

Analysis of Bovine Tuberculosis Surveillance in Accredited Free States

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Executive summary

Although bovine tuberculosis (TB) affected herds continue to be sporadically identified, prevalence of TB is at historically low levels. Recently, identification of TB affected herds has occurred in Accredited Free (AF) States or zones, resulting in the downgrading of State TB status. Thus, an analysis of TB surveillance in all current AF States was conducted to assess two objectives: 1) whether routine surveillance regulatory requirements are being met in AF States, and 2) if so, what slaughter surveillance implies about TB herd prevalence in AF States.

An analysis of surveillance data (Objective 1) finds that current surveillance in AF States exceeds routine regulatory requirements. In fact, either slaughter surveillance or caudal fold (CF) tuberculin testing alone meet regulatory requirements. Combined slaughter and CF tuberculin testing results are sufficient to detect a TB prevalence of 0.0002 percent in the adult cattle and bison population in AF States with 95 percent confidence. When stratified by length of years in AF status, data from States in AF status more than 5 years and up to 10 years had the lowest ability to detect tuberculosis (0.005 percent) with 95 percent confidence. Yet even this level exceeds domestic regulatory standards by 10-fold and International (OIE) standards for disease freedom by greater than 100-fold.

Despite meeting the regulatory standards for prevalence, low CF responder rates raise concern about the validity of tuberculin testing data. Overall performance is poor, even though most individual States adequately monitor CF responder rates, take corrective actions where necessary, and have demonstrated improvement in some cases. Of 24 State annual VS 6-38 reports reviewed, 71 percent reported less than 50 percent of veterinarians performing CF testing in compliance with the responder standard.

Although TB surveillance clearly exceeds regulatory requirements, objective 2 questions how effective it is in detecting TB infected herds. A measurement of the probability that a surveillance system will detect infected herds is called surveillance sensitivity (SSe). SSe considers all of the factors that affect the outcome of the surveillance system (a scenario tree) including the size of the herd and probability that the infected animal is culled, has a lesion, the lesion is observed and submitted to the laboratory, tests positive, is traced back to herd of origin, and herd confirmed positive. Herd-level prevalence is not easily determined directly because slaughter surveillance data are collected at the animal level rather than by herd. Herd information only becomes available once the animal is traced to its origin. Precise data are also not available for each node on the scenario tree, but simulation modeling tools allow incorporation of available data, research outcomes, and expert opinion coupled with a measurement of the uncertainty inherent in each. The simulations then allow inference back to the herd level.

The surveillance sensitivity analysis demonstrates that, regardless of surveillance strategy, it is not possible to prove with certainty that zero diseased herds exist in any cattle population. That is, current regulations requiring zero herd prevalence are well intended, but unrealistic for surveillance to prove. It is however, possible to estimate how quickly surveillance could detect

an infected herd and how many infected herds might be present before there is high confidence of detection. These estimates allow for informed decisions on TB management options.

Results of the SSe analysis estimates that slaughter surveillance alone provides 99% confidence in detecting a single infected herd in the largest tier of dairy cattle operations (greater than 500 head) in less than 5 years (Figure 7). These results also indicate that if as few as 4 herds were infected, at least one would be detected within one year with 95 percent confidence. This very high confidence in detection suggests alternative options to depopulation or repeat herd testing for management of the large dairy herds. The other end of the scale with the lowest SSe was in the smallest tier of beef herds (1-49 head) which had 16 percent probability of detecting a single infected herd in a 5-year period. If infected herds are present in the small beef strata, in order to have 95 percent confidence of detecting at least one herd in one year, there could be as many as 95 infected herds in the population. (Figures 6 and 7)

Finally, the analysis emphasizes shortcomings in data collection and storage systems. There is a lack of standardization for type of data collected on tuberculin testing events and where and how data are stored. Slaughter data are currently not maintained with CF testing data. Data for this analysis included data on the Food Safety Inspection Services eARDS database, records kept by program and regional staff, the Generic Database, VS 6-38 paper reports, and expert opinion about many data parameters and practices for identification and traceback of animals. An integrated data system would greatly enhance ability to thoroughly and accurately address questions about the TB surveillance system in a timely manner.

Acronyms used in this document

AF	Accredited Free Tuberculosis Status
APHIS	Animal and Plant Health Inspection Service
AWBDS	Automated Web-Based Data Submission
CFR	Code of Federal Regulations
CF	Caudal Fold Tuberculin Test
eARDS	Electronic Animal Database Disposition Reporting System
EMRS	Emergency Management Response System
FSIS	Food Safety and Inspection Service
GDB	Generic Database
MAA	Modified Accredited Advanced Tuberculosis Status
NAHMS	National Animal Health Monitoring System
NASS	National Agriculture Statistical Service
NVSL	National Veterinary Services Laboratory
OIE	World Organization for Animal Health
PCR	Polymerase Chain Reaction
TB	Tuberculosis
UM&R	Uniform Methods and Rules
USAHA	United States Animal Health Association
USDA	United States Department of Agriculture
VS	Veterinary Services
VS 6-38	Accredited Area Surveillance for Tuberculosis Report

Background

Prevalence of bovine tuberculosis (TB) is at historically low levels. Herd prevalence peaked at approximately 5 percent in 1917, when the bovine TB eradication program was initiated. In fiscal year (FY) 2007, the prevalence in U.S. cattle herds was estimated to be 0.0006 percent (report of the tuberculosis committee, 2007 USAHA meeting). Still, affected herds continue to be identified sporadically, which impacts the affected State's TB status.

In the United States, currently 49 States, zones, and territories have Accredited Free (AF) status. California and New Mexico have Modified Accredited Advanced (MAA) status, while Minnesota and Michigan have split-State status (Figure 1). Accredited Free States have maintained their status designation for varying periods (Table 1).

Figure 1 – Current Cattle and Bison TB State Status

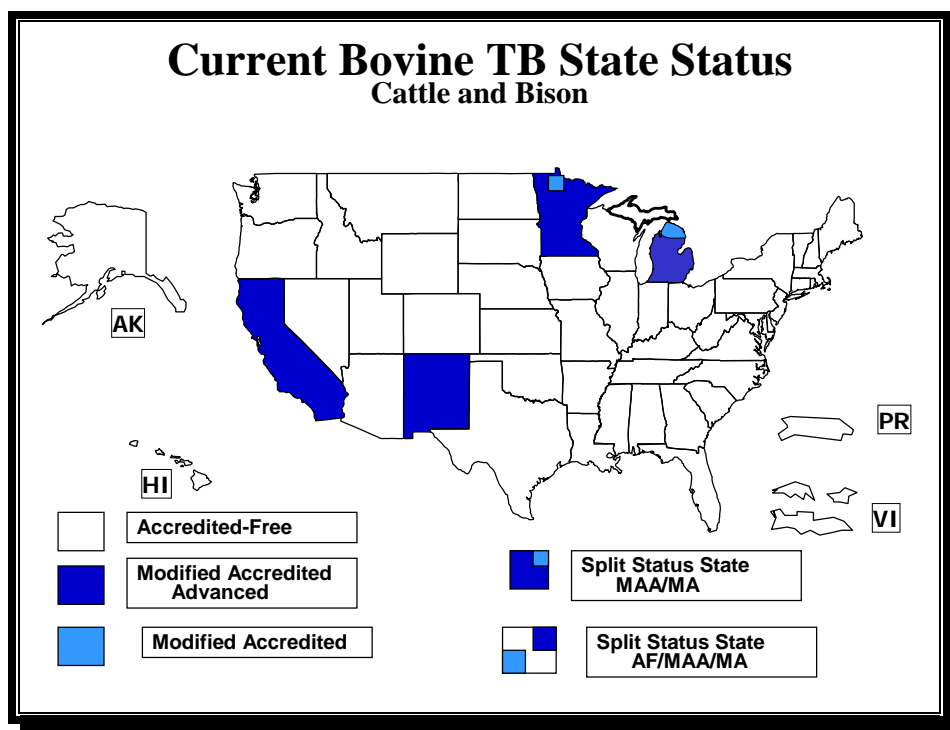


Table 1 – States by Years of AF Status

TB Free (Years)	Accredited Free (AF) States
> 25 yrs (20)	AZ, CO, CT, DE, ID, KS, MD, ME, MT, NC, ND, NH, NJ, RI, SC, SD, UT, VI, WI, WY
> 15 yrs (20)	AK, AL, AR, GA, HI, IA, IL, IN, KY, MA, MO, NE, NV, OH, OR, PA, TN, VT, WA, WV
> 10 yrs (5)	FL, LA, MS, NY, OK
> 5 yrs (2)	VA, PR
< 5 yrs (2)	TX, MI (upper peninsula)

Given that routine surveillance has met or exceeded regulatory requirements in States where affected herds have been identified, and State TB status has ultimately been downgraded, an analysis is warranted to determine whether routine surveillance requirements are adequate and appropriate in Accredited Free States.

Slaughter surveillance has been the primary case-finding tool for bovine tuberculosis since the 1950s. An important question is; “What is the herd sensitivity of slaughter surveillance?” (i.e., what is the probability of detecting tuberculosis at slaughter in an animal should the disease be present?); and “What can detection of TB at the individual animal level tell us about TB herd prevalence?”

Objectives of analysis

This analysis addresses two objectives:

- To determine if surveillance in AF States meets current regulatory requirements
- To determine the herd sensitivity of slaughter surveillance and what surveillance for TB in individuals at slaughter implies about TB herd prevalence

Objective 1: Does surveillance in AF States meet current regulatory requirements?

Regulatory requirements

To qualify for Accredited Free status, a State or zone must have a herd prevalence of zero for bovine tuberculosis in cattle and bison. AF status may be maintained if bovine tuberculosis is detected in an AF State or zone, the index herd is depopulated, epidemiological investigations are completed in a timely manner, and there is no evidence of further spread of tuberculosis within the State or zone.

General provisions to maintain State or zone status include having an adequate veterinary infrastructure to conduct a bovine tuberculosis eradication program that complies with provisions of the UM&R, and takes progressive steps to seek out and eliminate bovine tuberculosis. Additional provisions include compulsory notification to animal health authorities, supervision of boundaries, and the implementation of a management plan if bovine tuberculosis is diagnosed in wildlife or other animals within the state.

Current regulations require routine surveillance for a state to maintain TB status for cattle and bison. The tuberculosis regulations, as set forth in Title 9 Code of Federal Regulations, (9 CFR), stipulate that “States must maintain clinical and epidemiologic surveillance of animal species at risk of tuberculosis at a rate that allows detection of tuberculosis in the overall population of livestock at a 2 percent prevalence rate with 95 percent confidence.”

The Bovine Tuberculosis Eradication Uniform Methods and Rules (UM&R), effective January 1, 2005, requires more vigorous surveillance. This provision stipulates that, “Routine surveillance of cattle and bison in States or zones consists of slaughter inspection and tuberculin testing. In each state or zone, the total number of adult cattle and bison tested and/or inspected at slaughter should be sufficient to detect a 0.05 percent, or lower, prevalence level among that State’s, or zone’s cattle and bison with 95 percent confidence. For States or zones with more than 60,000 adult cattle and bison, this standard requires that at least 6,000 adult cattle and bison are documented to have been inspected at slaughter, or tuberculin tested, each year.”

The 2005 UM&R includes two additional requirements for adequate surveillance. First, to validate that carcasses are carefully inspected, each slaughter plant should submit suspicious granulomatous lesion(s) from at least one animal in every 2,000 adult cattle slaughtered at the facility.

Secondly, each State must implement a system to monitor the response rate reported by each individual authorized to conduct official tuberculin tests. Should performance standards for caudal fold tuberculin testing as outlined in the UM&R, Appendix C, not be met by individual(s), appropriate corrective action must be taken and documented.

OIE guidelines

The Terrestrial Animal Health Code, Chapter 11.7 for bovine tuberculosis was updated at the 76th World Organization for Animal Health (OIE) general session in May 2008, Guidelines for declaring a country or zone free from bovine tuberculosis were addressed. To initially establish a State or zone as free from tuberculosis, regular and periodic testing of bovine and bison herds must be conducted for 3 consecutive years without detecting *M. bovis* infection in at least 99.8 percent of herds (0.2 percent herd prevalence), and 99.9 percent of animals in the State or zone (0.1 percent animal prevalence). In addition, a surveillance program should be in place to detect bovine tuberculosis through antemortem and postmortem inspection.

Once *M. bovis* infection has not been detected for 5 consecutive years, surveillance may be maintained through slaughter inspection (antemortem and postmortem) alone.

Methods and data sources

FY 2007 data were used for this analysis of current tuberculosis surveillance. FY 2007 was selected since it is the most recent complete year of data available. Because tuberculosis testing and slaughter surveillance data are stored in multiple locations and formats, a number of data sources were employed for this analysis.

Adult cattle slaughtered by origin State

To estimate the number of adult cattle slaughtered from each state, the analysis looked at Accredited Area Surveillance for Tuberculosis (VS 6-38) Reports prepared annually by each AF State. These reports provide a process for States to report the number of adult animals

originating from their State that are slaughtered at both in-State and out-of-State slaughter establishments. VS 6-38 reports were available from 41 States and Puerto Rico.

Slaughter granuloma submission data

The U.S. Department of Agriculture (USDA) Food Safety and Inspection Service (FSIS) slaughter volume data by State, slaughter establishment, and class of animal were obtained from the FSIS eARDS (Electronic Animal Database Disposition Reporting System).

Laboratory testing of granulomas submitted from FSIS slaughter establishments is undertaken at 3 laboratories: National Veterinary Services Laboratories (NVSL) in Ames, IA; FSIS Eastern Laboratory, Athens, GA; and California Animal Health and Food Safety Laboratory, Davis, CA. Results from each laboratory are compiled in spreadsheets. VS TB program epidemiologists compile laboratory results and FSIS slaughter data to monitor granuloma submission rates by slaughter establishment and assure that submissions comply with slaughter validation performance standards (minimum 1 granuloma submitted per 2,000 adult cattle or bison slaughtered).

Individual slaughter cases

USDA Animal and Plant Health Inspection Service (APHIS) Veterinary Services (VS) TB program staff maintains a spreadsheet of all laboratory cases that are histocompatible for tuberculosis, and includes the animal's identification information, status of traceback investigation, herd/state of origin if known, and polymerase chain reaction (PCR) and *M. bovis* culture result.

Caudal fold tuberculin testing data

The caudal fold (CF) tuberculin skin test is the primary test used for initial screening for bovine tuberculosis in cattle and bison. Tuberculin testing data may be stored in a State's generic database (GDB), in a national reports database via the automated web-based data submission (AWBDS) process, in annual state "Accredited Area Surveillance for Tuberculosis" (VS 6-38) reports, in the Emergency Management Response System (EMRS) in outbreak investigations, and, in some cases, individual State recordkeeping systems.

Analysts queried all State GDBs for CF tuberculin testing data and obtained data from 40 State GDBs and Puerto Rico. Five States do not have data in the GDB. Lack of access prevented queries in two AF States, Texas and North Dakota. CF testing data for these two States were obtained from the AWBDS database and VS 6-38 Reports.

The AWBDS contains CF tuberculin testing data from States that either use the GDB for data storage or manually enter summary data via a Web interface. Data must be approved at the State level before being stored in the permanent database repository. AWBDS CF tuberculin testing

data was obtained from 44 States and Puerto Rico. Six States and the Virgin Islands had no approved testing data in AWBDS.

CF tuberculin test data from VS 6-38 annual reports were used when CF testing data were not available from AWBDS or GDB. VS-6-38 reports were available from 41 States and Puerto Rico.

Cattle population estimates

Cattle population estimates were obtained from the most recent complete data compiled by the USDA National Agricultural Statistics Service (NASS), 2002 (Table 2).

Table 2 - Cattle population estimates in AF States (NASS 2002)

AF States	All Cows That Have Calved	Beef Cows That Have Calved	Milk Cows That Have Calved	All Cattle And Calf Operations	Beef Cow Operations	Milk Cow Operations
All (49)	37,759,300	31,356,700	6,402,600	975,910	770,900	83,460
> 25 yrs (20)	11,845,800	9,335,400	2,510,400	211,380	152,310	29,840
> 15 yrs (20)	14,343,500	11,883,300	2,460,200	455,030	357,690	39,520
> 10 yrs (5)	5,010,000	4,008,000	1,002,000	132,500	105,900	10,500
> 5 yrs (2)	810,000	690,000	120,000	26,000	22,000	1,500
< 5 yrs (2)	5,750,000	5,440,000	310,000	151,000	133,000	2,100
US Cattle	42,209,300	33,099,700	9,109,600	1,050,910	814,400	97,560
ER	13,488,800	8,531,400	4,957,400	478,980	339,010	71,820
WR	28,720,500	24,568,300	4,152,200	571,930	475,390	25,740

Estimation of detectable animal and herd prevalence

The 2005 Bovine Tuberculosis Uniform Methods & Rules stipulates the following requirement for routine tuberculosis surveillance: *“Surveillance of cattle and bison in each State or zone consists of slaughter inspection and tuberculin testing. In each State or zone the total number of adult cattle and bison tested and/or inspected at slaughter should be sufficient to detect a 0.05 percent, or lower, prevalence level among that State’s, or zone’s cattle and bison with 95 percent confidence”*. An equation (Cannon and Roe, 1982) to calculate the required sample size needed to meet UM&R detection prevalence requirements was used during development of the 2005 UM&R used to determine: *“For States or zones with more than 60,000 adult cattle and bison, this standard requires that at least 6,000 adult cattle and bison are documented to have been inspected at slaughter, or tuberculin tested, each year”*.

The above equation (Cannon and Roe, 1982) can also be used to calculate detectable animal or herd prevalence at the 95 percent confidence level, if the sample size is known. However, this equation assumes that a perfect test is used (100 percent sensitivity and specificity). This may result in an estimate of the detectable prevalence that is lower than the actual detectable level given a certain number of samples and desired confidence level.

The assumption of virtually 100 percent specificity for slaughter surveillance and CF tuberculin testing can be justified as follows. For slaughter surveillance, granulomatous lesions submitted to the laboratory are examined by histopathology to determine if they are compatible with TB.

Follow-up testing by polymerase chain reaction (PCR) is performed to determine if *Mycobacterium* TB complex organisms are present and a bacterial culture is performed to isolate *M. bovis* organisms. In the case of caudal fold tuberculin testing, if the initial CF screening test is positive, a series of follow-up tests are conducted to determine true disease status. An initial responder to the test will be subject to some or all of the following diagnostic tests: comparative cervical and/or gamma interferon tests, necropsy and histopathology of lesions, PCR, and bacterial culture. This battery of testing greatly reduces the likelihood of false positive results to be extremely low.

However, the sensitivity of slaughter surveillance and the CF test is important in the initial identification of animals requiring follow-up diagnostics to determine whether they are truly infected. Therefore, to estimate detectable animal or herd prevalence in this analysis, an equation for sample size to detect presence or absence of disease (Cannon, 2001) that accounts for slaughter or CF test sensitivity was employed:

$$n \approx \frac{[1 - (1 - CL)^{1/D}] \times [N - \frac{1}{2}(SeD - 1)]}{Se}$$

where

n = the number required to test or inspect

N = the population size (adult cattle, beef, dairy, mixed populations in the State)

D = the expected number of diseased individuals when prevalence is 0.05 percent
(i.e., $D = 0.05\% \times N$) (i.e., detectable prevalence level)

CL = the confidence level as a fraction (e.g. 0.95)

Se = the sensitivity of the test (e.g., 0.285 or 0.82). Reported estimates of slaughter and CF test sensitivity vary. A slaughter sensitivity of 28.5%¹ was used. A CF test sensitivity of 82% was chosen based on tabulated and combined reported results from multiple field trials. (Thoen, Steele, Gilsdorf, 2006).

Results

To assess whether current surveillance in AF States meets regulatory requirements, slaughter surveillance data and CF tuberculin testing data are analyzed separately. Then, slaughter and CF tuberculin data are combined for analysis of overall TB surveillance.

Slaughter surveillance

Table 3 summarizes the estimated validated adult slaughter surveillance conducted in FY 2007, and results for the estimated percent of adult cattle tested and detectable animal prevalence in AF States stratified by years of AF status. Totals for all U.S. cattle as well as VS Eastern Region

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).

(ER) and Western Region (WR) States are included. These are presented for comparison and include totals for all States (not limited to just AF States).

Table 3 – FY 2007 Adult Slaughter Surveillance of Cattle Originating in AF States

AF States	All Cows That Have Calved	Adult Cattle Slaughtered	Validated Adult Slaughter	Percent Adult Cattle Tested	Detectable Animal Prevalence
All (49)	37,759,300	4,496,301	4,276,882	11.3%	0.0003%
> 25 yrs (20)	11,845,800	1,558,774	1,482,706	12.5%	0.0007%
> 15 yrs (20)	14,343,500	1,518,810	1,444,692	10.1%	0.0007%
> 10 yrs (5)	5,010,000	316,862	301,399	6.0%	0.0035%
> 5 yrs (2)	810,000	119,332	113,509	14.0%	0.0090%
< 5 yrs (2)	5,750,000	982,523	934,576	16.3%	0.0011%
US Cattle	42,209,300	5,276,513	5,019,019	11.9%	0.0002%
ER	13,488,800	1,735,384	1,650,697	12.2%	0.0006%
WR	28,720,500	3,541,129	3,368,322	11.7%	0.0003%

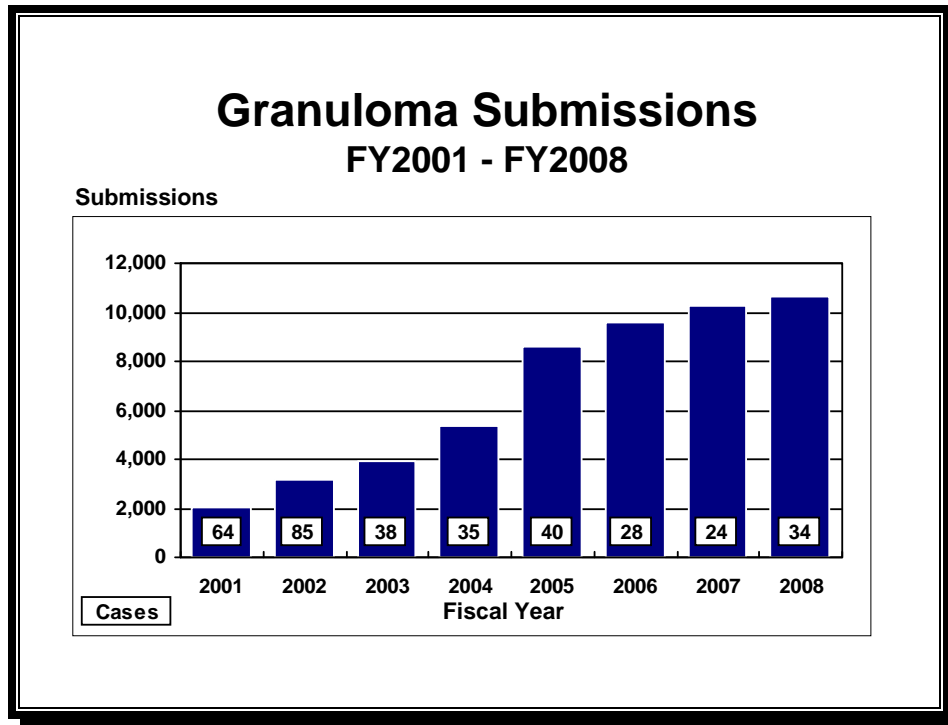
Validated adult slaughter

VS TB program analysts monitor submission rates using slaughter volume data by slaughter establishment, State, and class from the FSIS eARDS database, combined with laboratory granuloma submission data by slaughter establishment. Validated slaughter surveillance is defined for purposes of this analysis as those adult cattle slaughtered in plants that met the granuloma submission performance standard (submitted a minimum of 1 granuloma per 2,000 adult cattle slaughtered). According to FSIS data, 6,194,549 adult cattle were slaughtered in FY 2007. Across the United States, 5,892,252 adult cattle underwent validated slaughter surveillance. Nationally, 95.12 percent (5,892,252/6,194,549) of total adult cattle were slaughtered under validated slaughter surveillance in FY 2007.

To estimate the number of adult cattle slaughtered originating in AF States under validated slaughter inspection, AF State numbers of adult cattle slaughtered by origin State reported in annual VS 6-38 Reports were multiplied by the 95.12 percent national average (Tables 3-8).

Granuloma submission rates have been increasing since FY 2001 (Figure 2). Submissions have increased from 2,030 in FY 2001 to 10,666 in FY 2008. In FY 2007 a total of 8,523 granulomas were submitted from those establishments that slaughtered and inspected 6,194,549 adult cattle. Overall, 1 granuloma was submitted per 727 adult cattle slaughtered. The number of TB cases identified as a result of slaughter surveillance by fiscal year is shown in Figure 2 (range 24-85 cases).

Figure 2 – Granuloma Submission FY 2001 - 2008



Percent adult cattle tested

Percent of adult cattle (under validated slaughter surveillance) is the number of validated adult slaughter divided by the State's adult cattle population. Percent of adult cattle under validated slaughter inspection is underestimated (Tables 3-8). Some State VS 6-38 Reports were not available and reporting by other States was incomplete; thus total adult cattle slaughtered by State of origin from VS 6-38 Reports is less than the total of all adult cattle slaughtered in the United States in FY 2007 recorded in the FSIS eARDS database.

Detectable animal prevalence

Detectable animal prevalence (Table 3) can be estimated using the formula for sample size that incorporates test sensitivity (Cannon, 2001). Assuming 28.5 percent sensitivity of the slaughter surveillance, detectable animal prevalence can be derived with 95 percent confidence given that the population and sample size of adult cattle (adult cattle under validated slaughter inspection) are known.

Validated adult slaughter surveillance by individual AF States

Tables 4-8 show validated slaughter surveillance data for adult cattle by origin state from AF States stratified by number of years in AF status.

Table 4: FY2007 Adult Slaughter Surveillance of Cattle Originating from States with AF Status > 25 Years

AF States > 25 Yrs	All Cows That Have Calved	Adult Cattle Slaughtered	Validated Adult Slaughter	% Adult Cattle Tested
AZ	325,000	64,965	61,795	19.0%
CO	890,000	43,520	41,396	4.7%
CT	32,000	2,659	2,529	7.9%
DE	13,000	-	-	-
ID	870,000	201,645	191,805	22.0%
KS	1,580,000	178,421	169,714	10.7%
MD	122,000	-	-	-
ME	48,000	4,284	4,075	8.5%
MT	1,470,000	-	-	-
NC	500,000	206,732	196,643	39.3%
ND	1,050,000	136,895	130,215	12.4%
NH	22,000	1,787	1,700	7.7%
NJ	21,000	-	-	-
RI	2,800	1,963	1,867	66.7%
SC	230,000	7,649	7,276	3.2%
SD	1,890,000	256,014	243,521	12.9%
UT	450,000	15,873	15,098	3.4%
VI	-	-	-	-
WI	1,510,000	357,067	339,642	41.4%
WY	820,000	79,300	75,430	9.2%

Table 5 – FY2007 Adult Slaughter Surveillance of Cattle Originating from States with AF Status > 15 Years

AF States > 15 Yrs	All Cows That Have Calved	Adult Cattle Slaughtered	Validated Adult Slaughter	% Adult Cattle Tested
AK	5,500	287	273	5.0%
AL	770,000	-	-	-
AR	960,000	39,441	37,516	3.9%
GA	680,000	-	-	-
HI	85,000	8,423	8,012	9.4%
IA	1,190,000	200,986	191,178	16.1%
IL	560,000	67,342	64,056	11.4%
IN	380,000	31,209	29,686	7.8%
KY	1,200,000	54,916	52,236	4.4%
MA	27,000	6,186	5,884	21.8%
MO	2,200,000	45,249	43,041	2.0%
NE	2,000,000	229,959	218,737	10.9%
NV	265,000	31,445	29,910	11.3%
OH	540,000	77,000	73,242	13.6%
OR	710,000	15,870	15,096	2.1%
PA	740,000	432,920	411,794	55.6%
TN	1,150,000	38,107	36,247	3.2%
VT	166,000	31,394	29,862	18.0%
WA	500,000	185,576	176,520	35.3%
WV	215,000	22,500	21,402	4.3%

Table 6 – FY2007 Adult Slaughter Surveillance of Cattle Originating from States with AF Status > 10 Years

AF States > 10 Yrs	All Cows That Have Calved	Adult Cattle Slaughtered	Validated Adult Slaughter	% Adult Cattle Tested
FL	1,110,000	-	-	-
LA	520,000	45,549	43,326	8.3%
MS	610,000	43,313	41,199	6.8%
NY	750,000	228,000	216,874	28.9%
OK	2,020,000	-	-	-

Table 7 – FY2007 Adult Slaughter Surveillance of Cattle Originating from States with AF Status > 5 Years

AF States > 5 Yrs	All Cows That Have Calved	Adult Cattle Slaughtered	Validated Adult Slaughter	% Adult Cattle Tested
PR	-	42,000	39,950	-
VA	810,000	77,332	73,558	9.1%

Table 8 – FY2007 Adult Slaughter Surveillance of Cattle Originating from States with AF Status < 5 Years

AF States < 5 Yrs	All Cows That Have Calved	Adult Cattle Slaughtered	Validated Adult Slaughter	% Adult Cattle Tested
TX	5,750,000	982,523	934,576	17.8%

CF tuberculin skin testing

Multiple data sources were used to obtain CF tuberculin testing data. AWBDS was used as the primary source for number of CF tests performed. Before data is stored in the official AWBDS data repository, states must submit to a review and approval process for validating the data. In those instances where the number of CF tests was not available from AWBDS, GDB data or annual VS 6-38 Reports were used when available.

AWBDS lists the number of lots tested, in addition to the number of CF tests. This is the number of CF testing events that occurred. Because an individual herd is likely to be tested more than once, the number of lots tested overestimates the number of herds tested. To overcome this problem, GDB data were utilized. Queries of State GDBs for the number of distinct premises tested were run to obtain more accurate information on the number of herds tested.

Table 9 shows a summary of CF tuberculin testing in AF States stratified by years of AF status. Totals are included for all U.S. cattle as well as cattle in the VS regions. These are presented for comparison and include totals for all States (not limited to just AF states).

Table 9 – FY2007 Caudal Fold (CF) tuberculin testing in AF states

AF States	CF Tests	Responder Rate	Herds Tested	Lots Tested	% Cattle Tested	% Herds Tested	Mean Test Events/Herd
All (49)	746,639	0.88%	8,744	18,349	1.98%	0.90%	2.4
> 25 yrs (20)	358,738	0.92%	2,995	4,419	3.03%	1.42%	2.2
> 15 yrs (20)	226,614	0.69%	3,063	7,170	1.58%	0.67%	2.4
> 10 yrs (5)	57,476	1.37%	1,339	2,552	1.31%	1.22%	2.1
> 5 yrs (2)	14,215	0.13%	335	667	1.00%	0.68%	1.9
< 5 yrs (2)	89,596	0.98%	1,012	3,541	1.56%	0.67%	3.5
All US Cattle	1,212,455	1.19%	12,483	27,653	2.87%	1.21%	2.4
ER	515,883	1.84%	7,807	14,640	3.82%	1.63%	2.1
WR	696,572	0.96%	4,956	13,013	2.43%	0.87%	2.7

Detectable animal and herd prevalence

Detectable animal prevalence (Table 10) can be estimated using the formula for sample size that incorporates test sensitivity (Cannon, 2001). Assuming 82 percent sensitivity of the CF test, detectable animal prevalence can be derived with 95 percent confidence given that the population and sample size of adult cattle are known.

Crude estimates for detectable herd prevalence by length of time in AF status are given (Table 10). They are based on the number of herds tested and recorded in State GDBs and the number of herds per state from NASS data. Herd size data is not available in most cases; therefore the number of whole herd tests versus partial herd tests is unknown. Although estimates have uncertainty due to unavailability of herd size information, they are the best estimates available.

Table 10 – FY2007 Detectable Prevalence based on CF Test Sample Size with 82% CF test sensitivity and 95% confidence

AF States	All Cows That Have Calved	All Cattle And Calf Operations	CF Tests	Herds Tested	Detectable Animal Prevalence	Detectable Herd Prevalence
All (49)	37,759,300	975,910	746,639	8,744	0.0005%	0.042%
> 25 yrs (20)	11,845,800	211,380	358,738	2,995	0.0010%	0.120%
> 15 yrs (20)	14,343,500	455,030	226,614	3,063	0.0016%	0.120%
> 10 yrs (5)	5,010,000	132,500	39,707	1,258	0.0092%	0.289%
> 5 yrs (2)	810,000	26,000	31,984	416	0.0113%	0.870%
< 5 yrs (2)	5,750,000	151,000	89,596	1,012	0.0040%	0.360%
All US Cattle	42,209,300	1,050,910	1,212,455	12,483	0.0003%	0.029%
ER	13,488,800	478,980	515,883	7,807	0.0007%	0.046%
WR	28,720,500	571,930	696,572	4,956	0.0005%	0.073%

CF tuberculin testing by individual AF States

Tables 11-15 list FY 2007 caudal fold (CF) tuberculin testing data for individual AF States stratified by number of years in AF status.

Complete data were not available from all States. Availability depends on whether data are included in State GDBs, the AWBDS, and/or how data are reported in VS 6-38 annual reports.

Table 11 – FY2007 Caudal Fold (CF) tuberculin testing with AF Status > 25 Years

AF States > 25 Yrs	CF Tests	Responder Rate	Herds Tested	Lots Tested	% Cattle Tested	% Herds Tested	Mean Test Events/Herd
AZ	112,299	0.75%	-	-	34.52%	-	-
CO	123,624	0.76%	264	479	13.89%	1.81%	1.8
CT	4,579	0.13%	58	59	14.31%	4.83%	1.0
DE	-	-	-	-	-	-	-
ID	20,769	0.58%	155	495	2.39%	1.35%	3.2
KS	14,079	0.41%	242	569	0.89%	0.69%	2.4
MD	5,678	0.25%	239	548	4.65%	5.31%	2.3
ME	463	0.00%	44	88	0.96%	2.44%	2.0
MT	3,396	0.12%	109	286	0.23%	0.82%	2.6
NC	6,102	0.26%	185	299	1.22%	0.74%	1.6
ND	5,227	2.74%	47	165	0.50%	0.35%	3.5
NH	2,491	0.44%	175	199	11.32%	19.44%	1.1
NJ	290	1.38%	24	38	1.38%	1.41%	1.6
RI	963	2.91%	59	72	34.39%	29.50%	1.2
SC	2,730	1.03%	59	81	1.19%	0.54%	1.4
SD	12,836	1.50%	287	516	0.68%	1.47%	1.8
UT	7,873	0.10%	116	342	1.75%	1.45%	3.0
VI	-	-	-	-	-	-	-
WI	31,067	2.88%	821	2,066	2.06%	2.05%	2.5
WY	4,372	0.01%	111	172	0.53%	1.73%	1.5

Table 12 – FY2007 Caudal Fold (CF) tuberculin testing with AF Status > 5 Years

AF States > 15 Yrs	CF Tests	Responder Rate	Herds Tested	Lots Tested	% Cattle Tested	% Herds Tested	Mean Test Events/Herd
AK	2	-	-	-	0.04%	-	-
AL	2,837	0.07%	42	96	0.37%	0.16%	2.1
AR	4,835	0.43%	126	248	0.50%	0.42%	2.0
GA	20,293	1.92%	164	268	2.98%	0.75%	1.5
HI	3,032	1.48%	15	51	3.57%	1.82%	3.5
IA	40,148	0.67%	364	1,461	3.37%	1.04%	4.0
IL	6,648	0.71%	264	560	1.19%	1.10%	2.1
IN	9,306	1.81%	96	218	2.45%	0.48%	2.4
KY	16,582	0.05%	178	478	1.38%	0.38%	2.6
MA	1,602	0.69%	109	156	5.93%	9.08%	1.5
MO	31,123	0.47%	308	755	1.41%	0.46%	2.6
NE	8,907	0.61%	212	409	0.45%	0.82%	1.9
NV	1,671	0.66%	-	-	0.63%	-	-
OH	15,566	0.76%	203	568	2.88%	0.75%	2.8
OR	15,072	0.58%	220	474	2.12%	1.36%	2.1
PA	25,493	-	141	394	3.45%	0.50%	2.8
TN	5,638	0.50%	150	237	0.49%	0.29%	1.5
VT	2,779	1.12%	145	217	1.67%	4.83%	1.7
WA	11,776	0.96%	177	386	2.36%	1.18%	2.7
WV	3,304	0.15%	150	200	1.54%	1.15%	1.3

Table 13 – FY2007 Caudal Fold (CF) tuberculin testing with AF Status > 10 Years

AF States > 10 Yrs	CF Tests	Responder Rate	Herds Tested	Lots Tested	% Cattle Tested	% Herds Tested	Mean Test Events/Herd
FL	3,229	0.74%	51	103	0.29%	0.26%	1.7
LA	2,205	0.27%	61	162	0.42%	0.41%	2.7
MS	3,753	0.05%	31	87	0.62%	0.13%	2.2
NY	14,557	0.34%	509	1,125	1.94%	3.18%	2.2
OK	15,963	0.88%	606	935	0.79%	1.03%	2.1

Table 14 – FY2007 Caudal Fold (CF) tuberculin testing with AF Status > 5 Years

AF States > 5 Yrs	CF Tests	Responder Rate	Herds Tested	Lots Tested	% Cattle Tested	% Herds Tested	Mean Test Events/Herd
PR ¹	21,522	2.63%	112	227	-	-	2.0
VA	10,462	0.15%	304	580	1.29%	1.17%	1.9

1 – cattle animal and herd numbers not available from NASS data

Table 15 – FY2007 Caudal Fold (CF) tuberculin testing with AF Status < 5 Years

AF States < 5 Yrs	CF Tests	Responder Rate	Herds Tested	Lots Tested	% Cattle Tested	% Herds Tested	Mean Test Events/Herd
TX	89,596	0.98%	1,012	3,541	1.56%	0.67%	3.5

CF tuberculin testing by reason for testing and premises type

State GDBs were queried for CF tuberculin testing in AF States by reason for testing (Table 16) and by premises type (Table 17). Total CF tests shown are fewer than that shown for AF tuberculin testing above (Table 10). Table 10 includes additional CF tests reported via VS 6-38 Annual summary reports. VS 6-38 reports may include total CF tests conducted, but do not include by reason for testing or by premises type.

Table 16 shows CF tuberculin testing in AF States by reason for testing. Common reasons for CF testing include private sale (45.1 percent of herds tested, 33.5 percent of animals tested) and show (14.8 percent of herds tested, 9.3 percent of animals tested). Milk ordinance testing accounts for only 2.8 percent of herds tested, but 13.0 percent of animals tested. This reflects the smaller number of dairy herds overall, but larger average herd size for dairy animals.

Table 16 – FY2007 Caudal Fold (CF) tuberculin testing in States with AF Status by Reason for Testing

Reason for Testing	Herds Tested	% Herds Tested	CF Tests	% of CF Tests
Private Sale	3,940	45.1%	191,893	33.5%
Other	1,568	17.9%	108,719	19.0%
Milk Ordinance	242	2.8%	74,455	13.0%
Show	1,292	14.8%	53,390	9.3%
Herd Accreditation	557	6.4%	62,627	10.9%
Movement	490	5.6%	32,776	5.7%
Import	397	4.5%	35,718	6.2%
Export	66	0.8%	8,015	1.4%
Area	192	2.2%	4,386	0.8%
Total	8,744	100.0%	571,979	100.0%

CF tuberculin testing in AF States by premises type is shown in Table 17. Testing of dairy cattle predominates with approximately twice as many dairies tested as beef or mixed herds, and over half of all tests performed on dairy animals. Premises type could include dairy, beef, or mixed cattle. Of all CF testing, more than 90 percent was conducted on-farm; less than 10 percent was conducted at market or feedlots.

Table 17 – FY2007 Caudal Fold (CF) tuberculin testing in States with AF Status by Premises Type

Premises Type	Herds Tested	% Herds Tested	CF Tests	% of CF Tests
Dairy	3,767	43.1%	295,620	51.7%
Farm	2,346	26.8%	146,067	25.5%
Beef	1,987	22.7%	78,469	13.7%
Mixed	210	2.4%	9,919	1.7%
Sub Total On-Farm	8,310	95.0%	530,075	92.7%
Other	270	3.1%	24,058	4.2%
Market	41	0.5%	11,607	2.0%
Feedlot	123	1.4%	6,239	1.1%
Sub Total Other	434	5.0%	41,904	7.3%
Grand Total	8,744	100.0%	571,979	100.0%

Compliance with CF tuberculin performance standards

The UM&R, Appendix C, outlines performance standards for individuals administering caudal fold tuberculin tests. Each State must implement a system to monitor the response rate reported by each individual authorized to conduct official tuberculin tests (approximately 1 tuberculin responder per 300 tuberculin tests conducted is expected). Appropriate corrective action must be taken and documented if performance standards are not met.

For this analysis, VS 6-38 Accredited Area Surveillance for Tuberculosis Reports from 24 AF states were reviewed to assess the current status of tuberculin response rates and individual compliance with the performance standard.

States use multiple formats to report on monitoring of individual responder rates. Some States report responder rates for all individuals performing tuberculin tests; other States report only those individuals conducting more than 300 tests. These differences make direct comparisons between States difficult.

Of the 24 VS 6-38 State reports reviewed, 23 (95.8 percent) addressed the monitoring of veterinarians performing tuberculin testing in some fashion and indicated corrective actions taken. Overall, 68 percent of veterinarians were in compliance with performance standards, but this number is skewed by results in a few states with very good compliance. Seven States reported more than 50 percent of veterinarians are meeting the performance standard; one State reported 97 percent compliance; another State had 89 percent compliance. The remaining 17 States (71 percent) had less than 50 percent of veterinarians in compliance with the performance standard, and 5 States (20.8 percent) had zero veterinarians in compliance.

Most States are monitoring CF testing and taking follow-up corrective actions. Some States have shown improvements through these actions. Overall however, these data indicate an overall poor performance by individuals conducting CF tests. This may be due to lack of training, poor technique given the infrequency that some individuals perform CF testing, the level of subjectivity in interpreting the CF test responses, or other reasons.

Combined slaughter surveillance and CF tuberculin testing

The UM&R requires routine surveillance of cattle and bison in States or zones to maintain status. This consists of any combination of slaughter inspection and tuberculin testing sufficient to detect a prevalence of 0.05 percent or lower among cattle and bison in that State or zone with 95 percent confidence.

Table 18 shows a summary of the combined number of adult animals slaughtered under validated slaughter inspection and number of tuberculin tests conducted in AF States. Detectable animal prevalence is estimated at the 95 percent confidence level by combining total number of animals originating from a State under validated slaughter inspection (assuming 28.5 percent slaughter sensitivity) plus the number of tuberculin-tested animals in a State (assuming 82 percent test sensitivity). Totals for all U.S. cattle and VS Eastern and Western Regions (WR) are included. These are presented for comparison and include totals for all States (not limited to just AF States).

Table 18 – FY 2007 Adult Cattle TB Surveillance (slaughter and tuberculin testing)

AF States	All Cows That Have Calved	Validated Adult Slaughter	CF Tests	Total Adult Surveillance	% Adults Under Surveillance	Detectable Animal Prevalence
All (49)	37,759,300	4,276,882	746,639	5,023,521	13.3%	0.0002%
> 25 yrs (20)	11,845,800	1,482,706	358,738	1,841,444	15.5%	0.0004%
> 15 yrs (20)	14,343,500	1,444,692	226,614	1,671,306	11.7%	0.0005%
> 10 yrs (5)	5,010,000	301,399	39,707	341,106	6.8%	0.0025%
> 5 yrs (2)	810,000	113,509	31,984	145,493	18.0%	0.0050%
< 5 yrs (2)	5,750,000	934,576	89,596	1,024,172	17.8%	0.0009%
US Cattle	42,209,300	5,019,019	1,212,455	6,231,474	14.8%	0.0001%
ER	13,488,800	1,650,697	515,883	2,166,580	16.1%	0.0003%
WR	28,720,500	3,368,322	696,572	4,064,894	14.2%	0.0002%

Detectable animal prevalence

The equation for sample size to detect presence or absence of disease (Cannon, 2001) that accounts for test sensitivity is used to estimate the combined detectable animal prevalence for CF and validated slaughter surveillance testing for each beef and dairy herd-size strata. This requires a single test sensitivity for the two independent tests. To derive a single test sensitivity for combined CF and validated slaughter testing, the following formula is used:

$$Comb_{SE} = SE_L + (|SE_L - SE_H| * T_H/T_{Total})$$

Where

CombSE = combined test sensitivity for CF and validated slaughter testing, and

SE_L = sensitivity of the test with lower sensitivity, and

SE_H = sensitivity of the test with higher sensitivity, and

T_H = number of tests performed with the higher sensitivity test, and

T_{Total} = total number of tests performed with both tests

Example: *CombSE (all AF States)* = 0.285 + (|0.285 - 0.82| * 746,639/5,023,521) = 0.365 = 36.5%

Tables 19-23 include State-validated adult slaughter of animals and tuberculin testing stratified by number of years in AF status.

Table 19 – FY2007 Adult Cattle TB Surveillance (slaughter and tuberculin testing) States with AF Status > 25 Years

AF States > 25 Yrs	All Cows That Have Calved	Validated Adult Slaughter	CF Tests	Total Adult Surveillance	% Adult Cattle Under Surveillance
AZ	325,000	61,795	112,299	173,994	53.5%
CO	890,000	41,396	123,624	165,020	18.5%
CT	32,000	2,529	4,579	7,108	22.2%
DE	13,000	-	-	-	-
ID	870,000	191,805	20,769	212,574	24.4%
KS	1,580,000	169,714	14,079	183,793	11.6%
MD	122,000	-	5,678	5,678	4.7%
ME	48,000	4,075	463	4,538	9.5%
MT	1,470,000	-	3,396	3,396	0.2%
NC	500,000	196,643	6,102	202,745	40.5%
ND	1,050,000	130,215	5,227	135,442	12.9%
NH	22,000	1,700	2,491	4,191	19.0%
NJ	21,000	-	290	290	1.4%
RI	2,800	1,867	963	2,830	101.1%
SC	230,000	7,276	2,730	10,006	4.4%
SD	1,890,000	243,521	12,836	256,357	13.6%
UT	450,000	15,098	7,873	22,971	5.1%
VI	-	-	-	-	-
WI	1,510,000	339,642	31,067	370,709	24.6%
WY	820,000	75,430	4,372	79,802	9.7%

Table 20 – FY2007 Adult Cattle TB Surveillance (slaughter and tuberculin testing) States with AF Status > 15 Years

AF States > 15 Yrs	All Cows That Have Calved	Validated Adult Slaughter	CF Tests	Total Adult Surveillance	% Adult Cattle Under Surveillance
AK	5,500	273	2	275	5.0%
AL	770,000	-	2,837	2,837	0.4%
AR	960,000	37,516	4,835	42,351	4.4%
GA	680,000	-	20,293	20,293	3.0%
HI	85,000	8,012	3,032	11,044	13.0%
IA	1,190,000	191,178	40,148	231,326	19.4%
IL	560,000	64,056	6,648	70,704	12.6%
IN	380,000	29,686	9,306	38,992	10.3%
KY	1,200,000	52,236	16,582	68,818	5.7%
MA	27,000	5,884	1,602	7,486	27.7%
MO	2,200,000	43,041	31,123	74,164	3.4%
NE	2,000,000	218,737	8,907	227,644	11.4%
NV	265,000	29,910	1,671	31,581	11.9%
OH	540,000	73,242	15,566	88,808	16.4%
OR	710,000	15,096	15,072	30,168	4.2%
PA	740,000	411,794	25,493	437,287	59.1%
TN	1,150,000	36,247	5,638	41,885	3.6%
VT	166,000	29,862	2,779	32,641	19.7%
WA	500,000	176,520	11,776	188,296	37.7%
WV	215,000	21,402	3,304	24,706	11.5%

Table 21 – FY2007 Adult Cattle TB Surveillance (slaughter and tuberculin testing) States with AF Status > 10 Years

AF States > 10 Yrs	All Cows That Have Calved	Validated Adult Slaughter	CF Tests	Total Adult Surveillance	% Adult Cattle Under Surveillance
FL	1,110,000	-	3,229	3,229	8.8%
LA	520,000	43,326	2,205	45,531	0.4%
MS	610,000	41,199	3,753	44,952	7.4%
NY	750,000	216,874	14,557	231,431	30.9%
OK	2,020,000	-	15,963	15,963	0.8%

Table 22 – FY2007 Adult Cattle TB Surveillance (slaughter and tuberculin testing) States with AF Status > 5 Years

AF States > 5 Yrs	All Cows That Have Calved	Validated Adult Slaughter	CF Tests	Total Adult Surveillance	% Adult Cattle Under Surveillance
PR	-	39,950	21,522	61,472	-
VA	810,000	73,558	10,462	84,020	10.4%

Table 23 – FY2007 Adult Cattle TB Surveillance (slaughter and tuberculin testing) States with AF Status < 5 Years

AF States < 5 Yrs	All Cows That Have Calved	Validated Adult Slaughter	CF Tests	Total Adult Surveillance	% Adult Cattle Under Surveillance
TX	5,750,000	934,576	89,596	1,024,172	17.8%

Discussion

This analysis shows that current tuberculosis surveillance in AF States exceeds regulatory requirements to detect tuberculosis in adult cattle at 0.05 percent prevalence with 95 percent confidence for routine surveillance. In fact, the regulatory requirements are met by slaughter surveillance alone or by CF testing alone.

Despite meeting the regulatory standards, the data raise some concerns. While most individual States adequately monitor CF caudal fold responder rates, take corrective actions where necessary, and have demonstrated improvement in some cases, overall performance is poor. Of 24 State annual VS 6-38 reports reviewed, 71 percent reported less than 50 percent of veterinarians performing CF testing in compliance with the standard. This prompts questions regarding the validity of CF testing data.

Improvement of the data collection and storage system would greatly enhance the accuracy of conclusions in this assessment. Due to lack of standards for the type of data collected on tuberculin testing events and data storage issues, direct calculation of herd prevalence from the existing data is not possible. In this analysis, estimates of prevalence were achieved based on several assumptions about the data (e.g., number and frequency of herd tests, sensitivity of testing, number of animals retested, and extrapolation of data between GDB, AWBDS, and VS 6-38 reports)

Slaughter data is currently not maintained with CF testing data. It is compiled from multiple sources by program staff. An integrated data system would greatly enhance the ability to completely and effectively analyze the surveillance system.

Slaughter inspection has proven to be adequate on its own to meet animal-level regulatory standards. But how good is it at identifying disease when present? In other words, what is the slaughter sensitivity and what does slaughter surveillance imply about herd prevalence in AF States? These questions are addressed under objective 2, in the next section of this document.

Objective 2: What is the herd sensitivity of slaughter surveillance?

(i.e., What can detection of TB in individuals at slaughter tell us about TB herd prevalence in AF States?)

Effectiveness of slaughter surveillance

Emphasis on slaughter surveillance began in the 1950s. By that time, the prevalence of tuberculosis had been reduced to the point that routine area testing, or “down the road testing,” of herds had become costly and ineffective at identifying affected herds (Kaneene, Miller, Meyer, 2006). In addition, due to the poor sensitivity of diagnostic tests, many animals that responded to skin tests and were subsequently slaughtered for necropsy were found to have no gross lesions

present. This problem of “false positives” led to the culling of many apparently uninfected animals without confirming TB infection in the herd.

Slaughter surveillance continues to be the primary means of surveillance for tuberculosis, especially in most TB Accredited Free States. To validate that slaughter inspection for tuberculosis lesions is conducted carefully, the tuberculosis program requires submission of suspicious granulomatous lesions from slaughtered adult cattle at a rate of at least 1 granulomatous lesion per every 2,000 adult cattle or bison slaughtered.

In FY 2007, of the 594 federally inspected U.S. slaughter establishments, 508 slaughtered adult cattle. The top 40 adult cattle establishments are responsible for 95.7 percent of cows and bulls slaughtered annually. These top 40 slaughter plants are closely monitored for compliance with the granuloma submission standards. Of these 40 plants, 92.5 percent were in compliance with the validated slaughter standard in FY 2007. The rate of granuloma submissions was 1 per 756 cattle slaughtered, nearly 3 times higher than the standard requires.

The remaining 468 establishments that slaughter adult cattle are also subject to the granuloma submission standard. These plants represent only 4.35 percent of adult cattle slaughtered, but 98.5 percent of plants complied with the granuloma submission standard. For these plants, granulomatous lesions at a rate of 1 per 393 cattle slaughtered were submitted, a rate of more than 5 times higher than required by the standard. Given that many of the smaller plants slaughter a higher percentage of cull cows and bulls sent to slaughter for salvage, the higher submission rate in lower volume slaughter plants is consistent with processing higher risk cattle. Data are summarized below (Table 24).

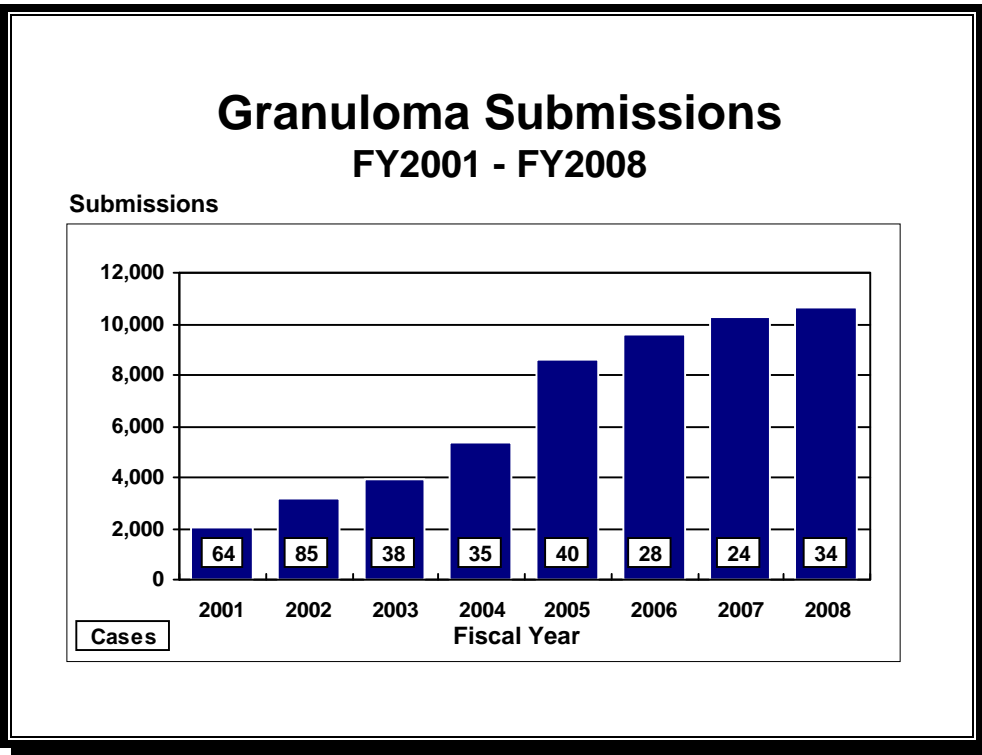
Table 24 – Adult Cattle Slaughter and Granuloma Submissions

	Adult Cattle Slaughter				Granuloma Submissions	
	No. Plants	Adult Cattle Slaughtered	% of Adult Slaughter	% Plants in Compliance	Number Submitted*	No. Slaughtered per Submission
Top 40 Adult Slaughter	40	5,924,852	95.65%	92.50%	7,836	756
Other Adult Slaughter	468	269,697	4.35%	98.50%	687	393
Total Adult Slaughter	508	6,194,549	100.00%	98.03%	8,523	727

* The number submitted from adult cattle slaughter establishments in Table 24 may include submissions from other than adult cattle (heifers, steers). Since reliable data identifying cattle sex and age from granuloma submissions is not available, the number of Adults Slaughtered per Submission may be underestimated (e.g., submission rates for adult cattle *only* are lower than shown in Table 24).

Slaughter surveillance has proven to be an effective case finding tool (Figure 2). It has resulted in identification of affected herds in cases where there has been successful traceback to the herd of origin, and disease in the herd can be confirmed with appropriate diagnostic testing. Routine slaughter surveillance of cattle originating from AF States has been demonstrated to meet current regulatory requirements of detecting prevalence of 0.05 percent or lower among a State’s or zone’s cattle and bison population with 95 percent confidence. Further, regulatory standards for submission of granulomatous lesions have been met or exceeded for > 95 percent of adult cattle slaughtered (i.e., standards that validate that slaughter inspections has been performed carefully).

Figure 2 – Granuloma Submission FY 2001 - 2008



Total granuloma submissions and number of TB cases detected (white boxes) by fiscal year. Includes both Mexican origin (87%) and domestic origin (11%) cattle.

Probability of detecting affected herds from slaughter surveillance

OIE guidelines for disease freedom allow for tuberculosis surveillance to be maintained through slaughter inspection alone provided *M.bovis* infection has not been detected for 5 consecutive years, as is the case in most AF status States. USDA-APHIS tuberculosis regulations for disease freedom (Accredited Free status), and other state or zone status (Modified Accredited Advanced, Modified Accredited, Accredited Preparatory etc.) are based on herd prevalence within a State or zone. OIE guidelines for adequate surveillance include both herd and animal level prevalence criteria. OIE guidelines state: “To initially establish a State or zone as free from tuberculosis, regular and periodic testing of bovine and bison herds must be conducted for 3 consecutive years without detecting *M. bovis* infection in at least 99.8 percent of herds (0.2 percent herd prevalence), and 99.9 percent of animals in the State or zone (0.1 percent animal prevalence). In addition, a surveillance program should be in place to detect bovine tuberculosis through antemortem and postmortem inspection.

Although both USDA and OIE regulations are based on herd level prevalence, herd level identification is not available for U.S. slaughter surveillance and inferences about herd prevalence cannot be directly calculated from current surveillance data. Therefore, in order to estimate herd prevalence of tuberculosis in Accredited-Free states, a statistical simulation model based on individual slaughter surveillance data was used.

Detection of an affected herd using slaughter surveillance requires a sequence of multiple steps; all must be successfully executed. If failure occurs at any step, an affected herd will go undetected. An infected animal must be culled and sent to slaughter, granulomatous lesions identified at slaughter inspection and submitted for laboratory testing, and the case identified as positive. The positive case (animal) must be traced to its herd of origin, where testing of herd mates would then confirm the herd as affected.

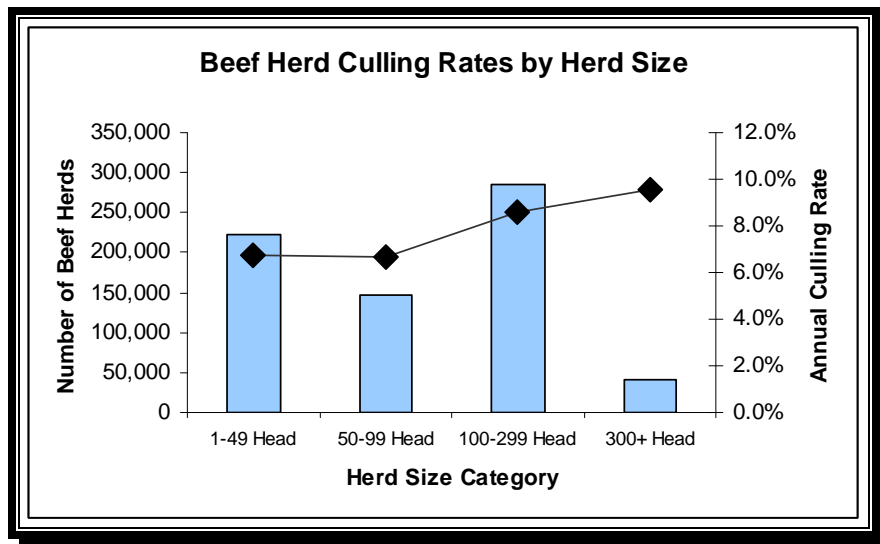
Herd sensitivity of slaughter surveillance is the conditional probability of detecting an affected herd, given it is affected, across one year of tuberculosis slaughter surveillance. Probabilities were estimated from available data and expert opinion for each step in the surveillance sequence. The herd sensitivity of slaughter surveillance was then estimated from:

- the annual culling rate,
- the within-herd prevalence of affected herds,
- the probability that visible lesions are present,
- the probability that lesions are observed at slaughter and submitted to the laboratory,
- the laboratory sensitivity of confirmatory tests,
- the probability of successfully tracing to the herd of origin, and
- the probability of confirming infection in the herd.

Annual culling rates

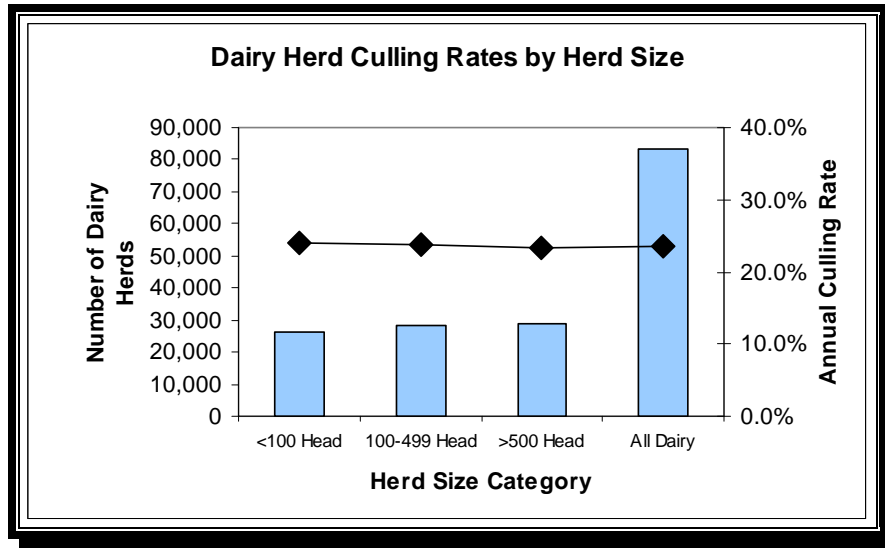
Beef herd culling rates vary more than dairy culling rates. Beef culling rates increase as herd size increases (NAHMS Beef 1997). This means that infected animals from the less frequently culled smaller beef herds are less likely to be detected at slaughter than animals from larger beef herds (Figure 3). Stratifying beef herds by size accounts for these different culling rates and allows for herd sensitivity estimates by herd size strata. For dairy herds, culling rates remain relatively constant for all dairy herd sizes (NAHMS Dairy 2007). (See dairy culling rates by herd size, Figure 4).

Figure 3 – Beef Herd Culling Rates by Herd Size



Number of Beef Herds (AF states); culling rates range from 6.7% to 9.5%

Figure 4 – Dairy Herd Culling Rates by Herd Size



Number of Dairy Herds (AF states); culling rate for all operations 23.6%; Range for various herd sizes (23.4% - 24.1%)

Increased likelihood of culling tuberculosis-infected cattle

Cull rates estimated from cattle production statistics under-represent the probability that an infected animal is culled from the herd for slaughter. It is reasonable to expect that tuberculosis-infected cattle are more likely than otherwise healthy cattle to be culled from the herd, particularly as disease progresses over time. Nevertheless, this is difficult to quantify due to the chronic nature of the disease and non-specific signs. Dairy production statistics (NAHMS Dairy 2007) suggest that culling for poor production reasons other than the most common disease reasons (e.g., mastitis, lameness, reproductive problems) is responsible for 16.1 percent of culls. Beef studies (NAHMS Beef 1997) report that nearly 90 percent of culling is due to old age and reproductive problems. They suggest that up to 12.9 percent of culling is due to reasons that may be compatible with tuberculosis. To estimate the effect of more likely culling of an infected animal, a conservative probability of 0.1 (10 percent) greater likelihood of culling an animal during its first year of infection given TB infection was used in the model (Tables 25, 26). For an infected animal that remains in the herd for two years following initial infection, a probability of 0.2 (20 percent) greater likelihood was used. For infected animals still in the herd three or more years after initial infection, 0.3 (30 percent) greater likelihood of culling was parameterized in the model.

Within-herd prevalence

To estimate within-herd prevalence for infected herds, the analysis used data compiled by VS tuberculosis program staff. Staff maintains a National Affected Herd spreadsheet, which includes data from 1998 to the present. Information collected on affected herds includes type (beef, dairy), and estimated numbers of infected animals and herd size. From this, estimates of a low, likely, and high herd prevalence by herd size strata were calculated. For model inputs,

distributions were derived for each herd size strata. Average within-herd prevalence estimates by herd size are included in Table 25 and Table 26.

Probability of tuberculosis detection by slaughter inspection

Probabilities for detection of tuberculosis by slaughter inspection consist of four elements. First, if an animal is infected with tuberculosis, is a visible lesion present? Secondly, will inspection personnel observe/identify the suspicious lesion? Third, will inspection personnel submit the lesion for laboratory diagnostics? Probabilities for these three actions have been investigated previously (Chioino 2003) by using an expert USDA panel to determine a low, likely, and high probability estimate for each step. The fourth element is whether validated slaughter inspection is being conducted as determined by granuloma submissions rates. As stated previously, in FY 2007, 95.12 percent of adult cattle were slaughtered under validated slaughter inspection. Tables 25 and 26 show average probability estimates for slaughter inspection parameters.

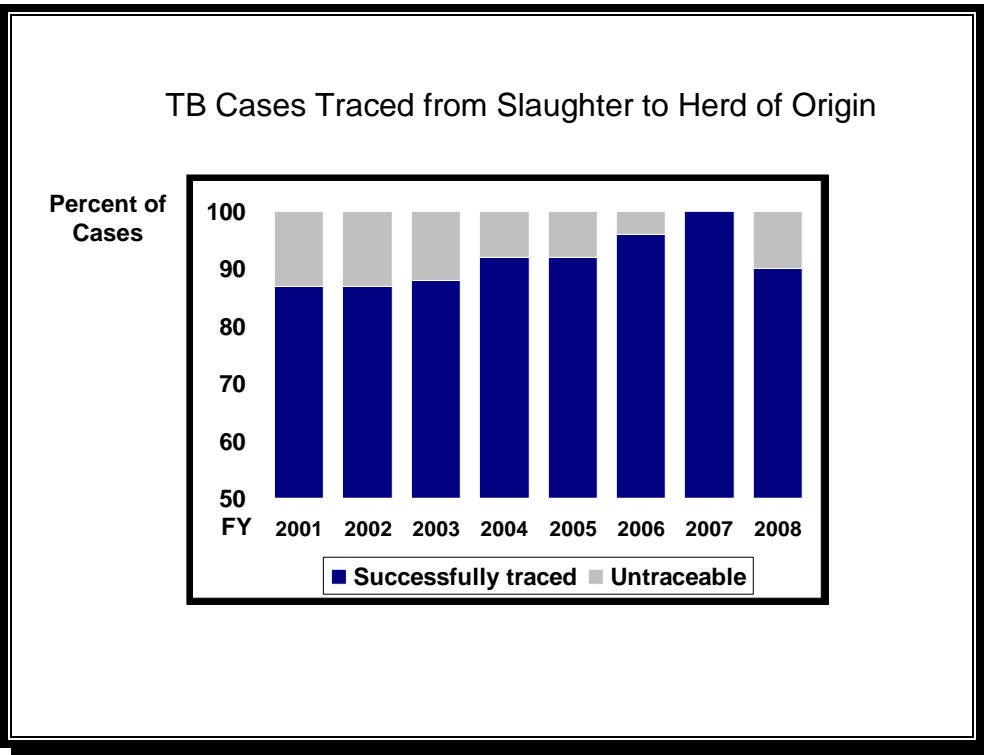
Probability of laboratory confirmation

Laboratory testing for tuberculosis consists of histopathology, PCR, and bacterial culture. Combined sensitivity and specificity estimates were used. Sources of this information included data from NVSL, regional/area studies, and previous investigations (Chioino 2003). Tables 25 and 26 show the sensitivity estimates.

Probability of successful traceback to herd of origin, confirmation of affected herds

TB cases identified at slaughter are traced to the herd of origin for further testing to confirm infection in the herd. Traceback to the herd of origin depends upon accurate record keeping and animal identification. National TB staff maintains spreadsheets on slaughter cases, which include the successful trace-backs from slaughter cases to the herd of origin. Percentage of successful tracebacks FY 2001 – FY 2008 has averaged 91.5 percent per year [range - 87 percent (FY 2001, FY 2002) to 100 percent in FY 2007] (Figure 5).

Figure 5 – Percent of Successful TB Tracebacks from Slaughter by Fiscal Year



National VS TB staff also tracks the number of herds confirmed as affected by follow-up testing of domestic herds traced from positive slaughter cases. For the period FY 2001 – FY 2008, of 21 slaughter cases traced to a domestic herd of origin, 14 affected herds were confirmed (0.6522 success). Probability estimates for successful traceback and confirmation of affected herds are shown in Table 25 and Table 26.

Summary of herd-level sensitivity model parameters

Animal-level and herd-level sensitivity from slaughter surveillance can be calculated using probability estimates by beef herd size (Table 25) and by dairy herd size (Table 26). Animal-level sensitivity is calculated $AnimalSens = 1 - (1-w*c*ct*l*d*s*v*se)^N$ where w = within-herd prevalence, c = culling rate, ct = increased probability of culling due to TB, l = probability of a visible lesion, d = probability of lesion detection by slaughter inspection, s = probability of lesion submission, v = probability of validated slaughter inspection, se = sensitivity of laboratory testing, and N = estimated herd size.

Herd-level sensitivity is calculated similarly to *AnimalSens* with two additional parameters. $HerdSens = 1 - (1-w*c*ct*l*d*s*v*se*t*a)^N$ where t = probability of successful trace-back to the herd of origin, and a = probability of confirming infection in the herd of origin.

Beef herd-level sensitivity model parameters

The probability of detecting an affected beef herd through a year of slaughter surveillance (Table 25) is lowest (3.2 percent) in small herds with 1-49 head. While within-herd prevalence is highest among this group, cull rates are lower than for larger herds. TB is less likely to be detected in these herds because fewer animals are sent to slaughter. For larger herds, herd sensitivity is fairly constant. As herd size increases, within-herd prevalence decreases. This is countered by the increased culling rates as herd size increases. Thus, the probability of detecting TB in larger herds is quite similar (7.2 – 8.3 percent).

Table 25. Necessary inputs (mean value of statistical model distributions) for calculation of herd-level sensitivity (probability of detection with a year of slaughter data) in AF states by Beef herd size.

	Beef Herd Size Category			
	1-49 Head	50-99 Head	100-499 Head	500+ Head
Estimated Herd Size (<i>N</i>)	15	64	200	950
Within-herd prevalence (<i>w</i>)	11.4%	8.9%	1.7%	0.42%
Cull Rate (<i>c</i>)	6.7%	6.7%	8.6%	9.6%
Increased likelihood TB culled (<i>ct</i>)*	10%	10%	10%	10%
p(Visible Lesion) (<i>l</i>)	75%	75%	75%	75%
p(Lesion Detected) (<i>d</i>)	80%	80%	80%	80%
p(Lesion Submitted) (<i>s</i>)	50%	50%	50%	50%
Validated Slaughter (<i>v</i>)	95.12%	95.12%	95.12%	95.12%
Lab sensitivity (<i>se</i>)	95%	95%	95%	95%
p(Traceback) (<i>t</i>)	91.6%	91.6%	91.6%	91.6%
p(Confirm Affected Herd) (<i>a</i>)	65.2%	65.2%	65.2%	65.2%
Animal-Level Sensitivity	5.3%	13.4%	11.6%	13.0%
Herd-Level Sensitivity	3.2%	8.3%	7.2%	8.1%

* TB infected animals were considered to be 10% more likely to be culled in the first year of infection; 20% more likely to be culled in the second year of infection; and 30% more likely to be culled if they remain in the herd for three or more years following infection

Dairy herd-level sensitivity model parameters

The probability of detecting an affected dairy herd through a year of slaughter surveillance (Table 26) increases as herd size increases. Within-herd prevalence is slightly higher in small herds (1-49 head), but similar among all herd size categories. With culling rates constant for all dairy herd size strata, the increased probability of detecting larger affected dairy herds is a function of sending more animals to slaughter, thus increasing the likelihood of detection.

Table 26. Necessary inputs (mean value of statistical model distributions) for calculation of herd-level sensitivity (probability of detection with a year of slaughter data) in AF States by Dairy herd size.

	Dairy Herd Size Category			
	1-49 Head	50-99 Head	100-499 Head	500+ Head
Estimated Herd Size (<i>N</i>)	25	65	200	950
Within-herd prevalence (<i>w</i>)	2.9%	1.4%	1.2%	2.1%
Cull Rate (<i>c</i>)	20.3%	20.3%	20.3%	20.3%
Increased likelihood TB culled (<i>ct</i>)*	10%	10%	10%	10%
p(Visible Lesion) (<i>l</i>)	75%	75%	75%	75%
p(Lesion Detected) (<i>d</i>)	80%	80%	80%	80%
p(Lesion Submitted) (<i>s</i>)	50%	50%	50%	50%
Validated Slaughter (<i>v</i>)	95.12%	95.12%	95.12%	95.12%
Lab sensitivity (<i>se</i>)	95%	95%	95%	95%
p(Traceback) (<i>t</i>)	91.6%	91.6%	91.6%	91.6%
p(Confirm Affected Herd) (<i>a</i>)	65.2%	65.2%	65.2%	65.2%
Animal-Level Sensitivity	7.4%	7.8%	19.1%	65.3%
Herd-Level Sensitivity	4.4%	4.6%	12.1%	50.6%

* TB infected animals were considered to be 10% more likely to be culled in the first year of infection; 20% more likely to be culled in the second year of infection; and 30% more likely to be culled if they remain in the herd for three or more years following infection

Herd-level prevalence in AF States implied by slaughter surveillance

TB national program staff maintains data on the number of cases and domestic herds detected annually via slaughter surveillance. Using the number of cases and herds detected for each beef and dairy herd size-strata over the last eight years of slaughter surveillance, estimates for herd level sensitivity of slaughter surveillance for each strata, and the estimated number of beef and dairy herds in each strata in AF States, we use a beta inverse function (Microsoft Xcel spreadsheet function) to estimate herd-level prevalence of tuberculosis by each beef and dairy herd size strata in AF States. The beta inverse function provides 95 percent confidence that herd prevalence estimates are at, or below calculated estimates. Results are shown in Table 27.

Table 27 - Herd-Level Prevalence Estimates by Beef and Dairy Herd Size Strata in AF States. There is 95% confidence that true herd prevalence is at, or below these estimates.

Herd Size Category	Beef Herd Prevalence	Dairy Herd Prevalence
1-49 Head	0.002%	0.034%
50-99 Head	0.004%	0.017%
100-499 Head	0.002%	0.023%
500+ Head	0.017%	0.041%

Beef herd-level prevalence in AF States

For beef cattle (Table 27), herd prevalence estimates range from 0.002 percent (herd size 1-49 head and 100-499 head) to 0.017 percent (herd size of 500 or greater head). All herd size strata exceed OIE disease freedom guidelines of adequate surveillance to detect disease at the 0.2 percent herd prevalence level.

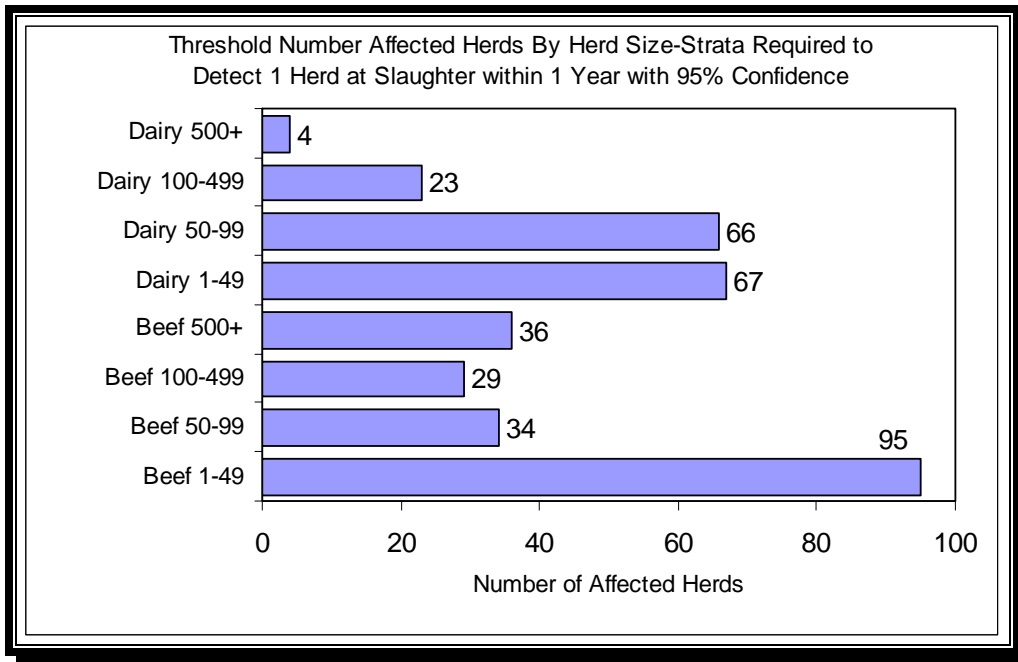
Dairy herd-level prevalence in AF States

Estimates for dairy cattle for each herd size strata are also shown (Table 27). Herd prevalence estimates range from 0.041 percent (herd size 500 or greater head) to 0.017 percent (herd size 50 – 99 head). All herd size strata comply with OIE disease freedom guidelines of adequate surveillance to detect disease at the 0.2 percent herd prevalence level.

Threshold number of affected herds for detection of tuberculosis at slaughter

Herd prevalence estimates for all beef and dairy herd size-strata in AF States are between 10 and 100 times lower than OIE guidelines for disease freedom in the absence of disease. Given this very low herd-level prevalence, and that zero affected herds from AF States have been detected through slaughter surveillance, how many herds must be TB-affected before slaughter surveillance will detect one in a year's time? We use a hypergeometric distribution to estimate this threshold. The hypergeometric distribution is based on the number of herds sampled, the herd-level sensitivity of slaughter surveillance, herd-level prevalence, and the number of herds in the population. Given that zero herds have been detected in AF States, we estimate how many TB affected herds must be present in each beef and cattle herd size strata before we are 95 percent confident that a year's slaughter inspection would detect at least one of the herds (Figure 6). For the largest dairy herds, we are 95 percent confident of detecting at least one herd in a single year of slaughter surveillance if there are at least four affected herds in the population. This concurs with estimates of a high herd-level sensitivity of slaughter surveillance for these herds. For the smallest dairy herd-size category (1-49 head), 95 affected herds would need to be present in the population for 95 percent confidence of detection of 1 herd during a year's slaughter surveillance.

Figure 6 – Number of Affected Herds in Each Herd Size-Strata Required for 95 percent Confidence in Detection of at least one in one year



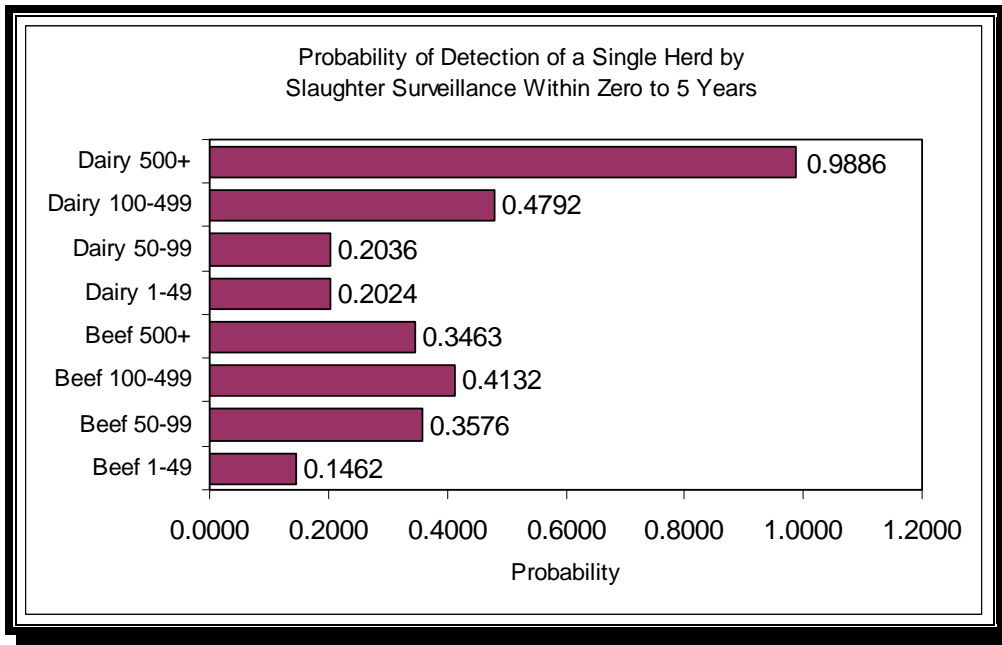
Probability of detection of a single affected herd within 5 years of slaughter surveillance

If we consider a single tuberculosis affected herd in a given herd size-strata, what is the probability of detection by slaughter inspection within zero to five years? This depends on many factors, including, within-herd prevalence, the number of animals culled to slaughter, and slaughter herd-level sensitivity as discussed above. The answer could be zero probability, if animals are not culled to slaughter, or slaughter inspection personnel don't submit granulomas for testing (non-validated slaughter inspection). However, from a statistical model we derive estimates for the probability of detection of a single affected herd within zero to five years of slaughter surveillance based on slaughter herd-level sensitivity estimates. As Figure 7 shows, the probability of detecting a single affected herd between zero to five years is highest in the largest dairy herds. The probability of detecting a single dairy affected dairy herd with 500 or greater head of cattle within zero to five years by slaughter surveillance is 0.9986 (98.86 percent). This is significantly higher than the probability of detecting very small sized dairy herds or beef herd of any size. This is intuitive as high dairy culling rates to slaughter, especially from large herds equate to more opportunity to detect infected individuals and confirm that the herd of origin is affected with tuberculosis.

It should be noted that these are estimates and may underestimate the probability of detection of a single affected herd in fewer than five years because the estimates used the same slaughter herd-level sensitivity for each year. In reality, slaughter herd-level sensitivity (i.e., probability of detection) would increase each year the herd is not detected due to the slow spread of disease within the herd and resulting increased within-herd prevalence. Estimates show that if tuberculosis-infected cattle remain in the herd, they may infect between 2.2 and 2.6 other cattle

annually (Barlow 1997, Perez, Ward 2002). Additionally, introduction of new disease exposure into a herd through replacement animals or contact with infected wildlife could increase within-herd prevalence and reduce the time for detection at slaughter. Intra-herd spread of tuberculosis and exposure from other sources was not considered in these probability estimates.

Figure 7 – Probability of detection of a single affect herd by slaughter surveillance in 5 years or less



Discussion

Tuberculosis Accredited Free status is based upon the number of affected herds, rather than individual animal prevalence in a State or zone. Because slaughter surveillance data are based on individuals instead of herds, this analysis uses a statistical model to derive distributions for herd-level slaughter sensitivity. From data on the number of affected herds detected through slaughter surveillance we estimate herd prevalence in Accredited Free States implied by slaughter surveillance. Because within-herd prevalence and culling rates to slaughter vary, this analysis stratified AF cattle populations by type (beef, dairy), and herd size.

Our analysis shows that of all AF cattle strata studied, the largest dairy herds (500 or greater head) have the highest estimated herd prevalence. We estimate with 95 percent confidence that the herd true herd prevalence is at, or below, 0.041 percent (i.e., at most four affected herds per 10,000 herds).

The current regulation, that maintaining AF State or zone status requires zero affected herds in the State or zone is not attainable without testing every animal/herd in the population. Even then, uncertainty would remain given the limitations of diagnostic tests. Regardless of surveillance strategy, it is not possible to say with certainty that zero diseased herds exist in a cattle population. Furthermore, AF state or zone status requirements do not take into account the number of herds in a State or zone. The identification of two epidemiologically unrelated

affected herds can result in loss of AF status for the State or zone regardless of whether the State or zone has 500 herds or 200,000 herds.

Perhaps a more appropriate way to address AF status is to consider the following questions. Given the absence of detection of disease, what level of surveillance constitutes disease freedom for a State or zone? Even for the largest dairy herds (500 or greater head), estimated herd prevalence is 10 times below the herd prevalence detection level suggested by OIE disease freedom guidelines in the absence of disease (0.2 percent herd prevalence).

Is 10 times below the detectable herd prevalence level needed for OIE disease freedom guidelines an adequate level of surveillance to meet future TB program needs? Does declaring disease freedom in the absence of disease meet a TB program goal, even knowing that some low level of undetected disease may be present? Ultimately, the answers depend upon whether we seek a TB control or eradication program, and, as importantly, how we define these terms.

Slaughter surveillance is most effective in detecting tuberculosis in large sized dairy herds. For large dairy herds with more than 500 head, it takes only four tuberculosis affected herds in the population before there is 95 percent confidence that at least one will be detected in one year of slaughter surveillance; the probability of detecting a single large tuberculosis affected dairy herd with zero to five years of slaughter surveillance is 98.86 percent. This has potential implications on the development of future policies for managing disease in these large dairy herds.

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Appendix A

A flow diagram showing the sequence of events that a TB infected animal must follow to be detected by slaughter surveillance is shown below. A simulation model using Microsoft Excel and Palisade AtRisk simulation software was used to estimate the probability of detection given each of the events described in the tree. Each probability was modeled using best available data and expert opinion to inform probability distributions (RiskPert distributions). The probability of detection given the surveillance nodes is defined as the surveillance sensitivity.

Appendix A – Probability Likelihood Diagram of TB Detection via Slaughter Surveillance

