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United States
Department of
Agriculture

VETERINARY SERVICES MEMORANDUM NO. 552.38

Animal and Plant
Health Inspection
Service

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

Veterinary
Services

TO: VS Management Team
Directors, VS

Washington, DC
20250

I. PURPOSE

The purpose of the memorandum is to update the tuberculosis (TB) regulations, as set forth in Title 9, *Code of Federal Regulations* (9 CFR), define the prevalence requirements for the different status levels of States or zones. The prevalence requirements are qualified for States or zones that contain fewer than 30,000 herds, in the case of modified accredited advanced States or zones; or fewer than 10,000 herds, in the case of modified accredited States or zones. At the Administrator's discretion, exceptions to the defined prevalence levels are allowed, but such allowances are constrained.

II. GENERAL

This memorandum outlines how Veterinary Services determines the maximum allowable number of affected herds within States or zones with fewer than 30,000 herds.

III. BACKGROUND

- A. Briefly, the prevalence requirements for relevant status levels are specified in 9 CFR, part 77.5 as follows:
1. Modified Accredited Advanced (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...**”
 2. Modified Accredited (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...**”



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3. Accreditation Preparatory (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. The exceptions **in bold** were included in the regulations because smaller States or zones could not meet the specific prevalence requirement without achieving complete eradication of TB affected herds. For example, a State or zone with 5,000 herds could not achieve the MAA status unless it reported zero affected herds (i.e., just one affected herd would result in a calculated herd prevalence of 0.02 percent, which is greater than the 0.01 percent required). Furthermore, a State or zone with 30,000 herds could only have one or two affected herds because the calculated prevalence with three affected herds (0.01 percent) is not *less than* 0.01 percent.

In general, the requirement to maintain complete freedom of infection within a State or zone should be reserved for the Accredited-Free status. Therefore, some allowance for infection should be maintained for status levels lower than Accredited-Free. If we compare a MAA State or zone with 50,000 herds to a similar State or zone with 8,000 herds, by prevalence alone is too restrictive because the smaller State or zone must continuously find zero infected herds to maintain its MAA status, while the larger State or zone could have 4 affected herds without threat of losing its MAA status. The exception in the regulation serves to avoid this inequity.

One important note: The regulations do not provide for exceptions in AP States or zones. Therefore, States or zones that cannot meet the specific prevalence requirement for this status level (i.e., less 0.5 percent, or less than one infected herd per 200 herds) must be classified Non-Status States or zones.

The definition for AP States or zones also establishes an absolute lower limit to the number of herds within a State or zone, effective on the date of this memorandum. If a State or zone were to have fewer than 201 herds, it could never qualify as AP unless it maintained absolute freedom of affected herds. Nevertheless, assuming a minimum of 201 herds will constrain MA and MAA States or zones to maintain freedom of infection.

III. CONDITIONS

- A. Previously approved zones with fewer than 201 herds will continue to be approved.
1. This discretionary prevalence calculation only applies to a State or zone that has had an official active tuberculosis eradication program in place for a minimum of 10 years.

2. To qualify for MAA status, any size State or zone would be allowed at least one affected herd.
 3. Smaller States or zones must maintain fewer affected herds, and a lower prevalence, than the maximum allowable for the next lower status. This rule ensures that,
 - a. herd prevalence in a State or zone is not greater than the maximum allowed for the next lower status, and
 - b. if a State or zone is downgraded because it exceeds the maximum allowable number of affected herds, it can still qualify for the next lower status.
- B. The Administrator has the discretion to allow up to a maximum of 10 affected herds within MA States or zones, but he or she is only allowed up to 3 affected herds within MAA States or zones. The Administrator will allow the maximum discretion, provided States comply with all other criteria. This gives States or zones the maximum allowable number of affected herds, within reason, to maintain or advance their status level.

In States or zones with large numbers of herds, the herd prevalence is calculated by dividing the number of affected herds that existed in the State or zone during any part of the year by the total number of herds in the State or zone. Given a large number of herds, the change in prevalence is small for a small change in the number of affected herds. In States or zones with small numbers of herds, small changes in the number of affected herds can substantially change the prevalence.

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. Similarly, a zone with 9,000 herds and 8 affected herds has a herd prevalence of 0.09 percent. This zone also qualifies as MA. However, if the smaller zone experiences just one more affected herd, its herd prevalence exceeds the threshold for an MA zone. In contrast, the larger zone can experience 9 more affected herds and still maintain its MA status. The larger zone, therefore, has a greater buffer between its current situation and a situation where its status is threatened. In contrast, the smaller zone's status can change dramatically simply by the occurrence of one more affected herd. The magnified effect of an increased number of affected herds in smaller zones creates an inequitable situation that should be addressed in our analysis.

To address this potential inequity, the number of affected herds in smaller zones is calculated using a time-weighted average. The number of affected herd-years is 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 the year, and one of these was depopulated after 6 months (0.5 herd-years) while the other was maintained throughout the year (1 herd-year), then the number of affected herd-years would be 1.5 for that State.

The time-weighted average reduces the influence of increased numbers of affected herds for smaller States or zones and corrects the inequity identified above. The total affected herd-years for a specific State is reduced whenever an affected herd is rapidly depopulated.

IV. SPECIFIC INSTRUCTIONS

- A. The maximum allowable number of affected herd-years for MAA, MA, and AP States or zones of various sizes is outlined in Table 1. For the MAA status, a maximum of 3 affected herd-years are allowed. If the calculated herd prevalence is less than 0.1 percent, this means that even though a State or zone cannot have more than three newly affected herds per year, previously affected herds can be carried over. However, this reduces the total number of affected herd years (3 years or 36 months) allowed each month for those herds classified as affected.
 1. Note that for MAA States or zones with 1,001 herds, one affected herd-year equates to a herd prevalence of nearly 0.1 percent. Nevertheless, the calculated herd prevalence is below the herd prevalence threshold for the next lower (i.e., MA) status.
 2. For the MA status, a maximum of 10 newly affected herds and 10 affected herd-years is allowed. Note, that if a zone with only 1,001 herds has 5 affected herd-years, then it must be downgraded to AP status. As a result of this downgrade, this State or zone meets the requirements for AP status (i.e., a maximum of 5 affected herd-years allowed).
- B. Strict adherence to this time-weighted prevalence measure could result in unacceptable risk, if the incidence of newly affected herds in these small States or zones is ignored. Therefore, to mitigate the risk of transmitting TB from a smaller State or zone, a limited number of newly affected herds may be detected during a given year to maintain the MAA and MA status levels. For small MAA States or zones, no more than three newly affected herds can be detected during a 1-year period. For small MA States or zones, no more than 10 newly affected herds can be detected during a 1-year period. These limits prevent a State or zone from maintaining MAA or MA status despite evidence of a substantial incidence of newly affected herds.

Table 1. Maximum numbers of affected herd-years allowed within Modified Accredited Advanced (MAA) States/zones with 1,000 to 30,000 herds or Modified Accredited (MA) States/zones with 1,000 to 10,000 herds; except that MAA States/zones are allowed no more than three newly affected herds in a year and MA States/zones are allowed no more than 10 newly affected herds in a year.

Number of herds in State or zone	Max herd-years MAA	Herd Prev	Max herd-years MA	Herd Prev	Max herds AP	Herd Prev
29,999	3	0.0100%			149	0.4967%
20,000	3	0.0150%			99	0.4950%
10,000	3	0.0300%	10	0.100%	49	0.4900%
9,000	3	0.0333%	10	0.111%	44	0.4889%
8,000	3	0.0375%	10	0.125%	39	0.4875%
7,000	3	0.0429%	10	0.143%	34	0.4857%
6,000	3	0.0500%	10	0.167%	29	0.4833%
5,000	3	0.0600%	10	0.200%	24	0.4800%
4,000	3	0.0750%	10	0.250%	19	0.4750%
3,000	2	0.0667%	10	0.333%	14	0.4667%
2,000	1	0.0500%	8	0.400%	9	0.4500%
1,500	1	0.0667%	6	0.400%	7	0.4667%
1,001	1	0.0999%	4	0.400%	5	0.4995%

This policy is consistent with published regulations, and it strikes a balance between conservatively classifying States or zones and allowing large numbers of affected herds to exist within States or zones.

It is important to note that the regulations further explain that the Administrator’s discretion depends on the “veterinary infrastructure, livestock demographics, and tuberculosis control and eradication measures in the State or zone.”

For States or zones with questionable TB control, the maximum number of affected herd-years will be adjusted down from the levels included in this memo.

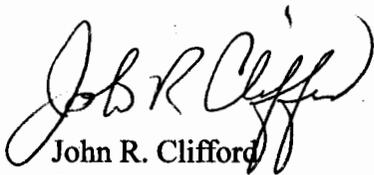
Effective as of the date of this memorandum, the minimum size of States or zones must be greater than 1,000 herds. If a State or zone contains 1,000 or fewer herds, then the constraint of allowing one affected herd-year in MAA zones conflicts with the rule that the prevalence in such States or zones should be less than the allowable prevalence in the next lower status level (i.e., the 0.1 percent prevalence for MA zones).

We realize that a 1,000 herd minimum may not be practical in all situations. Nevertheless, it is noted that a minimum of 201 herds within a zone is implied by 9 CFR and the Bovine Tuberculosis Eradication Uniform Methods and Rules because there is no discretionary authority for AP States or zones. A State or zone with just one affected herd could not qualify for AP status if that State or zone comprises 200 or fewer herds.

Variances from this policy would need to be approved and justified by sound epidemiologic reasoning. Due to the small number of herds present, any State or zone given exception to this policy and wishing to retain the status they have been granted will be restricted in what they can do with animals and herds within the zones that are approved for regionalization.

In cases where discretionary authority is used, the maximum number of affected herd-years required to maintain or advance in each program status level will be specified as part of the Memorandum of Understanding developed to establish a zone.

Alternative methods to this analysis might derive different results. The methods used in this analysis are only risk-based in the sense that they depend on the rules written into the regulations. More direct estimates of risk trade-offs for different numbers of allowable affected herds would require substantial risk modeling. Although such modeling could be done, it could require data that are not currently available. More quantitative approaches could be used to modify these decisions as data becomes available.



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