

A Concept Paper for a New Direction for the Bovine Brucellosis Program Animal and Plant Health Inspection Service Veterinary Services

Executive Summary

Bovine brucellosis is a serious disease of livestock that has significant animal health, public health, and international trade consequences. The cooperative Federal-State-industry effort to eradicate this disease from cattle in the United States has made significant progress since the program's inception in 1934. However, unique challenges impede eradication.

This concept paper presents Veterinary Services' (VS) current thinking about changes we are planning to address these challenges.

The concept paper provides an action plan that:

1. Effectively demonstrates the disease-free status of the United States through a national status-based program supported by a national surveillance strategy
2. Enhances efforts to mitigate disease transmission from wildlife
3. Enhances disease response and control measures
4. Modernizes the regulatory framework to allow VS to address risks quickly and sensibly
5. Implements a risk-based disease management area concept

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 national livestock herd.

This action plan will benefit Federal and State animal health officials, the regulated industries, and producers by allowing a more adaptable science-based response that is both effective and timely and that addresses the unique challenges facing the program today.

Introduction: The Need for Change

VS established a national brucellosis program to safeguard the health of domestic livestock, maintain the economic viability of the U.S. cattle industry in national and international trade, protect public health, and ensure food safety. The goal of the program is to eradicate brucellosis from the United States.

VS launched the program in 1934 to assist the cattle industry during an economic depression. At that time, 11.5 percent of adult cattle were reactors (i.e., tested positive). In 1954, Congress officially appropriated funds for a national program, supporting the organization of a comprehensive State-Federal cooperative effort to eradicate brucellosis from domestic cattle herds. Throughout the 1960s and 1970s, the program evolved, incorporating changes in both program management and field activities to meet the changing needs of States and industry as marketing opportunities developed and disease eradication progressed. Changes included “down-the-road” (i.e., systematic) herd testing; use of calfhood and adult vaccination; use of new and better serology tests; testing of cattle at first point of concentration; implementing the concept of local control; placing emphasis on epidemiology and adjacent and community herd testing; and affected herd management. By 1989, 27 States were classified as brucellosis free. However, finding the last vestiges of infection in livestock had become tedious, difficult, and costly.

An in-depth review of the program led to a Rapid Completion Plan in 1989. This plan identified several program elements critical to achieving disease eradication. In 1997, the program again underwent an extensive review that reaffirmed eradication goals and developed the Brucellosis Emergency Action Plan (BEAP). BEAP strategies include handling brucellosis eradication and surveillance activities as a priority and managing new cases as an emergency action. By 2007, the national herd prevalence hit an all-time low of 0.0001 percent (1 affected herd in approximately 1 million cattle herds). VS continues to use the program elements identified in the BEAP.

In February 2008, every State and the territories of Puerto Rico and the Virgin Islands achieved Class-Free State status (i.e., disease-free status) for the first time in the 74-year history of the program. This accomplishment was short-lived, however. In September 2008, Montana lost its Class-Free status after finding a second brucellosis-affected cattle herd within a year. In the last 5 years, Idaho and Wyoming, the other two States in the Greater Yellowstone Area (GYA), have also lost their Class-Free status. All three States are now Class Free, but infected wildlife populations in the GYA were implicated as the source of outbreaks.

Despite cooperative Federal-State-industry efforts to eradicate this disease and the significant progress we have made, final eradication will not become possible unless the country adopts new strategies to address the current challenges. Eradication depends on finding the last remaining brucellosis-reactor animal, the last remaining brucellosis-affected herd, and eliminating the disease from wildlife reservoirs. All potential risks for exposure and transmission of brucellosis from infected wildlife populations must be mitigated and eliminated as well. Currently, the last known reservoir of disease is the wildlife populations in the GYA. A new direction is needed that will allow VS and States to apply limited resources effectively and efficiently to this unique disease risk.

The Proposed Action Plan: A New Direction for the Brucellosis Program

The success of the brucellosis program has resulted in large part from our ability to adapt program activities, when needed, to be more effective. Now it is time to address the remaining challenges that impede eradication.

This new action plan will do the following:

1. Effectively demonstrate the disease-free status of the United States through a national status-based program supported by a national surveillance strategy
2. Enhance efforts to mitigate disease transmission from wildlife
3. Enhance disease response and control measures
4. Modernize the regulatory framework to allow VS to address risks quickly and sensibly
5. Implement a risk-based disease management area concept

1. Demonstrate the Disease-Free Status of the United States

Developing a National Surveillance Strategy

Current Federal regulations require States to conduct routine surveillance to maintain their status. The Bovine Brucellosis Eradication Uniform Methods and Rules (UM&R), effective October 1, 2003, describes minimum standards for the Cooperative State-Federal Brucellosis Eradication Program. Within the UM&R are standards for certifying herds; classifying States and areas; and detecting, controlling, and eradicating brucellosis. Requirements for intrastate and interstate movement of cattle and bison are also included. Both the UM&R and regulations in title 9 of the *Code of Federal Regulations* (9 CFR), part 78, guide the program surveillance activities.

In 2006, the National Surveillance Unit (NSU) of VS' Centers for Epidemiology and Animal Health evaluated the brucellosis program and identified redundancies and imbalances in surveillance testing. In 2007, NSU provided recommendations based on this evaluation to a Federal-State working group on National Brucellosis Surveillance Planning. Using these recommendations, the working group developed a proposed surveillance plan. VS presented this plan to the United States Animal Health Association (USAHA) Committee on Brucellosis in October 2007. The plan included reducing slaughter surveillance, eliminating the brucellosis ring test, and eliminating Federal funding for first-point testing in low-risk States (i.e., States that do not border the GYA and have maintained Class-Free status for 5 or more years). In addition, this plan called for consolidating laboratory testing and using a standardized testing protocol for all slaughter surveillance samples. The USAHA endorsed the plan.

In 2008 to 2009, NSU re-evaluated the slaughter surveillance recommendations to improve the efficiency and cost effectiveness of this component. The objective was to describe a strategy that would maintain confidence that brucellosis is present in less than one animal per million in the national beef and dairy cattle herd. This new sampling approach moves away from the current census-based sampling originally designed for disease eradication to one more appropriate for the current situation. Using statistical sampling for slaughter surveillance based on the national cattle herd size, this strategy will result in an approximate 50 percent reduction in the number of

slaughter surveillance samples needed. The plan eliminates State-by-State census sampling while still effectively demonstrating the national herd's disease-free status. This new national status-based surveillance strategy exceeds the standards set by the World Organization for Animal Health (OIE) for a country recognized as disease-free for brucellosis.

To shift from a State-by-State surveillance system to a national surveillance strategy, VS must:

- Amend the current program regulations to remove State-required surveillance activities
- Redirect Federal funds to support the national slaughter surveillance plan and specific activities associated with disease management areas
- Develop and implement an appropriate slaughter surveillance sampling strategy that represents the national cattle herd
- Proceed with laboratory consolidation, including a standard testing protocol for brucellosis slaughter surveillance
- Develop teams of Federal, State, and laboratory officials to communicate and implement the action plan

Consolidate Surveillance Laboratories and Use Standardized Protocols

To improve the efficiency and cost effectiveness of a national slaughter surveillance strategy, we propose consolidating laboratory testing for slaughter surveillance and using a standardized testing protocol. The NSU recently evaluated the laboratories currently conducting surveillance testing for their ability to handle changes in the volume of samples and the associated costs. The analysis assumed current slaughter surveillance levels and used the new standardized testing protocol and a standard shipping protocol designed to improve sample quality. The results of the analysis outline a regional laboratory concept that uses the two Federal laboratories in Kansas and Kentucky plus State-Federal laboratories in 22 additional States (including the three GYA States). Though there are initial start-up costs, implementing these changes will enhance the efficiency and effectiveness of the national surveillance program.

Because surveillance activities, laboratory consolidation, and use of standardized testing protocols are interrelated, we are proposing an integrated implementation plan to progressively initiate changes to all three areas. The proposed 50 percent reduction in slaughter surveillance levels will impact slaughter surveillance laboratory testing volumes and possibly the overall laboratory consolidation plan; therefore, an efficient and effective slaughter surveillance plan includes maximizing volume of testing and minimizing shipping costs. A multi-stage implementation plan for laboratory consolidation should be developed as slaughter surveillance levels decrease. The two Federal laboratories can significantly increase testing volume and may be able to test the majority of surveillance samples. Since May 2008, a Brucellosis Laboratory Consolidation and Testing Standardization working group has been developing an implementation plan and defining standard laboratory protocols. The brucellosis program is currently implementing the first step of the standardized testing protocol in the two Federal laboratories.

2. Enhance Efforts to Mitigate Disease Transmission from Wildlife

Brucellosis-affected wildlife can transmit the disease to domestic livestock. To demonstrate the disease-free status of the United States, we must mitigate risks from wildlife. The last known

reservoir of *Brucella abortus* in the United States exists in the wild elk and bison populations in the GYA. Diagnostic testing and epidemiological investigations have shown that the brucellosis-affected elk population in the GYA is the most likely source of infection for affected cattle herds in Idaho, Montana, and Wyoming in recent years. This last reservoir of brucellosis in wildlife has adversely affected eradication efforts for years and will continue to be a significant challenge in the future.

VS has partnered with wildlife agencies and other entities to enhance mitigation and elimination efforts. The Greater Yellowstone Interagency Brucellosis Committee, although currently inactive, developed risk mitigation strategies to address the risk of brucellosis from the GYA's wildlife. The Interagency Bison Management Committee (IBMP) partners work together, as outlined in the IBMP memorandum of understanding (MOU), to mitigate the risk of disease from potentially infected GYA bison. We need continued collaborations to develop effective strategies to determine the location and range of brucellosis-affected wildlife, reduce the prevalence of disease in wildlife, and mitigate the risks of disease transmission.

Potential strategies include:

- Partnering with State and Federal wildlife agencies to conduct wildlife surveillance in areas with brucellosis-affected livestock
- Establishing minimum requirements for a brucellosis mitigation plan that targets wildlife surveillance as part of a comprehensive, national surveillance plan
- Developing on-farm mitigations to control disease-transmission risks between wildlife and livestock and to evaluate their effectiveness
- Supporting research to find tools (e.g., vaccination and contraceptives) and strategies (e.g., habitat management) to reduce the prevalence of brucellosis in wildlife and instituting those strategies, as appropriate

3. Enhance Disease Response and Control Measures

Conducting Epidemiological Investigations

VS will continue to require epidemiological investigations of affected herds, will continue to rely on State animal health agencies to issue immediate herd quarantines, and will collaborate with States to conduct epidemiological investigations. Epidemiologically linked herds (herds that have supplied or received cattle from the affected herd) will be quarantined and tested, as appropriate.

However, VS is proposing to modify certain practices and to implement additional actions in conjunction with these epidemiologic investigations. One such modification would be to define prevalence on a "case" basis. This modification would allow multiple epidemiologically linked affected herds to be counted as one case. This would allow for a risk-based decision in determining the boundaries of a disease management area.

Applying Whole-Herd Depopulation and Developing Alternative Strategies

The strategy outlined in the BEAP is to depopulate brucellosis-affected herds to eliminate any possible reservoir of infection. VS continues to offer indemnity (depending on the availability of funding) to compensate producers for depopulation. However, as herd size continues to increase

and as the value of breeding and dairy cattle increases, it becomes difficult to justify depopulating large herds when only one or two infected animals are identified. 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 at a time when we expect future indemnity funds to be limited and emergency funding to be unavailable. A viable alternative to herd depopulation is a risk-based affected-herd management plan that includes multiple test-and-removal protocols and mitigation strategies to prevent intra-herd transmission of the disease.

Applying Animal Identification (ID) Standards

While slaughter surveillance has proven to be effective, traceback to herds-of-origin is limited by the lack of ID for a particular animal and incomplete documentation kept by owners, dealers, or brokers. Incomplete identification hampers not only successful tracebacks but also 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 requires additional resources. Therefore, rapid and effective response to brucellosis occurrences will depend on full implementation of an animal ID system.

VS is proposing that official animal ID and, when appropriate, electronic movement certificates be used for animals leaving affected herds or disease management areas to ensure compliance with necessary testing requirements. This would provide assurance that the risk of disease spread is minimal and would enable animal health officials to 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 disease management areas and that high-risk cattle are moving only to slaughter or terminal feeding operations where the risk of spread can be controlled.

4. Modernize the Regulatory Framework

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.

The brucellosis regulations in 9 CFR 51 and 78 and the 2003 UM&R (not incorporated by reference in the regulations) and other related regulations (e.g., 9 CFR 71) contain specific standards, measures, or requirements that regulated entities must follow. With such specific detail in the regulations, any change requires rulemaking, which is a lengthy process. This tendency to include detailed standards in the regulations, coupled with the lengthy regulatory process, inhibits the program from quickly adapting to changing program needs. VS realizes more flexible rulemaking is needed to address disease situations based on risk. VS is evaluating ways to develop rulemaking that supports a performance-based regulatory framework, rather than prescriptive, rigid requirements that are quickly outdated.

With protecting animal health as the priority, VS is proposing to revamp the regulatory framework underlying several of its animal disease programs, including the brucellosis program. VS must structure underlying regulations to allow for quick response to changing program needs, employ up-to-date science, and be flexible enough to adapt to unique and varying disease situations. This type of regulatory framework is consistent with VS' vision for 2015 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 disease management area approach that addresses disease risk more appropriately than a geopolitical State-based approach
- Maintaining a description of disease management or surveillance areas on our Web site, rather than in the regulation
- Notifying the public of changes through notices published in the Federal Register, rather than through rulemaking, making the process more timely and flexible

5. Implement Risk-Based Disease Management Areas

The OIE adopted the concept of zoning (or regionalization) to define distinct subpopulations for disease control and international trade purposes. OIE defines a zone or region as a clearly defined geographical part of a country containing an animal subpopulation with a distinct health status with respect to a specific disease that requires surveillance, control, and biosecurity measures for international trade. VS proposes to apply this concept to the brucellosis program by designating disease management areas to facilitate disease risk mitigation and provide confidence in the United States' disease-free designation. In the GYA, this management area will be known as a "designated surveillance area."

Historically, U.S. disease eradication programs have relied on a State-by-State geopolitically defined area approach. VS classifies States according to a multi-level system based on disease prevalence. A State's status determines the requirements for interstate movement of livestock; a lower classification requires more restrictive controls. This method has been effective because program standards allow States to enforce intrastate movement and testing requirements while Federal officials oversee and enforce interstate movement and testing requirements.

Although maintaining geopolitically defined areas at the State level has been effective, it can be costly when only a few livestock herds in a small geographic area are involved. For brucellosis, when an affected livestock herd is identified anywhere in a State, the entire State may be downgraded. When that happens, all producers must meet the additional testing and mitigation requirements, resulting in more costs for them and State and Federal governments.

To minimize the impact to the State during an outbreak, 9 CFR 78.40 and the brucellosis UM&R allow States to designate a two-area classification, called *split-State status*. One benefit of split-State status is that brucellosis-free areas may ship livestock interstate and internationally with minimal restrictions. However, the application process for split-State status can take over a year to complete, and some States have indicated their opposition to this approach. States are responsible for the majority of the workload and are required to have the legal and financial resources necessary to implement and maintain separate areas. Increasing or decreasing the size of the areas as risks change can be difficult and burdensome for the State. In addition, split-State status currently requires an amendment to the regulations.

The State-based 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, geographical barriers, or even industry practices. Many States find the current system rigid, prescriptive, and unable to adapt to the rapidly changing agricultural landscape. The prolonged time period necessary to change a State's status or implement split-State status does not allow for a quick response.

As an alternative to split-State status, VS proposes to define brucellosis-affected areas or areas at risk for brucellosis as disease management areas. This type of definition is consistent with OIE standards. The application of such risk-based areas would offer several advantages. Similar to split-State status, a disease management area would allow the remainder of the country to maintain its brucellosis-free status. Additionally, a disease management area would allow flexibility in modifying the boundaries of the disease management area as the risks associated with brucellosis change.

Managing a disease management area would be a collaborative State-Federal effort, minimizing each State's burden when areas in multiple States are a part of the disease management area. VS would still rely on States to implement and enforce intrastate movement restrictions. Adopting this approach will enable VS to move quickly to protect animal health and focus limited resources on geographic areas where the disease actually exists, while minimizing the economic impact on producers. Key to the success of the disease management area concept is the States' acceptance and collaboration.

VS envisions the disease management area concept to include:

- Promulgating performance-based regulations that allow VS to:
 - Establish and dissolve a disease management area around clusters of affected herds or other areas at risk for brucellosis based on a risk assessment provided by the State
 - Impose testing standards and movement restrictions associated with establishing the disease management area
- Identifying situations that would initiate establishing a disease management area
- Developing criteria to define boundaries, redefine boundaries to increase or decrease the disease management area over time, and to dissolve the disease management area. These boundaries would be unique for each situation and may cross State borders
- Establishing requirements for supplemental surveillance within the disease management area

- Using a risk-based assessment to assign risk to individual herds within the disease management area

In practical terms, this concept would require the following:

- States impacted by endemic disease in wildlife or other increased risk situations would submit a risk assessment to the Animal and Plant Health Inspection Service (APHIS) that justifies the creation of a defined disease management area. States would have the ability to modify the area based on changes such as the further spread or absence of brucellosis from the original area.
- The State veterinary and wildlife authorities and APHIS would develop an MOU for the disease management area. The goal of the MOU would be to focus disease eradication efforts on prevention and surveillance, rapid and timely disease response, and disease management in areas of increased risk for brucellosis. The MOU would include:
 - Using herd management plans based on individual herd risk assessments that include requirements for individual animal ID, herd testing, and, when appropriate, vaccination and movement controls (permits)
 - Surveillance of disease seroprevalence in both cattle and wildlife populations and implementing mitigation strategies
 - Quarantine of infected and potentially exposed cattle herds and effective quarantine enforcement
 - Rapid and timely disease response and reporting

Implementation, Oversight, and Monitoring of the New Approach

VS' proposed action plan represents a dramatic change for one of our long-standing disease eradication programs. Modernizing the Federal regulatory framework by implementing performance-based regulations, including those needed to officially establish brucellosis disease management areas 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 will continue to work closely with our stakeholders to obtain input on these new strategies, program standards, surveillance plans, and other policy concepts. VS has established a Brucellosis Surveillance Working Group and a Brucellosis Laboratory Consolidation and Testing Standardization Working Group, which have been working together since 2006 to develop new program strategies. These working groups, which comprise State and Federal animal health officials and State and Federal laboratory personnel, have shared their proposed strategies with Federal, State, and industry stakeholders. Both working groups are addressing implementation needs and developing standard protocols to enhance the overall efficiency and effectiveness of the new program strategies.

Roles and Responsibilities

The success of this new approach for the brucellosis program will depend on the long-standing cooperation among Federal and State animal health officials, Federal and State wildlife agencies, regulated industries, and producers. Each cooperator will have specific roles and responsibilities, which will be developed further as the plan evolves.

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
- Implementing a national standardized, integrated, electronic data collection system for brucellosis surveillance and annual reporting
- 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 for program and research objectives

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 disease management areas
- 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 for program and research objectives
- Serving as a liaison with individual producers

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

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

Efficient Use of Fiscal Resources

Both Federal and State funds currently support the brucellosis program. The Federal appropriation for brucellosis has been steadily declining over the last 10 years. In

fiscal year 2009, the program received approximately \$9.5 million in funds appropriated through the brucellosis line item. Congressional language accompanying this annual appropriation stipulates, “no funds shall be used to formulate or administer a brucellosis eradication program for the current fiscal year that does not require minimum matching by the States of at least 40 percent.” Cost-share data indicates that the State contribution to eradication activity funding exceeds 50 percent. Additional Federal appropriations supporting VS surveillance activities, including brucellosis, come from the Animal Health Monitoring and Surveillance (AHMS) line item. AHMS funds supporting brucellosis surveillance activities have been estimated to be approximately \$30 million. The program has also been expending approximately \$600,000 in indemnity funds annually, which comes from the brucellosis line item.

Flat or decreasing Federal budgets are forecast to continue at least through fiscal year 2015. VS assumes the Federal annual appropriation for brucellosis eradication will remain at approximately \$9 million to \$10 million and may decrease. State funding resources face similar limitations. VS must prioritize program activities to ensure we are making the best use of these resources, which includes focusing brucellosis program activities on areas of highest risk and on mitigating the risk of disease transmission.

A national disease status program supported by a national surveillance program will efficiently use resources. Risk-based disease mitigation activities supported by an adaptable regulatory framework will effectively apply limited resources. Reducing slaughter surveillance, eliminating the brucellosis ring test, and eliminating Federal funding for first-point testing in low-risk States will free up funds that can be appropriately redirected to ensure we achieve program objectives within a limited budget. Coordination and collaboration among various Federal, State, and industry partners will be essential. We may also need to consider broader cost sharing or other new alternative sources of funding.

An Example of the New Approach

While the term “disease management area” has been used in this document to describe a national concept, the term “designated surveillance area” is being used for the GYA. This term can be found in the core principles that were presented at a meeting held in Idaho Falls, Idaho, on June 18, 2009. This meeting included representatives from the Idaho, Montana, and Wyoming State livestock, agriculture, and fish and wildlife departments; representatives of the offices of the governors of Idaho and Wyoming; congressional staff for each State; staff from APHIS VS and Legislative and Public Affairs; and representatives of the National Park Service. This meeting focused specifically on the issues associated with the endemic brucellosis situation in elk and bison in the GYA and the risk posed to livestock in the area.

The core principles include the following four components:

A. Prevention and Surveillance

Idaho, Montana, and Wyoming currently have comprehensive prevention and surveillance programs within designated surveillance areas (DSA) located in the GYA. These programs incorporate risk assessment, mandatory calfhood vaccination, adult vaccination on a risk assessment basis, individual animal ID, testing, and development of

herd plans. The flexibility to adjust the boundaries of the DSA should remain with the State. APHIS will have the opportunity to review and approve the DSA boundaries and determine that surveillance and mitigation activities occurring within the DSA are adequate and appropriate. The purpose of the DSA is to facilitate disease prevention and surveillance in livestock populations and surveillance, prevention, and disease management in elk and bison. The DSA should not be used as a boundary to effect a different classification or status than that held by the rest of the State or nation.

B. Disease Response

The response to an outbreak of brucellosis in a cattle herd will be limited to that herd and to potentially exposed herds. The State Veterinarian, in consultation with APHIS, will quarantine such herds until adequate testing and removal or depopulation has occurred. Herds within the DSA but outside the quarantine will not be affected by the issuance of the quarantine. As long as the quarantine is rigorously enforced, the classification or status of other livestock both within and outside the DSA will remain unaffected. If brucellosis is found outside of the DSA (this includes Idaho, Montana, Wyoming, and the other 47 States), it will be treated as a foreign animal disease.

C. Disease Management

Eradicating brucellosis in the GYA remains the long-term goal, with the short-term goals of disease management and prevention. Resources and cooperation from all partners are needed to achieve these goals. While many tools are available, research still is needed on topics such as improved livestock and wildlife diagnostic tests, vaccines, and vaccine delivery systems. Finding cooperative solutions to the problem of disease transmission from elk and bison to cattle should be the primary short-term goal.

D. The Federal Role

The States should support APHIS in its efforts to declare the United States brucellosis free. Currently, outbreaks of brucellosis in livestock occur sporadically. Therefore, a classification system that adjusts the status of entire States or regions within States is no longer needed. The brucellosis program should instead focus on criteria that must be met in a joint State-Federal response to a disease risk in livestock that uses a practical quarantine process that protects the industry and the individual producer's viability.

Potential Obstacles to Implementing the New Approach

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

States are concerned that establishing disease management areas will require them to deal with the disease alone, which may reduce their incentive to promptly investigate cases and mitigate potential disease transmission.

States and producers criticized VS for a previously proposed concept. Their concerns are:

- Lack of funding and human resources required to eliminate brucellosis in cattle and wildlife populations in disease management areas
- States will have to manage disease management areas without proper financial support and Federal involvement
- VS will not financially support enforcing movement restrictions required in disease management areas

However, under the proposed approach, movement restrictions and testing requirements would be limited to disease management areas where the disease exists, rather than statewide. VS believes the costs of restrictions and testing applied to a disease management area will provide the same market incentive for producers and States managing such disease management areas to implement the necessary disease control measures. Furthermore, VS will continue to cooperate with and provide financial support to States to implement minimum brucellosis surveillance and program standards.

VS only proposes to establish brucellosis disease management areas in distinct geographic areas that present a significant risk for brucellosis exposure or transmission to domestic livestock. For example, disease management areas 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 current guidelines of the program.

In addition, to ensure transparency and consistency, VS will clearly describe the criteria for developing a risk assessment that justifies establishing a disease management area and defines the disease management area boundaries. These criteria will incorporate epidemiology, disease dynamics, and ecological factors related to livestock and wildlife; information from investigations of brucellosis outbreaks in livestock; surveillance data from both domestic livestock and wildlife populations; livestock marketing practices; and wildlife movement patterns. Our goal will be to recognize disease management areas with distinct and identifiable boundaries that will contain the potential risk for brucellosis exposure and transmission while allowing herds at low risk to operate without increased requirements or restrictions.

Elimination of brucellosis in wildlife should not be the burden of livestock stakeholders; it should be the responsibility of wildlife agencies.

Implementing a disease management area is only part of a successful approach to eliminating brucellosis in an area of increased disease risk such as the GYA. It also requires a concurrent planning effort with the many wildlife and land-management agencies and entities that have jurisdiction and authority over the impacted area. VS fully recognizes the role that wildlife plays in spreading brucellosis and the critical role that the U.S. Department of Interior and State Departments of Natural Resources and Land Management play in managing wildlife and

combating this disease. VS has engaged these entities to ensure that the wildlife issue is addressed appropriately. VS is eager to partner with these entities to develop and implement appropriate strategies for the disease management area concept.

It will not be possible to enforce program requirements without specifically including them in the CFR.

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

For example, current standards in 9 CFR 78.1 stipulate that if officials find a single brucellosis affected herd in a Class-Free State, the State's status may only be retained if the herd is depopulated and a thorough epidemiologic investigation — including area, trace, and contact herd testing — is completed within 60 days with no additional affected herds disclosed. A State or area may retain its status in this manner only once during any 2-year period. If more than one brucellosis-affected herd is disclosed, the State status is automatically downgraded.

In a national status-based program, these standards might be amended to remove the automatic downgrade and provide guidelines for establishing a disease management area based on a risk assessment and the number of case-associated affected herds. In this way, officials can manage single brucellosis-affected herds through quarantine, stringent testing, and appropriate disease mitigation and herd management activities without imposing additional requirements on all herds in the State. The revised regulations would give the Administrator the option to impose a disease management area if continued detections of brucellosis-affected herds indicated an increased risk of disease transmission and spread.

VS would define various methods for meeting this performance standard in program documents that can be revised 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.

Conclusion

Challenges impeding brucellosis eradication are unique and require new and innovative solutions. With the brucellosis program nearing its goal of officially declaring the United States free of brucellosis, VS is exploring concepts that will provide a national status-based program. This new program will mitigate disease transmission from wildlife, enhance disease response and control measures, use a modernized regulatory framework that can respond to risks quickly, and employ a flexible risk-based disease management system. VS can now focus on transitioning from a State status-based program to a national one supported by a national surveillance plan. A disease management area approach for managing areas of increased risk will be an integral part of this new program. VS' goal is to establish a disease-free designation for the United States and direct resources to effectively mitigate the spread of disease when it is found.