



OCT 05 2009

United States
Department of
Agriculture

VETERINARY SERVICES MEMORANDUM NO. 552.38

Animal and Plant
Health Inspection
Service

TO: Veterinary Services Management Team (VSMT)

Veterinary
Services

FROM: John R. Clifford
Deputy Administrator
Veterinary Services

Washington, DC
20250

SUBJECT: Discretionary Bovine Tuberculosis Herd Prevalence Calculations
in States or Zones with Small Numbers of Herds

I. PURPOSE

This memorandum outlines the bovine tuberculosis (TB) regulations as defined in title 9 of the *Code of Federal Regulations* (9 CFR) regarding prevalence requirements for TB status levels of States or zones. At the Administrator's discretion, exceptions to the defined prevalence levels are allowed but such allowances are constrained. The Administrator has the discretion to allow up to the maximum number of affected herds for a smaller State or zone provided that the State complies with all other criteria. This policy provides a State or zone the maximum allowable number of affected herds, within reason, to maintain or advance the status level.

II. CANCELLATION

Veterinary Services (VS) Memorandum 552.38 dated March 7, 2008, is hereby canceled.

III. BACKGROUND

Specific guidelines are used by VS to determine the maximum allowable number of affected herds within modified accredited advanced (MAA) States or zones with fewer than 30,000 herds, modified accredited (MA) States or zones with fewer than 10,000 herds, accreditation preparatory (AP) States or zones with fewer than 5,000 herds, and the time intervals applied by the Administrator to determine bovine TB herd prevalence levels.

- A. The herd prevalence requirements for relevant status levels in 9 CFR, part 77.5 are summarized as follows:

MAA: "A State or zone...in which tuberculosis has been prevalent in less than 0.01 percent of the total number of herds of cattle and bison in the State or zone...Except that: The Administrator...may allow a State or zone with fewer than 30,000 herds to have up to 3 affected herds for each of the most recent 2 years..."



Safeguarding American Agriculture

APHIS is an agency of USDA's Marketing and Regulatory Programs
An Equal Opportunity Provider and Employer

Federal Relay Service
(Voice/TTY/ASCII/Spanish)
1-800-877-8339

VETERINARY SERVICES MEMORANDUM NO. 552.38

Page 2

MA: "A State or zone...in which tuberculosis has been prevalent in less than 0.1 percent of the total number of herds of cattle and bison in the State or zone...Except that: The Administrator...may allow a State or zone with fewer than 10,000 herds to have up to 10 affected herds for the most recent year..."

AP: "A State or zone...in which tuberculosis is prevalent in less than 0.5 percent of the total number of herds of cattle and bison in the State or zone."

- B. In general, the requirement to maintain complete freedom from infection within a State or zone should be reserved for accredited-free status; therefore, some allowance for infection should be maintained for status levels lower than accredited-free. The discretionary maximum prevalence thresholds have been included in 9 CFR because States or zones with smaller numbers of herds could not meet the specific prevalence requirements without achieving complete eradication of TB-affected herds.

The status of a State or zone based on prevalence alone is overly restrictive because smaller States or zones must continuously find zero infected herds to maintain their status, while larger States or zones may identify affected herds without the threat of losing their status.

- C. Regulations for TB do not provide exceptions to the defined prevalence level for an AP State or zone; however, the concept of herd-years is extended to include AP States or zones with fewer than 5,000 herds because strict application of the prevalence rate may penalize small States or zones with active programs when TB is found in a sufficient number of herds, and exceeds the allowable prevalence rate. By applying the concept of herd-years to AP States or zones, allowance is made for these active programs and rapid depopulation of affected herds is encouraged.

The prevalence requirement for AP States or zones implies an absolute lower limit to the number of herds within a State or zone. Based solely on prevalence, if a State or zone has fewer than 201 herds it could not qualify as AP unless it maintained absolute freedom of affected herds. By extending the concept of herd-years to AP States or zones and maintaining a time-weighted herd prevalence of less than 1 percent, the lowest acceptable limit to the number of herds within an AP State or zone is 101 herds.

D. Definitions

- States and zones with large numbers of herds are defined as greater than or equal to 30,000 herds for MAA States and zones, greater than or equal to 10,000

VETERINARY SERVICES MEMORANDUM NO. 552.38

Page 3

herds for MA States and zones, and greater than or equal to 5,000 herds for AP States and zones.

- States and zones with small numbers of herds are defined as fewer than 30,000 herds for MAA States and zones, fewer than 10,000 herds for MA States and zones, and fewer than 5,000 for AP States and zones.

IV. CONDITIONS

- A. In no instance can an MAA State or zone with fewer than 30,000 herds have more than three newly disclosed affected herds for each of the most recent 2 years. Disclosure of more than three newly affected herds in any continuous 12-month period during the previous 2 years will result in the removal of a State or zone from the list of MAA States or zones and the State or zone will be reclassified as MA. This limit of three newly disclosed affected herds will remain applicable in the event that all newly affected herds have been depopulated in fewer herd-years than allowable for small MAA States or zones.
- B. In no instance can an MA State or zone with fewer than 10,000 herds have more than 10 newly disclosed affected herds in any continuous 12-month period. Disclosure of more than 10 newly affected herds in any continuous 12-month period will result in the removal of a State or zone from the list of MA States or zones and the State or zone will be reclassified as AP. This limit of 10 newly disclosed affected herds remains applicable in the event that all newly affected herds have been depopulated in fewer herd-years than allowable for small MA States or zones.
- C. In no instance can an AP State or zone with fewer than 5,000 herds have more than 25 newly disclosed affected herds in any continuous 12-month period. Disclosure of more than 25 newly affected herds in any continuous 12-month period will result in the removal of a State or zone from the list of AP States or zones and the State or zone will be reclassified as nonaccredited (NA). This limit of 25 newly disclosed affected herds remains applicable in the event that all newly affected herds have been depopulated in fewer herd-years than allowable for small AP States or zones.
- D. This discretionary prevalence calculation only applies to States or zones that have completed an official program review and are found to have an active, official TB program in place.
- E. To qualify for MAA status, any size State or zone may be allowed at least one affected herd.

VETERINARY SERVICES MEMORANDUM NO. 552.38

Page 4

- F. Smaller States or zones must maintain fewer affected herds and a lower prevalence than the maximum allowable for the next lower status. While there is no maximum allowable prevalence for NA States or zones, a time-weighted herd prevalence of 1 percent is used as the maximum allowable for the determination of herd-year calculations for AP States or zones. This policy ensures that herd prevalence in an MAA or MA State or zone is not greater than the maximum allowed for the next lower status. If an MAA or MA State or zone is downgraded because it exceeds the maximum allowable number of affected herd-years, it may still qualify for the next lower status.
- G. VS acknowledges that States may prefer to establish zones of various sizes; therefore, States applying for zoning or split-State status must follow the requirements outlined in VS Memorandum 552.44.

In cases where the Administrator's discretionary authority is used for zones with small numbers of herds, the maximum allowable number of affected herds or herd-years to maintain or advance in status will be specified as part of the required Memorandum of Understanding for zone recognition.

V. HERD PREVALENCE CALCULATIONS AND THRESHOLDS

- A. Discretionary Prevalence for States or Zones with Small Numbers of Herds
 - 1. A time-weighted average prevalence calculation may be used. This method calculates prevalence based on the fraction of a year each affected herd existed in a State or zone summed across all affected herds in that State or zone. For example, if two affected herds existed in a State during a consecutive 12-month period and one herd was depopulated 6 months after being detected, it would contribute 0.5 herd-years (6 affected herd months/12 months). If the second herd was present in the State for the entire year, that herd would contribute 1 affected herd-year (12 affected herd months/12 months). The total number of affected herd-years would be 1.5 for that State.

A herd-month is defined as any month (or any part of a month) an affected herd is present in a State or zone. One herd-month equals 1/12 of a herd-year. The timeframe for calculation of herd-months begins with the month that the laboratory report is generated (indicating histopathology-compatible or suggestive findings) and ends with the month that the herd is depopulated or the last required negative herd test is conducted.

VETERINARY SERVICES MEMORANDUM NO. 552.38

Page 5

Only herd-years or herd-months will be used when determining the status of States or zones with small numbers of herds. Time units other than herd-years or herd-months (e.g., herd-weeks or herd-days) are not allowed.

The time-weighted average reduces the influence of increased numbers of affected herds for smaller States and zones. The total affected herd-years for a specific State is reduced whenever an affected herd is rapidly depopulated. Using a time-weighted average prevalence calculation reduces the inequity that occurs between areas when newly affected herds occur in areas with large numbers of herds versus areas with small numbers of herds. An area with larger herd numbers has a greater buffer between its current status and one where the status is threatened. In contrast, the status of the smaller State or zone can change dramatically by the occurrence of one additional affected herd.

2. Maximum time-weighted prevalence thresholds: The maximum allowable number of affected herd-years for small MAA, MA, and AP States or zones of various sizes is shown in Table 1. For MAA status, a maximum of three affected herd-years is allowed. Previously affected herds can be carried over even though a State or zone cannot have more than three newly affected herds per year. Each affected herd that has not been depopulated (i.e., carried over) will reduce the total allowable herd-years by 1/12 (1 herd-month) for each month (or part of a month) that the herd remains on the premises of disclosure.
3. Strict adherence to the time-weighted prevalence measure may result in unacceptable risk if the incidence of newly affected herds in small States or zones is completely ignored. Therefore, the number of newly detected herds supersedes the time-weighted prevalence in all circumstances. For small MAA States or zones, no more than three newly affected herds can be detected during any consecutive 12-month period during the previous 2 years. For small MA States or zones, no more than 10 newly affected herds can be detected during any consecutive 12-month period; and for small AP States or zones, no more than 25 newly affected herds can be detected during any consecutive 12-month period. These limits prevent a State or zone from maintaining MAA, MA, or AP status when there is evidence of a substantial incidence of newly affected herds.

B. Prevalence Calculations for States and Zones with Large Numbers of Herds

1. The Administrator uses *period* prevalence—not *point* prevalence—to determine a State or zone's status for States and zones with either large or small numbers of herds. The timeframes used for calculating this period prevalence are not established based on calendar or fiscal years. Restricting the calculation of period prevalence by using such set timeframes may artificially reduce the calculated prevalence and misrepresent the extent of disease present within a region by only counting the herds that have accumulated since the beginning or end of a calendar or fiscal year.
2. Herd prevalence is calculated by dividing the number of affected herds that existed in the State or zone during any consecutive 12-month period by the total number of herds in the State or zone for the same consecutive 12-month period. For States or zones with large numbers of herds, the change in prevalence is small for a minor change in the number of affected herds. For example, a zone with 90,000 herds and 80 affected herds has a herd prevalence of 0.09 percent. This zone qualifies as MA status.
3. Prevalence thresholds: The prevalence thresholds for status levels are defined in 9 CFR, part 77.5.

VETERINARY SERVICES MEMORANDUM NO. 552.38

Page 7

Table 1: Maximum numbers of affected herd-years allowed for MAA States or zones with fewer than 30,000 herds, MA States or zones with fewer than 10,000 herds, and AP States or zones with fewer than 5,000 herds.

Number of herds in State or zone	MAA max herd years ¹	Herd prev (%)	MA max herd years ²	Herd prev (%)	AP max herd years ³	Herd prev (%)
29,999	3	0.0001				
20,000	3	0.0150				
10,000	3	0.0300	10	0.1000		
9,000	3	0.0333	10	0.1110		
8,000	3	0.0375	10	0.1250		
7,000	3	0.0429	10	0.1430		
6,000	3	0.0500	10	0.1670		
5,000	3	0.0600	10	0.2000	25	0.5000
4,000	3	0.0750	10	0.2500	25	0.6250
3,000	2	0.0667	10	0.3330	25	0.8333
2,000	1	0.0500	8	0.4000	19	0.9500
1,500	1	0.0667	6	0.4000	14	0.9333
1,001	1	0.0999	4	0.4000	9	0.8991

1. In no instance can an MAA State or zone of fewer than 30,000 herds have more than three newly disclosed affected herds during any consecutive 12-month period for each of the most recent 2 years and retain MAA status.
2. In no instance can an MA State or zone of fewer than 10,000 herds have more than 10 newly disclosed affected herds in any continuous 12-month period year and retain MA status.
3. In no instance can an AP State or zone of fewer than 5,000 herds have more than 25 newly disclosed affected herds in any continuous 12-month period and retain AP status.

The policy outlined herein is consistent with APHIS regulations and provides a balance between conservatively classifying States or zones based solely on prevalence and allowing large numbers of affected herds to exist within States or zones based solely on herd-years. The regulations further state that the Administrator's discretion depends upon the "...veterinary infrastructure, livestock demographics, and tuberculosis control and eradication measures in the State or zone"; therefore, the maximum number of affected herd-years may be adjusted down from the levels included in this Memorandum for States or zones with questionable TB control.