program animals into the State or Tribe
- Testing of program animal for movements within the State or Tribe
- Milk ordinance testing for dairy cattle

**Additional Live Animal Testing**

There are several reasons for testing program species beyond baseline national TB surveillance requirements. This testing is critical to overall bovine tuberculosis national eradication efforts. Reasons may include:

- Testing to comply with disease investigation requirements as described in 9 CFR 77
- Testing for targeted ongoing surveillance, including testing of source and at-risk populations of program animals
- Testing to establish or monitor disease in States or zones with modified accredited advanced or lower status.

**Monitoring tuberculin testing**

Tuberculin testing of cattle, bison, and captive cervids, whether required by the regulations or specified by a State or Tribe as a means of targeted surveillance is an important component of TB surveillance. Properly conducting and interpreting the CFT test is essential for disease diagnosis, control, and eradication.

Tuberculin testing should only be conducted by an accredited veterinarian or a State/Federal regulatory veterinarian. Requirements for States, Tribes, and accredited veterinarians (training, monitoring, reporting, enforcement, and meeting the CFT performance standard when conducting tests) can be found in the 2005 TB UM&R and VS Memo 552.29.
**Performance Standard:**

- Each State must implement a system to monitor the response rate reported by each accredited veterinarian authorized to conduct official tuberculin tests. A response rate of less than one responder for each progressive specified range of CFT tests conducted as outlined in Appendix C 2005 TB UM&R and VS Memo 552.29, after 300 animals have been tested, must be addressed and appropriate action taken and documented.

**ANALYSIS, REPORTING, AND PRESENTATION**

10. Data Analysis and Interpretation

Numerous groups within VS conduct data analysis. This includes national CHC staff, VS regional epidemiology officers, and CEAH personnel.

11. Data Presentation and Reports

States are required to submit annual reports for monitoring by national TB staff. Reports include data on how States monitor and document tuberculin testing response rates and address non-compliance for each accredited veterinarian authorized to conduct official tuberculin tests.

Staff from CHC and CEAH will compile cattle slaughter and granuloma submission data from all Federal slaughter establishments. A TB granuloma submission rates quarterly report will be generated for the 40 largest by volume U.S. adult cattle and bison slaughter establishments and distributed to FSIS and the AD and State Veterinarian in each State.

Reports produced by NSU may include an annual summary report. The annual summary report is intended to estimate the detection level of tuberculosis slaughtered under validated slaughter inspection. In addition, live animal testing performed by accredited veterinarians will contribute data to national surveillance and increase the level of detection of the surveillance system. The information provided by the annual report may be further tabulated for public consumption at the request of the Deputy Administrator.

**IMPLEMENTATION, BUDGET, AND EVALUATION**

12. Surveillance System Implementation: Priorities, Timelines, and Internal Communications

APHIS-VS developed a concept paper in 2009 titled “A New Approach for Managing Bovine Tuberculosis” on the future of the tuberculosis program. This followed a series of public meetings to elicit feedback on the direction of the TB program. In 2010 and 2011, VS formed a working group of
internal and external stakeholders to develop a new regulatory framework for the tuberculosis and brucellosis programs. Numerous public meetings were held to communicate the new regulatory framework. In 2012, VS developed a performance standard document to accompany the new regulations. The performance standards document describes State responsibilities, among which are to develop a State animal health plan for tuberculosis and identify sources or at-risk populations in which targeted surveillance may be required.

The intent is to implement as much of this national surveillance plan as possible at the beginning of FY 2016 (October 2015) in parallel with a new bovine brucellosis national surveillance plan. However, certain elements of the plan will not be able to be implemented immediately; they will be phased in pending the finalization of the tuberculosis and brucellosis rule or official approval of tests. These include requirements for QAVs and Federal testing requirements as specified in 9 CFT 76.6. Until full implementation, CFT performance standards will be in effect as per the 2005 Bovine Tuberculosis Eradication Uniform Methods and Rules (UM&R), Appendix C; current Federal testing requirements will remain in effect.

### 13. Resources

The VS tuberculosis program is now funded under cattle and cervid commodity-specific line items rather than a tuberculosis-only line item. This provides flexibility to direct funding to cattle and cervid programs where most needed and should provide the tuberculosis program adequate funds to meet its goals and objectives.

Human resources essential for the success of the tuberculosis program include national commodity centers staff, VS field office staff, VS and State animal health field personnel, and NVSL and CEAH personnel. Additional external resources include the California Animal Health and Food Safety Laboratory System (CAHFS), FSIS slaughter inspection personnel and pathology laboratory, accredited veterinarians that perform the bulk of field skin testing, and State diagnostic laboratories approved to perform the interferon γ test (Texas, Colorado, California, Michigan, Nevada, and Washington).

### 14. Surveillance Plan Performance Metrics

<table>
<thead>
<tr>
<th>Performance Metrics (Performance Standards) - Adult cattle and bison slaughter surveillance stream:</th>
</tr>
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<tbody>
<tr>
<td>• The total number of adult cattle and bison slaughtered under inspection in U.S. establishments should be sufficient to detect a 0.0003 percent or higher prevalence level among the U.S. cattle and bison population with 95 percent confidence.</td>
</tr>
<tr>
<td>• Each cattle and bison slaughter establishment must submit suspicious granulomatous lesion(s) from at least one animal in every 2,000 adult cattle or bison slaughtered at the facility.</td>
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<table>
<thead>
<tr>
<th>Performance Standard - Adult cattle and bison live animal testing surveillance stream:</th>
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<td></td>
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</table>
• Each State must implement a system to monitor the response rate reported by each QAV authorized to conduct official tuberculin tests. A response rate of less than one responder for each progressive specified range of CFT tests conducted as outlined Appendix C, 200 TB UM&R and VS Memo 552.29, after 300 animals have been tested, must be addressed and appropriate action taken and documented.

15. Surveillance System Evaluation

The tuberculosis surveillance system should be evaluated regularly to determine how well the system fulfills its stated objectives and meets accepted standards. The evaluation process identifies system strengths and areas for improvement. The document titled “Surveillance and Data Standards for Veterinary Services, Version 1.0, July 2006” is the guidance document for surveillance system evaluation. It is recommended that this surveillance plan be evaluated within 2 to 3 years of its implementation, and then periodically thereafter.
APPENDIX 1

Background on the Granuloma Submission Standard

The adult cattle and bison granuloma standard of submission of one TB-like granuloma per every 2,000 carcasses processed was officially established in 2005. This standard will be continued; however, VS continues to assess the appropriateness of the standard and may make changes to it if necessary. The following information is provided as background on the analysis used to support the development and implementation of the standard in 2005.

In slaughter surveillance, every carcass is inspected for TB. If we know the number of cattle slaughtered annually, then the threshold of infection we can detect via slaughter surveillance can be determined. Yet, inspection must be thorough to detect TB in carcasses. There is much pathology that grossly resembles TB lesions. If carcass inspection is valid, then granulomas must be submitted with sufficient frequency to conclude that monitoring activities are valid.

Slaughter inspection for TB should have some fraction of false positive carcasses. These are carcasses with lesions that resemble TB but are distinguished by histopathology or culture (or PCR assay) as not being caused by TB. Among the population of cattle carcasses processed in the United States with any type of gross lesion, there is a subpopulation of carcasses with lesions that can be loosely called granulomatous. For example, there is some percent of actinomycosis, actinobacillosis, coccidiomycosis, and malignant lymphoma lesions that grossly resemble TB.

During 2003, there were 5,078 submissions from slaughter establishments to the NVSL and CAHFS for suspicion of TB (Figure 1). The largest percent of these lesions were classified as Acti – meaning either actinobacillosis or actinomycosis. Acti is a condition that FSIS specifically tracks in its Animal Disease Reporting System database. Other histopathology categories, such as pyogranuloma, are not specifically identified in this FSIS database. Instead, these other conditions may fall within FSIS categories including pneumonia, abscess pyemia, or miscellaneous inflammation.
FIGURE 1. The frequency of various histopathologic classifications of TB submissions in 2003 is shown.

FSIS reports the number of carcasses that are restricted because they have evidence of Acti. Most of the time, these restrictions simply involve trimming out the affected part, although a small fraction of Acti-affected carcasses are condemned.

Because Acti is a common histopathologic diagnosis for TB, and it can be linked to the FSIS database, this condition is used to establish a minimum submission frequency standard for suspicious TB-lesions by slaughter establishments. The minimum submission frequency standard is defined as $S = P \times f$, where $S$ is the fraction of carcasses with TB-suspicious lesions slaughtered in an establishment, $P$ is a prevalence of Acti-affected carcasses, and $f$ is the fraction of Acti-affected carcasses whose lesions resemble TB.

To establish a standard that all slaughter establishments can meet, the lowest regional prevalence of Acti-affected carcasses (0.38 percent) was chosen as the value for $P$. The number of Acti-affected carcasses reported by FSIS in 2003 was evaluated for VS’ eastern and western regions, as well as north and south regions of the United States (Figure 2 and Table 1). There was little difference in the prevalence of Acti-affected carcasses between the north and south regions, but there was a much lower prevalence in the eastern U.S. compared to the west. Nevertheless, Acti was reported at perceptible levels regardless of region.
FIGURE 2. An outline of eastern and western regions used to compare TB submission rates. The dashed line signifies separation of northern and southern regions.


<table>
<thead>
<tr>
<th>Region</th>
<th>Number slaughtered</th>
<th>Number of Acti-affected carcasses</th>
<th>Fraction affected</th>
</tr>
</thead>
<tbody>
<tr>
<td>U.S.</td>
<td>6,057,653</td>
<td>57,024</td>
<td>0.94%</td>
</tr>
<tr>
<td>Eastern U.S.</td>
<td>2,969,802</td>
<td>11,137</td>
<td>0.38%</td>
</tr>
<tr>
<td>Western U.S.</td>
<td>3,087,851</td>
<td>45,887</td>
<td>1.49%</td>
</tr>
<tr>
<td>Northern U.S.</td>
<td>4,296,066</td>
<td>36,478</td>
<td>0.85%</td>
</tr>
<tr>
<td>Southern U.S.</td>
<td>1,761,587</td>
<td>20,546</td>
<td>1.17%</td>
</tr>
</tbody>
</table>
To estimate the fraction of Acti-affected carcasses whose lesions resemble TB, data from the 40 largest cow-bull slaughter establishments were examined. Regardless of regional location of the slaughter establishment, there was a concentration of slaughter establishments that submitted less than 5 TB samples for every 10,000 carcasses processed (Figure 3). Nevertheless, 13 establishments submitted samples at substantially higher frequencies. Based on experience, it is recognized that these establishments are staffed with veterinarians committed to TB surveillance.

The relationship between the number of TB samples with histopathologic diagnoses of Acti and the number of carcasses reported as Acti-affected suggests that establishments committed to TB surveillance are likely submitting lesions from Acti-affected carcasses because those lesions look like TB (Figure 4). A proportional trend in this relationship is noted for the top 12 submitting slaughter establishments, but no such trend is evident among the other 27 slaughter establishments. One establishment among the top submitting establishments was considered an outlier because personnel changes at the establishment that occurred late in 2003 contributed to an improvement in TB submission frequency.

Using data from the top 12 submitting slaughter establishments, the fraction of Acti-affected carcasses whose lesions resemble TB \((f)\) is estimated at 14 percent. From the top 12 submitting slaughter establishments, there were 3,213 TB submissions from more than 2 million adult cattle slaughtered in 2003. Following histopathology, 990 (31 percent) of these 3,213 TB submissions were diagnosed as Acti. According to FSIS data, there were 5,919 carcasses reported as Acti-affected from these top 12 slaughter establishments in 2003. Assuming the TB submissions that were later diagnosed as Acti contribute to...
the total number of acti-affected carcasses from these establishments, the fraction of Acti-affected carcasses whose lesions resemble TB equals

\[ 14\% = \frac{990}{990 + 5919}. \]

Based on this analysis, it is concluded that slaughter establishments should be submitting samples suspected of TB at a frequency of 0.05% \((P \times f = 0.38\% \times 14\%)\). This equates to one submission per 2,000 carcasses processed. Failure to meet this standard suggests that inspection of carcasses for TB may be inadequate.
REFERENCES


USDA APHIS VS CEAH National Surveillance Unit (NSU), Surveillance and Data Standards for USDA/APHIS/Veterinary Services. July 2006.

USDA APHIS VS CEAH National Surveillance Unit (NSU), Guidelines for developing an animal health surveillance plan. September 2006.


USDA National Agriculture Statistics Service (NASS), NASS Cattle report. 2012.


ACRONYMS USED IN THIS DOCUMENT

AD – Assistant director
APHIS – Animal and Plant Health Inspection Service
CAHFS – California Animal Health and Food Safety Laboratory System
CHC – Cattle Health Center
CEAH – Centers for Epidemiology and Animal Health
CFR – Code of Federal Regulations
CFT – Caudal Fold Test
CCT – Comparative Cervical Tuberculin Test
CT – Cervical Tuberculin Test
FDA – Food and Drug Administration
FSIS – Food Safety and Inspection Service
MIM – Mobile Information Management
NGL – No Gross Lesions
NSU – National Surveillance Unit
NVSL – National Veterinary Services Laboratories
PCR – Polymerase Chain Reaction
PHIS – Public Health Information System
PMO – Pasteurized Milk Ordinance
PPD – Purified Protein Derivative
QAV – Qualified Accredited Veterinarian
REO – Regional epidemiology officer
RMA – Recognized Management Area
SCS – Surveillance Collaborative Services
SCT – Single Cervical Test
SSE – Slaughter Sensitivity
TB – Bovine Tuberculosis
TRP – Test and Removal Protocol
UM&R – Uniform Methods and Rules
USAHA – United States Animal Health Association
VS – Veterinary Services