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**United States Department of Agriculture
Animal and Plant Health Inspection Service
Veterinary Services**

**A New Approach for Managing Bovine Tuberculosis:
Veterinary Services' Proposed Action Plan**



A New Approach for Managing Bovine Tuberculosis: Veterinary Services' Proposed Action Plan

Executive Summary

Bovine tuberculosis (TB) is a serious disease with animal health, public health, and international trade consequences. The cooperative Federal-State-industry effort to eradicate bovine TB from cattle in the United States has made significant progress since the program's inception in 1917. However, the goal of eradication remains elusive.

This proposed action plan presents Veterinary Services' (VS') current thinking about changes we are considering for the TB program to address our current challenges.

This action plan will:

1. Reduce the introduction of TB into the U.S. national herd from imported animals and wildlife by:
 - Applying additional requirements to cattle imports from Mexico
 - Enhancing efforts to mitigate risks from wildlife
2. Enhance TB surveillance by:
 - Crafting a comprehensive national surveillance plan
 - Accelerating diagnostic test development to support surveillance
3. Increase options for managing TB-affected herds by:
 - Conducting epidemiological investigations and assessing individual herd risk
 - Applying whole-herd depopulation judiciously and developing alternative control strategies
 - Applying animal identification (ID) standards to meet animal ID needs
4. Modernize the regulatory framework to allow VS to focus resources where the disease exists
5. Transition the TB program from a State classification system to a science-based zoning approach to address disease risk

To succeed, this new approach will require VS' continued partnership with State animal health and wildlife officials, other Federal agencies, industry, international partners, academia, and other stakeholders. Successful partnerships will allow us to use available resources efficiently to

achieve program objectives and protect our nation's herd.

Implementation of the VS proposed action plan will benefit Federal and State animal health officials, the regulated industries, and producers by allowing a more rapid response that employs up-to-date science and can adapt rapidly to changing situations.

Introduction: The Need for Change

Bovine TB is a serious disease with animal health, public health, and international trade consequences. The cooperative Federal-State-industry effort to eradicate bovine TB from cattle in the United States has made significant progress. Since the program's inception in 1917, the disease prevalence rate in cattle herds dropped from 5 percent to less than 0.001 percent. Many consider this one of the great animal and public health achievements in the United States. However, our ultimate goal of eradication remains elusive as animal health officials continue to detect TB sporadically in livestock herds.

Numerous challenges hinder our efforts to eradicate the disease:

- Epidemiological investigations conducted by VS and the States indicate that most TB-infected cattle detected at slaughter were imported. Most of these cases originated from Mexico despite significant reductions in the prevalence of TB in all Mexican States.
- In 1995, animal health officials found an endemic focus of TB infection in free-ranging white-tailed deer in the northeastern lower peninsula of Michigan. More recently, TB has been confirmed in free-ranging white-tailed deer in Minnesota. This wildlife TB reservoir continues to impact the program.
- Today's cattle industries feature fewer herds of increased size. Producers are more specialized and often transport animals long distances. This frequent movement of some classes of cattle among multiple premises and herds has led to increased risks of TB transmission.

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- The absence of a fully implemented national animal ID system negatively impacts the ability to identify affected herds.
- The primary diagnostic tool for TB, tuberculin skin testing, requires multiple veterinary visits to administer the test and interpret results. The tuberculin skin test and all other available diagnostic tests for TB fail to detect all infected cattle, especially in populations with low-disease prevalence.

The TB program is primarily supported with Federal funds, including appropriated funding and emergency funding. The Federal annual appropriation for the TB line item has grown substantially since fiscal year (FY) 2000, but reached its plateau at approximately \$15 million since FY 2003. Approximately \$207 million of emergency funding has been infused into the TB program since 2001. The Animal and Plant Health Inspection Service (APHIS) obtained these emergency funds through Commodity Credit Corporation requests or APHIS contingency funds when the costs of investigation, control, and eradication activities exceeded the appropriated program budget. However, Federal budget deficits are forecast to continue. We expect federally appropriated funds to remain constant or decrease and do not anticipate having emergency funds available.

Compounding these challenges is a lack of flexibility in the regulations. The current bovine TB regulations in title 9 of the *Code of Federal Regulations* (9 CFR), parts 50 and 77, the 1999 Uniform Methods and Rules (UM&R) incorporated by reference, and other related regulations (e.g., 9 CFR 71) contain detailed standards and requirements. This means that additional rulemaking is necessary every time we must change any details. VS, like other regulatory agencies, faces a complex, lengthy process to implement changes or develop new regulations. This results in rigid, outdated requirements that cannot adapt to a changing agricultural landscape.

It is time for a new approach.

This document presents VS' current thinking about changes we are considering for the TB

program. We hope it will stimulate critical feedback from our partners and stakeholders.

The Proposed Action Plan: A New Approach for Managing Bovine TB

This action plan will:

1. Mitigate the introduction of TB into the U.S. national herd from imported animals and wildlife
2. Enhance surveillance for TB
3. Increase options for managing TB-affected herds
4. Modernize the regulatory framework to allow VS to focus resources where the disease exists
5. Transition the TB program from a State classification system to a science-based zoning approach to address disease risk

1. Mitigate Disease Introduction

Apply Additional Requirements to Cattle Imports from Mexico

Each year, the United States imports approximately 1 million cattle from Mexico. The prevalence of TB-affected herds in virtually all Mexican States and the number of TB cases in imported Mexican cattle have declined substantially from the late 1990s. However, epidemiological investigations indicate that the majority of TB-infected cattle detected at slaughter in the United States originated in Mexico. Exposing U.S. cattle not intended for immediate slaughter to Mexican TB-infected cattle poses a significant risk.

Working with our stakeholders, VS will develop new standards to supplement existing import requirements that will further mitigate this risk. VS will continue to collaborate with the Mexican Government to provide technical support to their TB program.

The alternatives VS is considering include:

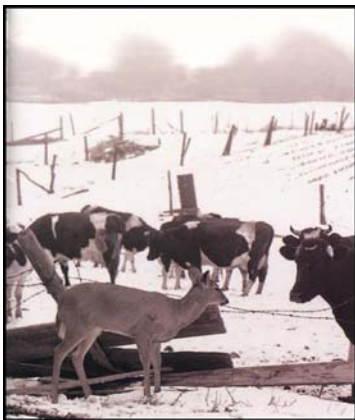
- Requiring additional testing of livestock prior to entry into the United States (including tests conducted at the port of entry)
- Requiring certain classes of imported cattle be sent to quarantined feedlots or terminal feedlots where animals are only destined for slaughter

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- Prohibiting the exposure of domestic cattle not destined for slaughter with high-risk imported cattle in feedlots
- Requiring risk evaluations, herd plans, or additional testing requirements for herds exposed to imported animals
- Conducting supplemental surveillance in geographic areas that have an increased risk for exposure to imported cattle
- Requiring annual TB testing for interstate movement of cattle used for rodeo events, regardless of origin

Enhance Efforts to Mitigate Risks from Wildlife

The discovery of an endemic TB infection in free-ranging white-tailed deer in the northeastern lower peninsula of Michigan in 1995 was the first report of self-sustaining bovine TB in wild, free-ranging U.S. cervids. More recently, TB has been confirmed in free-ranging white-tailed deer in Minnesota. TB in wildlife can be transmitted to domestic livestock. VS believes TB in wildlife is the primary reason we continue to find affected cattle and captive cervid herds in Michigan. Identifying TB in wildlife has impacted the direction and success of the TB program for the last decade and will continue to be a significant challenge in the future.



VS will partner with wildlife agencies and other entities to enhance our TB control and elimination efforts. We must establish measures to detect TB in wildlife, reduce the prevalence of the disease in wildlife, and mitigate the risks for transmission of TB between livestock and wildlife.

The alternatives VS is considering include:

- Conducting supplemental surveillance in wildlife in geographic areas where TB has been identified in livestock
- Establishing minimum requirements for targeted surveillance in wildlife as part of a comprehensive, national surveillance plan
- Developing on-farm mitigations to control the risk of disease transmission between wildlife and livestock and evaluate the effectiveness of these mitigations
- Supporting research to identify tools (e.g., vaccination) and strategies (e.g., bait delivery strategies) to reduce the prevalence of TB in wildlife and instituting those strategies as appropriate

2. Enhance Surveillance

Crafting a Comprehensive National Surveillance Plan

Since its inception, the TB program has shifted from a “down-the-road,” systematic testing approach, where all cattle herds were individually tested using tuberculin skin testing, to the designation of entire geographic areas as TB free with slaughter surveillance as our major case-finding tool. Current Federal regulations require States to conduct routine surveillance to maintain their TB status for cattle and domestic bison (i.e., permanently captive and privately owned free-range animals). The Bovine TB Eradication UM&R, dated January 1, 2005, includes guidelines for surveillance, and the World Organization for Animal Health (OIE) has established international guidelines for declaring a country free from bovine TB. Surveillance has been and will continue to be an integral component of the TB program.

A cornerstone of VS' future TB program will involve enhancing our existing surveillance to create a comprehensive national surveillance plan that includes ongoing surveillance in cattle, domestic bison, and captive cervid herds (both in live animals and at slaughter) as well as targeted surveillance in wildlife. As a first step, VS is evaluating its current system to determine how well we can detect TB and demonstrate freedom from the disease in individual States.

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An enhanced comprehensive national plan will integrate slaughter surveillance, herd testing, and other possibly novel surveillance streams to establish minimum requirements necessary to detect infected cattle, domestic bison, and captive cervid herds nationally. Additionally, VS will improve existing practices to enhance the overall efficiency and effectiveness of our surveillance system.



We envision components of this comprehensive national surveillance plan to include:

- Slaughter surveillance as our primary case-finding tool. VS plans to continue our collaboration with the Food Safety and Inspection Service to ensure slaughter surveillance remains a priority so we may achieve surveillance standards at the national, State, and slaughter establishment levels.
- Live animal testing in cattle, domestic bison, and captive cervid herds. VS may require a minimum level of herd surveillance in areas without documented cases of TB. This testing may be conducted for herd accreditation, movement testing, or to meet requirements of the Grade "A" Pasteurized Milk Ordinance.
- Minimum requirements for surveillance in wildlife. Similarly, VS may incorporate ongoing surveillance in wildlife populations to monitor the risk of TB exposure for domestic livestock. This type of surveillance

will require developing and implementing alternative surveillance streams such as testing in sentinel species (e.g., coyote), integrating with existing surveillance for other diseases of hunter-killed cervids (e.g., chronic wasting disease), or other novel approaches.

- Supplemental surveillance in areas with TB-affected livestock or wildlife. Increased sampling rates or "targeted" testing in nearby cattle, domestic bison, and captive cervid herds and surveillance in wildlife will ensure rapid disease detection and prevent further spread. The perceived risk of exposure resulting from observed herd management and biosecurity practices may also be used to "target" cattle, domestic bison, and captive cervid herds for supplemental surveillance testing.
- Surveillance standards that integrate sampling from these streams. VS will establish Federal surveillance standards necessary to support claims about the TB status of the United States, or zones within the United States, consistent with OIE guidelines. While we will no longer certify and publish the TB status of individual States, State and Federal animal health officials will still be expected to meet established surveillance standards, including reporting deadlines, to substantiate the national TB status claim.
- A national standardized, integrated, electronic data collection system for TB surveillance and case management. As with any surveillance effort, collecting, validating, and reporting accurate surveillance data demonstrate effectiveness and enable rapid response. We will use existing data collection and management systems, including the Mobile Information Management System, the Animal Health Surveillance and Monitoring System, and animal ID standards, to enhance future surveillance capabilities.

Accelerating Diagnostic Test Development to Support Surveillance

Tuberculin skin testing was first recognized as a useful diagnostic tool in the late 1800s and continues to be the primary diagnostic tool in both human and animal medicine. However, this

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test has limitations. Aside from the need for multiple veterinary visits to administer the test and interpret the results, tuberculin skin testing fails to detect all infected cattle, especially those tested too early or too late in the course of infection, while as many as 15 percent of infected cattle will test negative. At the same time, approximately 3 percent of uninfected cattle may test positive. Because of these limitations, APHIS evaluates an individual animal's infection status using a combination of tests requiring multiple visits to the farm.

Despite the considerable need for improved diagnostic methods for bovine TB, significant breakthroughs in developing new tests are not likely in the immediate future. While several technologies are being developed, these methods still require further testing and evaluation.

To partially address this need, VS established a serum bank in 2006 to support research and validation of new technologies for TB testing. In 2009, VS provided additional funding to collect a large number of high volume serum samples from both infected and uninfected cattle and white-tailed deer. The objective of the serum bank is to provide well-characterized samples that are linked with skin test results for samples from uninfected animals, and skin test, histopathology, and TB culture results from infected animals. We hope this bank will assist stakeholders in the research, development, and timely validation of bovine TB serologic tests.

In addition to the expansion of the serum bank, VS will continue to collaborate with other U.S. Department of Agriculture (USDA) agencies such as the Agricultural Research Service and the Cooperative State Research, Education, and Extension Service to identify priorities and conduct critical research to develop and validate diagnostic methods and tests. VS will clearly describe the process to obtain licensure and approval as an official test for the TB program and identify approaches to expedite this process.

VS is considering other possibilities to accelerate the development of diagnostic tests, including:

- Identifying alternative sources of funding within the Federal Government to support test development and validation
- Expanding existing partnerships with international animal health agencies to further support diagnostic test development
- Exploring new partnerships with public health agencies and human health companies to better leverage the limited funding and personnel available to support this process
- Investigating novel detection methods that do not rely on organism or antibody detection

3. Manage TB-affected Animals and Herds

Conducting Epidemiological Investigations and Assessing Individual Herd Risk

VS will continue to require epidemiological investigations of affected herds. Upon the disclosure of a TB-affected herd, VS will continue to rely on State animal health agencies to issue an immediate quarantine of the herd and will collaborate with these entities to initiate an epidemiological investigation. Epidemiologically linked herds (i.e., herds that have supplied or received cattle from the affected herd) will be quarantined and tested as appropriate.

VS is proposing to modify certain practices and to implement additional actions in conjunction with these epidemiological investigations. These alternatives include:

- Revising program definitions, such as those for "herd" and "feedlot," to reflect current industry practices
- Developing a standardized tool to evaluate and classify the risk of TB transmission associated with individual herds under investigation based on producer-identified risks (e.g., wildlife exposure), management practices, and biosecurity
- Using observations from these assessments to establish supplemental surveillance requirements in nearby cattle, domestic bison, and captive cervid herds and wildlife

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Applying Whole Herd Depopulation and Developing Alternative Strategies

Traditionally, VS has encouraged producers to voluntarily depopulate TB-affected herds as the only approach certain to eliminate infection. VS continues to offer indemnity (depending on the availability of funding) to compensate producers considering depopulation. However, as herd size continues to increase, it becomes difficult for VS to justify depopulating herds that often exceed 1,000 animals when only one or two animals are diagnosed with TB. In addition, the public perceives whole-herd depopulation as a less acceptable approach for disease control. Changing social values concerning the care and well-being of livestock, the recognition of the environmental consequences of animal disposal, and the value of proteins derived from livestock also drive the need to develop new approaches to disease control. Finally, the costs of depopulation have increased with herd sizes at a time when we expect future indemnity funds to be limited and emergency funding to be unavailable.

VS is considering these alternatives:

- Revising our regulations to include a performance standard for eliminating TB from affected herds and identifying options to achieve this standard. This could include multiple test-and-removal protocols to control disease spread, whole-herd depopulation, and other options.
- Developing objective criteria to determine if whole-herd depopulation is economically viable and to prioritize how limited indemnity funds should be used either to remove specific animals or depopulate entire herds.
- Providing incentives for producers to remove exposed animals from the herd through early culling.
- Reducing the maximum amount of Federal indemnity paid per individual animal.
- Linking Federal indemnity payments to the implementation of specific risk mitigation and biosecurity practices within a herd.
- Identifying alternative or supplemental sources for indemnity funding and exploring the feasibility of these options. These may include cost sharing with the industry or State or developing industry-funded "insurance" programs.

Applying Animal ID Standards to Meet Animal ID Needs

While slaughter surveillance has proven to be effective, traceback to herds-of-origin has been limited by lack of information. The lack of ID for a particular animal and incomplete documentation kept by owners, dealers, or brokers continue to hamper successful tracebacks and epidemiological investigations. These limitations and the frequent movement of some classes of cattle among multiple premises and herds prolong the time required to complete traces and require additional resources. Therefore, rapid and effective response to TB occurrences will depend on full implementation of an animal ID system.

VS is proposing that official animal ID and electronic movement certificates be used for animals leaving affected herds or zones to ensure compliance with necessary testing requirements. This would provide assurance that the risk of disease spread is minimal and would ensure that animal health officials can perform effective trace investigations. Individual State authorities will be responsible for applying and enforcing these movement controls to ensure that only low-risk cattle are moving outside affected herds or zones and that high-risk cattle are moving only to slaughter or terminal feeding operations where the risk of spread can be controlled.



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4. Modernize the Regulatory Framework

The mission of VS is to prevent, control, and eliminate animal diseases and to monitor and promote animal health and productivity. These activities are vital to the health of the U.S. cattle and livestock industries and to the safety of the U.S. food supply. VS' regulatory activities are authorized by the Animal Health Protection Act, which consolidates laws related to animal health and quarantine and includes key provisions for VS animal health programs and services.

VS' regulations, including the bovine TB regulations, are largely written as design standards (also sometimes called prescriptive or "command-and-control" standards). Design standards contain details that regulated entities must follow. Having such details in the regulations means additional rulemaking is necessary every time a detail must change. This tendency to include design standards, coupled with the lengthy regulatory process, means that VS' animal health regulations become outdated quickly and cannot adapt to a changing agricultural landscape.

VS is proposing to revamp the regulatory framework underlying several of its animal disease programs, including the TB program. We must structure underlying regulations to allow us to respond quickly, employ up-to-date science, and be flexible to changing situations. These proposed changes are consistent with the VS 2015 Vision to place greater emphasis on disease prevention, create a more agile national veterinary strike force to direct emergency response activities, and increase cooperation between animal and public health organizations.

VS envisions the characteristics of these proposed regulatory changes to include:

- Developing regulations that use performance standards to describe a regulatory goal or desired outcome rather than including prescriptive, inflexible design standards
- Stating specific guidelines or approaches for meeting the regulatory goal in program standard documents, surveillance plans, and other policy documents rather than in the regulations

- Using a science-based zoning approach that addresses disease risk more appropriately than a geopolitical State-based approach
- Maintaining a description of zones on our Web site, rather than in the regulations
- Notifying the public of changes through notices published in the *Federal Register*, rather than through rulemaking, making the process more timely and flexible



5. Transition to a Zoning Approach

Historically, VS has classified States according to a multi-level system based on TB prevalence. A State's status is the primary determinant for requirements for interstate movement of livestock. A lower rank requires controls that are more restrictive. As a result, there is considerable economic incentive for a State to have the highest status level possible.

This State status approach was successful in managing TB when the prevalence of TB was high. Enforcement of interstate movement and testing requirements assisted animal health officials to identify infected animals and affected herds. Requirements associated with State status encouraged States to investigate cases promptly and mitigate the spread of disease.

Given the current low prevalence of TB in the United States, reclassifying the status of an entire State when a disease is present only in a small geographic area may not be necessary to contain the disease and can be costly for the industry. When a State's status is downgraded, every producer in the State incurs additional costs to meet restrictive movement and testing requirements.

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To minimize the impact on industry during these outbreaks, our current regulations allow States to create zones within the State, commonly referred to as establishing split-State status. This means one or more zones have a separate disease classification from the rest of the State. One benefit of split-State status is that zones considered free of disease are able to ship livestock interstate and internationally with minimal restrictions. However, the application process for split-State status can take over a year to complete. Implementing the zone requires regulatory changes at both State and Federal levels, further prolonging the time required to increase or decrease the size of the zone.

The system also fails to consider factors that may either contribute to or limit the risk of further disease transmission such as clustering of affected herds in a defined geographic area, geographic barriers, or even industry practices. Many States find the current system rigid, prescriptive, and unable to adapt to changing conditions.

Therefore, VS is proposing to replace the current State status system. Instead, VS envisions a risk-based approach that imposes testing requirements and movement restrictions that associate with a zone rather than an entire State. Such zoning is consistent with OIE standards. Adopting this approach will enable us to move quickly to protect animal health and focus limited resources on geographic areas where the disease exists, while simultaneously adapting to changes in agricultural practices and minimizing the economic impact on industry. VS envisions the elements of this proposed approach will include:

- Promulgating performance-based regulations that allow VS to establish and dissolve TB elimination or containment zones around clusters of affected herds or other high-risk areas.
- Defining testing requirements and movement restrictions associated with these zones that States will apply and enforce.
- Identifying conditions that would initiate establishing a TB elimination or containment zone.
- Developing criteria to define or redefine boundaries to increase or decrease zone

size and eventually dissolve the zones. These boundaries would be unique for each situation and may cross State lines.

- Establishing requirements within the zone for supplemental surveillance in areas with TB-affected livestock herds or wildlife.

Implementation, Oversight, and Monitoring of the New Approach

VS' proposed action plan represents a dramatic change for one of VS' longstanding disease eradication programs. Modernizing the Federal regulatory framework by implementing performance-based regulations, including those needed to officially establish TB elimination or containment zones according to internationally accepted guidelines, will take time. State-level regulatory changes may also be required. Once promulgated, however, these new rules will benefit Federal and State animal health officials, the regulated industries, and producers by allowing a more rapid response that employs up-to-date science and is flexible to changing situations.

VS is aware that these proposed changes will impact the regulated industries and our stakeholders. Prior to publishing the proposed rule to establish these regulations, VS intends to work closely with our stakeholders to obtain input on these proposed strategies, program standards, surveillance plans, and other policy concepts. VS has already initiated these discussions with various stakeholders.

Resources

VS assumes the Federal annual appropriation for the bovine TB program will remain at \$15.1 million, with potential decreases and without additional Federal emergency funds. State resources face similar limitations. This fiscal scenario will require careful prioritization of program activities that focus on affected or high-risk geographic areas to ensure that we achieve program objectives within this limited budget. Coordination and collaboration among various Federal, State, and industry partners will be essential. Finally, we may need to consider

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broader cost sharing or other new alternative sources of funding.

Roles and Responsibilities

The success of this new approach will depend on the longstanding cooperation among Federal and State animal health officials, regulated industries, and producers. Each cooperator will have specific roles and responsibilities.

In addition to rulemaking, Federal animal health officials will be responsible for:

- Developing program standards, surveillance plans, and other policy documents that describe specific guidelines and approaches for meeting the performance standards stated in the regulations
- Establishing the national program objective and priorities
- Designing and implementing a national standardized, integrated, electronic data collection system for TB surveillance and case management
- Monitoring data and supplemental documentation regularly to verify that minimum standards and national program objectives are met
- Providing States with timely feedback, guidance, and technical expertise as we implement regulations and policies
- Collaborating with other Federal agencies, stakeholders, and industry to leverage resources and ensure integrated planning

State animal health officials will be responsible for:

- Revising State regulations where necessary to be consistent with Federal regulations
- Implementing program standards, surveillance plans, and other policies to achieve the performance standards in the regulations
- Overseeing, monitoring, and enforcing testing requirements and movement controls associated with established zones
- Monitoring data on a regular basis to document progress and submitting data and additional documentation as required
- Collaborating with other State agencies, Federal agencies, and industry to leverage resources and ensure integrated planning

- Serving as a liaison with individual producers

In this new approach, producers and industry will also have responsibilities:

- Advancing their knowledge about bovine TB and risk factors for introducing TB into their herds
- Evaluating their management practices to identify if any of these risk factors are present and implementing mitigations to reduce these risks
- Developing industry- and producer-driven components of the TB program and generating the funds necessary to support these activities
- Continuing to engage in discussions with State and Federal animal health officials concerning the TB program



Potential Obstacles to Implementing this New Approach

VS recognizes that our partners, stakeholders, and regulated industries may have reservations about these new concepts. While there will likely be others, we can address three reservations already expressed to VS through stakeholder dialog.

Replacing the current State status system may reduce or eliminate incentives for States to promptly investigate cases and mitigate the continued spread of TB.

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Under the proposed approach, movement restrictions and testing requirements would be limited to zones where the disease exists, rather than applying these restrictions statewide. However, VS believes that the costs of the restrictions and testing applied to an affected zone will provide the same market incentive for producers and States managing such zones to implement the necessary disease control measures. Furthermore, VS will continue to cooperate with and provide financial support to States to implement minimum TB surveillance and program standards.

The described zoning approach may be inappropriate to manage a chronic disease such as TB and cannot be applied consistently across the country.

VS only proposes to establish TB elimination or containment zones in distinct geographic areas that present a high risk for TB exposure or transmission to domestic livestock herds. For example, zones may be established when multiple affected herds are identified or when infected wildlife exists in a geographic area. Otherwise, we expect States to quarantine and manage individual affected herds, including implementing movement restrictions and herd testing, within the guidelines of the program.

Furthermore, to ensure transparency and consistency, VS will clearly describe in our regulations the risk criteria that will initiate the establishment of a zone and define zone boundaries. These criteria will use a risk evaluation that incorporates epidemiology, disease dynamics, and ecological factors related to livestock and wildlife; information from investigations of TB outbreaks in livestock; surveillance data from both domestic livestock and wildlife populations; livestock marketing practices; and wildlife movement patterns. Our goal will be to define zones with distinct and identifiable boundaries that will contain the potential risk for TB exposure and transmission, while allowing herds at low risk to operate without increased requirements or restrictions.

It will not be possible to enforce program requirements without specifically including them in the text of the regulations contained within the CFR.

While developing official rules establishing these concepts, VS intends to work closely with USDA's Office of the General Counsel to ensure our regulations include well-designed performance standards that can be enforced.

For example, standards in 9 CFR 77.17(a) include specific instructions that regulated entities must follow precisely for identifying TB reactor cattle. These include the type and method of applying ear tags; the dimensions and locations of branding; and the type, location, and color of tattoos. Alternatively, these standards could be written as performance-based regulations that only require that TB reactor cattle must be individually identified and visibly marked as a reactor in a manner approved by the Administrator. Various methods for meeting this performance standard would be defined in program standard documents that can be revised readily and updated as technology and market practices change.

Such standards will provide greater regulatory flexibility while still ensuring that the core requirements of the regulation remain enforceable.



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Conclusion

There are numerous challenges that hinder our efforts to eradicate bovine TB. VS recognizes that it is time for a new approach to managing this disease. Our proposed action plan will:

1. Reduce the introduction of TB into U.S. livestock from imported animals and wildlife
2. Enhance nationwide TB surveillance
3. Increase options for managing TB-affected herds
4. Modernize the regulatory framework to allow VS to focus resources where disease exists
5. Transition the TB program from a State classification system to a science-based zoning approach to address disease risk that will enable us to respond quickly to changing conditions

To succeed, this new approach will require VS' continued partnership with State animal health and wildlife officials, other Federal agencies, industry, international partners, academia, and other stakeholders. Successful partnerships will allow us to use available resources efficiently to achieve program objectives and protect our nation's herd.

