



United States  
Department of  
Agriculture

Animal and Plant  
Health Inspection  
Service

Veterinary Services

October 2021

# National Bovine Tuberculosis Surveillance Plan



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## Executive Summary

Surveillance is a key activity supporting the goal of bovine tuberculosis (bTB) eradication. The objectives for tuberculosis (TB) surveillance activities include:

- Detecting the disease in bTB program species (cattle, bison, and cervids),
- Providing metrics to evaluate consistent compliance with program standards,
- Measuring progress toward regulatory goals as defined by meeting the granuloma submission per-carcass slaughter rate, and
- Giving stakeholders and decision makers timely and relevant actionable information.

This plan outlines TB national surveillance activities. These activities are conducted using Federal and cooperating State resources. States may elect to supplement this surveillance, or the United States Department of Agriculture (USDA) Animal and Plant Health Inspection Service (APHIS) may require States to supplement surveillance as part of active TB epidemiology investigations or when States fail to meet testing or reporting guidelines.

Slaughter inspection is the foundation of adult cattle and bison national TB surveillance in the United States. State or USDA Food Safety and Inspection Service (FSIS) personnel individually inspect all adult cattle and bison slaughtered in the United States for wholesale or retail purposes for evidence of tuberculosis unless exempted as defined in 9 CFR 303.1 (USDA FSIS, 2012). Similarly, State and USDA personnel also inspect fed cattle slaughtered in the United States for evidence of tuberculosis. Fed cattle are steers and heifers managed for slaughter and meat production.

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. The total number of adult cattle and bison slaughtered under Federal inspection in U.S. establishments combined with meeting the granuloma submission standard is 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. APHIS has not set a national TB granuloma submission performance standard for fed-cattle establishments or for those slaughtering farmed cervids. However, APHIS strongly encourages submission of any suspicious granulomatous lesion(s) for laboratory evaluation for TB.

In addition to slaughter surveillance, tuberculin skin testing and serologic testing of program animals also contribute to national TB surveillance. Live animal testing is the primary means of surveillance for TB in farmed cervids as there are no granuloma submission standards for establishments that slaughter cervids. Federal testing requirements for all program animals include testing for interstate movement, if moving from a non-accredited free State, as regulated under 9 CFR 77, and testing for export from the United States (CFR 91.5). Testing program species for these purposes contributes to national TB surveillance and enhances the detection of bTB. In addition to the required Federal

testing, State or Tribes may impose further TB testing. This 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 may be required by certain conditions defined within 9 CFR 77.7, 77.9, 77.11, 77.13, and the Uniform Methods and Rules (UM&R). Targeted surveillance may incorporate slaughter surveillance components and/or live animal testing that exceeds the national surveillance described in this plan. States must conduct targeted surveillance when:

- A State or zone status changes to less than accredited free,
- A known source of TB in livestock or wildlife poses a risk of transmission to program animals, or
- An epidemiologic investigation is being conducted.

These targeted surveillance efforts are critical to overall tuberculosis national surveillance.

# 1. Disease Description

## Etiology

Tuberculosis (TB) is a subacute or chronic, infectious, granulomatous zoonotic disease caused by Gram positive acid-fast bacilli bacteria from the genus *Mycobacterium*. TB affecting mammalian hosts is caused by bacteria that are part of the *M. tuberculosis* complex including *M. tuberculosis*, *M. canettii*, *M. bovis*, *M. caprae*, *M. pinnipedii*, *M. microti*, *M. mungi*, and *M. africanum* (Thoen, 2014). The bacterial types differ in cultural characteristics and pathogenicity. All types may produce infection in multiple species, but members of the *M. tuberculosis* complex are of concern for cattle, bison, and cervids; primarily *M. bovis*, which is maintained in cattle. *M. bovis* can survive for several months in the environment, particularly in cold, dark, and moist conditions.

## Distribution

Though the disease is distributed worldwide, many developed countries have successfully controlled it in cattle. It is difficult to eradicate, however, and efforts to eliminate the disease are costly. In the United States, the herd prevalence of bovine tuberculosis (bTB) has dropped from 5 percent to less than 0.001 percent since eradication efforts began in 1917 (Humphrey et al., 2014). Although bTB has not been detected in most U.S. States for many years, TB-affected herds continue to be detected periodically.

## Epidemiology

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 (Spickler, 2019), 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.

## Clinical Signs

TB clinical signs are typically similar among species though it is usually a subclinical disease. Infections can remain dormant for years and reactivate during periods of stress or in advanced age. Clinical signs in cattle, 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.

## Diagnosis

Live animals are screened for *M. bovis* by using tuberculin skin tests and whole blood in cattle and bison or serology in cervids (Appendix A). TB may be diagnosed via slaughter inspection of cattle and bison or diagnostic necropsy. Granulomatous lesions are sent to the APHIS Veterinary Services (VS) National Veterinary Services Laboratories (NVSL). Histopathology is useful in identifying the presence of consistent pathologic tissue changes and acid-fast bacteria (TB compatible). Polymerase chain reaction (PCR) can show the presence of *Mycobacterium tuberculosis*-complex genetic material. Isolation of the organism from bacterial culture is still the gold standard for identifying *M. bovis*. Genotyping using whole genome sequencing is a high-resolution method for determining the relatedness of isolates, understanding TB transmission, and prioritizing investigations.

## Management

Herds confirmed as infected with TB (affected herds) are either depopulated or managed with a test-and-removal protocol. The 2005 Bovine Tuberculosis Eradication UM&R and VS Memorandum 552.47 (2011) provide details on managing TB-affected herds.

## 2. Purpose and Rational for Surveillance

Tuberculosis has an important worldwide impact on animal industries and human health. Control measures are based on prevention and eradication (Palmer & Waters, 2011). Surveillance is a key element supporting prevention and control programs. The World Organization of Animal Health (OIE) outlines criteria for classifying a country or zone as free from infection with TB. These criteria require a minimum of 3 years of routine surveillance demonstrating no infection with TB in at least 99.8 percent of the herds representing at least 99.9 percent of the bovinds in the country or zone (OIE, 2019).

Surveillance for TB in the United States serves as an important case-finding tool, critical to starting investigations, particularly given the currently low prevalence of TB in U.S. livestock populations.

## 3. Surveillance Objectives

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

- Detection of bTB in program species of animals (i.e., case-finding),
- Providing metrics to aid in evaluating compliance with program standards, and
- Giving stakeholders and decisionmakers timely and relevant actionable information.

This surveillance plan outlines national activities that are carried out via State involvement. It is updated every 5 years and evaluations are conducted in the interim to ensure national surveillance standards are achievable and appropriate. These activities will be conducted using Federal and cooperating State resources.

In addition to national surveillance activities, 9 CFR 77 requires targeted or risk-based surveillance. The details are described in the 2005 UM&R. Targeted surveillance may incorporate slaughter surveillance components and/or live animal testing that go beyond the national surveillance focused on in this plan. States must conduct targeted surveillance when:

- A State or part of a State has been downgraded in accredited status,
- A known source of TB in livestock or wildlife poses a risk of transmission to program animals, or
- An epidemiologic investigation is being conducted.

#### **4. Expected Outcomes: Products, Decisions, and Actions**

National tuberculosis surveillance is used to track the incidence of TB in the United States. Surveillance program results are an important component in documenting the ability to detect TB-infected cattle and bison at a 0.0003 percent prevalence threshold with a 0.95 probability of detection. Given the low prevalence of TB in the United States, surveillance is a valuable case-finding tool, and results are used for annual reporting, decision making, and policy development. USDA expects that this 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 farmed 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,
- State government entities including Departments of Agriculture (or equivalent), Departments of Natural Resources (or equivalent), Divisions of Wildlife, and Departments of Public Health,
- Federal government, primarily USDA's APHIS and FSIS, and the Food and Drug Administration via the Pasteurized Milk Ordinance,



- APHIS-VS-NVSL, responsible for testing samples and reporting results,
- Taxpayers who fund tuberculosis surveillance and benefit from disease freedom, and
- International trading partners.

Responsible parties include all stakeholders, specifically:

- Producers who support and take part in surveillance despite absence of overt disease evidence,
- Accredited veterinarians who conduct TB testing,
- FSIS inspection program personnel who collect surveillance samples,
- Slaughter plant employees who ensure the correct correlation of carcasses to ID tags,
- 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, and
- Taxpayers who provide funding for surveillance activities.

## 6. Population Description and Characteristics

### A. Adult Cattle Population

There are approximately 42 million adult cattle in the United States. This includes approximately 31 million beef cows, 9 million dairy cows, and 2 million bulls (NASS, 2021). Annually, between 6-7 million adult cattle are slaughtered under Federal and State slaughter inspection. State meat inspectors or FSIS personnel individually examine all adult cattle and bison slaughtered in the United States for wholesale or retail purposes for evidence of tuberculosis (Kaneene et al., 2006). 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 U.S. regions.

### B. Fed Cattle Population

Based on APHIS-VS data from fiscal year 2020, approximately 25 million cattle on feed are slaughtered annually. State or FSIS personnel individually inspect each animal for evidence of tuberculosis.

### **C. Farmed Cervid Population**

According to the NASS data from the 2017 census, there are an estimated 3,172 captive deer farms in the United States with an estimated 212,449 deer. There are approximately 759 captive elk farms with an estimated 31,555 elk in the United States (NASS, 2019). Currently there are interstate movement testing requirements for farmed cervids not destined for immediate slaughter.

## **7. Case Definition**

### **A. Disease Information**

Bovine tuberculosis is an infectious, granulomatous disease caused by *Mycobacterium bovis*. *M. bovis* can survive for several months in the environment, particularly in cold, dark, and moist conditions. It affects all species of warm-blooded vertebrates, and clinical signs and lesions are typically similar in the various species. The clinical signs 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.

### **B. Laboratory Criteria**

Agent isolation and identification: The presence of *M. bovis* in clinical and post-mortem specimens may be demonstrated by examination of stained smears or tissue sections and confirmed by cultivation of the organism on primary isolation medium. Isolates are usually identified by determining cultural and biochemical properties. Nucleic acid recognition methods (PCR) can provide rapid identification.

Delayed hypersensitivity test: In live cattle, tuberculosis is typically diagnosed in the field with the tuberculin skin test. A positive test is indicated by a delayed hypersensitivity reaction following an intradermal injection of tuberculin.

### **C. Case Definitions**

- Suspect case:
  - Tuberculosis should be suspected when abscesses of unknown etiology are found. In developed countries, few infections become symptomatic; most are diagnosed by routine testing or at the slaughterhouse.
- Presumptive positive case:
  - A presumptive diagnosis can be made by histopathology and/or the microscopic demonstration of acid-fast bacilli. The intradermal tuberculin skin test also enables presumptive diagnosis.
- Confirmed positive case:
  - Confirmation of diagnosis is by isolation and identification of the organism, with culture taking 4-8 weeks, or by PCR, which requires only a few days.

## 8. Data Sources

### A. Slaughter Data

APHIS-VS staff compile data from adult cattle, bison, and fed-cattle slaughter and granuloma submissions, which come from a variety of sources. FSIS provides slaughter volume data by plant from its Public Health Information System database. NVSL provides granuloma submission data. These data are collated and updated in the Data Integration Services (DIS) software to evaluate whether slaughter plants meet granuloma submission performance standards.

### B. Live Animal Testing Data

In addition to slaughter surveillance, routine tuberculin skin and/or interferon-gamma release assay testing of cattle and bison, and skin and/or serology testing (Dual Path Platform assay) of cervids as required by national or State regulations also contribute to national TB surveillance. Live-animal testing is the primary means of surveillance for TB in farmed cervids. There are no standards for granuloma submissions from establishments that slaughter cervids. Skin testing data are documented manually on VS 6-22 forms or are entered into mobile information management (MIM) devices. These data are then uploaded into State databases that communicate with the Surveillance Collaboration Services (SCS) system. Gamma interferon and Dual Path Platform test results are processed through NVSL and data are entered into the STRAND application. Trace investigations and TB-affected herd data are entered into the Emergency Management Response System (EMRS). APHIS-VS receives data from the SCS system, EMRS, and STRAND application, and epidemiological summary data are provided by States upon request annually. Data from some of the databases are collated into DIS software to make data available on a single platform. Data obtained 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

### A. Adult Cattle and Bison Slaughter Surveillance Component

Slaughter inspection by State or FSIS personnel is the foundation of adult cattle and bison national TB surveillance in the United States.

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 (USDA FSIS, 2016, Directive 6100.2, Rev. 1). Specific classes of high-risk animals undergo other postmortem procedures. Expanded postmortem inspection procedures are performed as outlined in Guideline #4 for TB reactors (USDA FSIS, 2005).

Modified expanded procedures are performed on TB suspect or TB exposed animals (USDA FSIS, 2015, Directive 6240.1, Rev. 2). APHIS-VS rewards FSIS inspection program personnel and public health veterinarians when they submit granulomatous lesions, along with corresponding animal identification devices, to the NVSL and other approved laboratories, that result in detection of bovine TB cases and identification of previously unrecognized TB-affected cattle, bovine, or farmed cervid herds.

Performance standards to meet the adult cattle and bison slaughter surveillance component are:

- 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, and
- 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 a 0.95 probability of detection.

The first standard is used to validate that carcass inspection is sufficient (Ebel, 2003). Failure of establishments to meet this granuloma submission rate may compromise the effectiveness of national tuberculosis surveillance. This particularly applies to facilities in the top 40 adult slaughter plants. In 2019, APHIS-VS evaluated this surveillance standard via retrospective analyses of adult cattle granuloma submissions from 2011-2017. During this period, a total of 61,256 bTB-like lesions were submitted for testing. Of these submissions, only 39,763 could be age-classified from NVSL data entered in the source database. The remaining submissions were not associated with adequate data for age classification in our databases. Based on the age-classified submissions, approximately 70 percent were adult submissions. Given these percentages, the national adult submissions were estimated to surpass the one in 2,000 required submission rate each year. However, the estimated annual submission rates have steadily decreased over time (Appendix B).

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 that the laboratory tests the sample and finds it to be positive (Chioino, 2003). Using this approach, an overall animal SSE estimate of 20.9 percent was found appropriate when considering weighted SSE averages for beef and dairy herds by herd type and size (USDA NSU, 2009).

Between 6 and 7 million adult cattle and bison are slaughtered annually under validated inspection<sup>1</sup>. Using estimates of the overall SSE and total adult cattle population<sup>2</sup>, APHIS-VS analysts can determine the slaughter detection level with 95 percent confidence.

Table 1 shows the number of validated slaughter samples required to reach three different detection levels with 95 percent confidence, assuming an SSE of 20.9 percent.

**Table 1. Number of validated adult cattle slaughter samples required to reach detection levels with 95% confidence**

Number of Validated Slaughter Samples Required	Resulting Detection Level
3,551,651	0.0004%
4,721,530	0.0003%
7,040.532	0.0002%

<sup>1</sup> In FY 20206,944,606 adult cattle slaughtered; Validated slaughter = 6,447,205 (92.8%) e.g., had adequate granuloma submissions to meet 1 per 2,000 standard

<sup>2</sup>U.S. adult cattle: Beef cows—31,200,000 head, Milk cows—9,440,000 head, Bulls – 2,210,000 head; NASS Cattle report, January 29, 2021.

The total number of adult cattle and bison slaughtered under inspection in U.S. establishments combined with meeting the granuloma submission standard is 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.

Current limitations affecting bTb eradication in the United States are the low slaughter sensitivity estimate, the challenge of identifying bTb source introductions, and the time involved to make disease freedom claims through test-and-remove modeling methods. Following introduction of bTb into a herd, the estimated median time to detection at slaughter is approximately 5 years. This has negative implications for bTb early detection processes as slaughter traceback investigations identify other bTb-positive animals in the herd of origin 65 percent of the time (Humphrey et al., 2014). This is particularly challenging given the current low prevalence of bTb in the United States. Whole-herd depopulation procedures are limited given national indemnity constraints (Whipple & Palmer, 2014) and the long-term consequences to producers involved in such activities. The current slaughter performance standard is based on the historic achievement of bTb detection in the United States. To improve this standard, surveillance assessments should include re-evaluation of the slaughter sensitivity estimate to ensure appropriate detection levels and targeting of high-risk sources of introduction and spread.

## **B. Fed-Cattle Slaughter Surveillance Component**

Fed cattle slaughtered in the United States for wholesale or retail purposes are individually inspected for evidence of tuberculosis by State or FSIS personnel as described for adult cattle above. APHIS-VS has not set 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 setting 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 as it was determined that a standard would not increase bTb case

detection. While FSIS regulations require inspection program personnel to submit suspicious granulomatous lesions(s) for laboratory evaluation for TB (FSIS Directive 6240.1), a voluntary submission rate of one or more lesions for every 20,000 fed cattle slaughtered per slaughter establishment is recommended. According to the 2019 national surveillance standard evaluation, this recommended submission rate was achieved by fed cattle slaughter establishments from 2011-2017 (Appendix B).

### **C. Targeted Slaughter Surveillance**

APHIS-VS and States/Tribes may collaborate to evaluate data and identify specific establishments for targeted slaughter surveillance. Considerations for targeted surveillance may include identification of known high-risk source populations and cattle types received (e.g., adult, beef, etc.) by slaughter establishments. The cattle movement model, for example, can help identify establishments through a more quantitative approach. Where targeted slaughter surveillance is called for, APHIS-VS will work with FSIS and State/Tribal officials to develop an appropriate granuloma submission standard and to monitor compliance with the standard.

### **D. Farmed Cervid Slaughter Surveillance Component**

APHIS-VS has not set a national TB granuloma submission standard for establishments slaughtering cervids.<sup>3</sup> However, VS encourages these plants to submit granulomas for TB testing.

### **E. Monitoring Adult Cattle and Bison Slaughter Surveillance in Federal Establishments**

APHIS-VS will:

- Monitor TB granuloma submissions for all federally inspected slaughter establishments in the U.S. (staff from CHC, NVSL, 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 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 to monitor surveillance activities and to aid meat inspection personnel and establishment management in resolving surveillance issues (staff from VS field offices). Fewer visits may be made at the discretion of the VS Area Veterinarian in Charge (AVIC) according to available resources (USDA, 2018), and
- Report quarterly to FSIS and the District Director TB granuloma submission rates for the 40 largest volume U.S. adult cattle and bison slaughter establishments (staff from CHC and the Center for Informatics).

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<sup>3</sup>Deer, elk, bison, catalo, and other exotic animals are under voluntary inspection per 9 CFR 352.

## **F. Monitoring Adult Cattle and Bison Slaughter Surveillance in State-Inspected Establishments**

Each State or Tribe is encouraged to:

- Monitor TB granuloma submissions for all State-inspected adult cattle and bison slaughter establishments to ensure that each facility 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 meet granuloma submission standards (if applicable) and ensure appropriate corrective actions in cases when plants do not comply,
- Conduct at least one visit per calendar quarter to each State-inspected adult cattle and bison slaughter establishment by State and/or Federal animal health officials to monitor surveillance activities and assist the attending meat inspection personnel and establishment management in resolving any surveillance issues that may arise.

## **G. Live Animal Testing Surveillance Component**

In addition to slaughter surveillance, tuberculin skin testing of program animals and serologic testing of cervids contribute to national TB surveillance. Live animal testing is the primary means of surveillance for TB in farmed cervids as there are no standards for granuloma submissions from establishments that slaughter cervids.

The following are reasons for live animal testing. 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 modified accredited advanced (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 must be tested for TB prior to export from the U.S (9 CFR 91.5). Importing countries may also require more TB testing for these animals.

- **Testing for Herd Accreditation**

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

- **State or Tribal Testing Requirements**

Along with the Federal testing requirements for interstate movements, State or Tribes may impose further 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,
- Testing to establish new free-ranging wild-caught bison and cervid herds or augment existing ones, and
- Testing to adhere to submitted plans for a recognized Tribal status apart from the State status.

- **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 meet 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, and
- Testing to establish or monitor disease in States or zones with modified accredited advanced or lower status.

## **H. Monitoring tuberculin testing**

Tuberculin testing of cattle, bison, and farmed cervids is an important component of TB surveillance, whether required by the regulations or specified by a State or Tribe as a means of targeted surveillance.

Properly conducting and interpreting the caudal fold tuberculin (CFT) test is essential for disease diagnosis, control, and eradication. Only accredited veterinarians or State/Federal regulatory veterinarians should conduct tuberculin testing. Those authorized individuals must meet a performance standard that has been set on the minimum annual response rate expected after an individual has tested 300 animals. 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.

## **10. Data Analysis and Interpretation**

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

## **11. Data Presentation and Reports**

States must 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 VS CHC and the Center for Informatics (CFI) will compile cattle slaughter and granuloma submission data from all Federal slaughter establishments. The analysts will generate a quarterly TB granuloma submission rate report for the 40 largest volume U.S. adult cattle and bison slaughter establishments and distribute it to FSIS and the AVIC in each State.

Reports produced by the CEAH-SDA unit 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 VS Deputy Administrator may request information provided by the annual report to be further tabulated for public consumption.

## **12. Surveillance System Implementation: Priorities, Timelines, and 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.

In 2015, a proposed rule was published in the Federal Register to combine the regulations governing TB and those governing brucellosis into a consolidated 9 CFR 76, which would amend both domestic and import regulations. It would change the State classification from that based on

prevalence level of disease to a system based on a State-drafted animal health plan, approved by USDA, to address diseases. Following public commentary and concerns, it was decided to withdraw the proposed consolidated rule as part of 9 CFR 76. Currently, a new proposed rule is being developed that seeks to amend the current 9 CFR 77. The new rule would transition the TB program away from a State classification system based on disease prevalence to a two-tier system based on disease management.

## 13. Resources

The VS tuberculosis program is funded under cattle and cervid commodity-specific line items rather than a tuberculosis-only line item. This allows 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 VS CFI, NVSL, and CEAH personnel. Additional external resources include the FSIS slaughter inspection personnel and pathology laboratory, and accredited veterinarians who perform the bulk of field skin testing.

## 14. Surveillance Plan Performance Standards and Metrics

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### Adult cattle and bison slaughter surveillance component

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- Each cattle and bison 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.
- The total number of adult cattle and bison slaughtered under inspection in U.S. establishments combined with meeting the granuloma submission standard is sufficient to detect a 0.0003% or higher prevalence level among the U.S. cattle and bison population with a 0.95 probability of detection.

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### Adult cattle and bison live animal testing surveillance component

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- The minimum annual response rates of individuals authorized to conduct CFT tests in cattle or bison, after 300 animals have been tested, are as outlined in the 2005 UM&R, Appendix C. Each State must implement a system to monitor the response rate reported by each accredited veterinarian authorized to conduct official tuberculin tests, and appropriate action documented when response rates are not achieved.

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### Plan update and evaluation

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- The National Tuberculosis Surveillance Plan will be updated every 5 years or sooner pending significant rule changes governing bTB, to reflect the current surveillance monitoring needs for the bovine, bison, and farmed cervid populations.
- The surveillance plan will be evaluated 2-3 years following institution of the updated plan to ensure performance metrics are met or exceeded.

## 15. Surveillance System Evaluation

The tuberculosis surveillance system should be evaluated regularly to review how well the system fulfills its stated objectives and meets accepted standards. The evaluation process identifies system strengths and areas for improvement. Given that the last evaluation on slaughter sensitivity was performed in 2009, our intent is to re-evaluate the sensitivity estimate in the future. Input probabilities of an animal having a bTB-like lesion, detection of a lesion by slaughter inspectors, submission of a lesion to the laboratory, and subsequent positive result testing may vary from the 2009 estimates. New weighted averages for beef and dairy herds, by size, should be considered as components affecting the sensitivity of the slaughter surveillance system. The evaluation should incorporate updated annual granuloma submission numbers, as those will affect the sensitivity of the overall bTB slaughter detection process. The document titled “Surveillance and Data Standards for Veterinary Services, Version 1.0, July 2006” is the guidance document for the surveillance system evaluation. This surveillance plan should be evaluated within 2 to 3 years of its implementation, and then periodically after that.

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## **Acronyms Used in This Document**

APHIS – Animal and Plant Health Inspection Service

AVIC – Area Veterinarian in Charge

CHC – Cattle Health Center

CEAH – Center for Epidemiology and Animal Health

CFR – Code of Federal Regulations

CFT – Caudal Fold Tuberculin Test

CCT – Comparative Cervical Tuberculin Test

CT – Cervical Tuberculin Test

DIS – Data Integration Services

DPP – Dual Path Platform

FSIS – Food Safety and Inspection Service

MIM – Mobile Information Management

NSU – National Surveillance Unit

NVSL – National Veterinary Services Laboratories

PCR – Polymerase Chain Reaction

PPD – Purified Protein Derivative

SCS – Surveillance Collaborative Services

SCT – Single Cervical Tuberculin Test

SDA – Surveillance Design and Analysis Unit

SSE – Slaughter Sensitivity

bTB – Bovine Tuberculosis

TB – Tuberculosis (*M. bovis* and other members of the *Mycobacterium tuberculosis* complex)

UM&R – Uniform Methods and Rules

USAHA – United States Animal Health Association

VS – Veterinary Services

## Appendix A

### Live Animal Screening Diagnostics

The caudal fold tuberculin (CFT) test in cattle and bison and single cervical tuberculin test (SCT) or dual path platform (DPP) serological test in cervids are the primary official screening tests currently used in live animal TB surveillance (Thoen et al., 2006). The intradermal tuberculin skin tests use a purified protein derivative 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 animals that have 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 are 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 (Norby et al., 2004). 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 sensitivity of the tests in series is lower than either test alone. Testing in series risks missing more TB-infected animals than by using either test alone.

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 (De la Rúa-Comenech, 2006). This is an example of using tests in parallel. This method is used when cattle are judged to be of high risk for TB infection and the highest possible test sensitivity is desired. The specificity of the tests in parallel is lower than either test alone. Testing in parallel risks removing more uninfected cattle than by using either test alone.

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.

## Appendix B

Estimated number of age-classed bovine TB-like lesion submissions from slaughter establishments and approximate adult and fed submission rates, FY 2011-2017.

Fiscal Year	Number Lesion Submissions*	Number Age-Classed Lesion Submissions	Age-Classed Adult Lesion Submissions (%)	Age-Classed Fed Lesion Submissions (%)	Estimated Adult Lesion Submissions‡	Estimated Fed Lesion Submissions‡	Estimated Adult Lesion Submission Rate‡	Estimated Fed Lesion Submission Rate‡§
2011	12,828	7,604	5,183 (68)	2,421 (32)	8,744	4,084	1/830	1/6,520
2012	10,171	6,170	4,256 (69)	1,914 (31)	7,016	3,155	1/1,002	1/8,001
2013	11,376	6,545	4,769 (73)	1,776 (27)	8,289	3,087	1/848	1/8,099
2014	7,727	4,916	3,545 (72)	1,371 (28)	5,563	2,164	1/1,102	1/11,084
2015	6,246	3,512	2,394 (68)	1,118 (32)	4,258	1,355	1/1,315	1/16,473
2016	6,354	5,105	3,573 (70)	1,532 (30)	4,447	1,335	1/1,088	1/14,499
2017	6,554	5,900	3,984 (68)	1,916 (32)	4,426	1,437	1/1,401	1/17,208
<b>Total</b>	<b>61,256</b>	<b>39,763</b>	<b>27,710 (70)</b>	<b>12,053 (30)</b>	<b>42,688</b>	<b>12,940</b>	<b>1/1,033</b>	<b>1/12,927</b>

\*Calculated from Submission\_SlaughterTBEval\_NVSL with care taken not to count duplicate plant entries associated with positive submissions (SDA, 2019). These data are based on FSIS reports and compiled and cleaned by CEAH.

‡Approximation based on age classifications of 39,763 submissions out of a total of 61,256 submissions. The percent of submissions per year in an age class was applied to the total submissions per year to estimate submissions in an age class.

§Fed animal denominator used includes all bison slaughtered as majority of bison slaughtered are in the fed category (7:1)