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National Brucellosis Surveillance Strategy
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Introduction

Bovine brucellosis, caused by the bacterium *Brucella abortus*, is a serious livestock disease that has significant animal health, public health, and national and international trade consequences. The cooperative State-Federal-industry effort to eradicate brucellosis from livestock in the United States has made significant progress since the program's inception in 1934. The program's success has resulted in large part from our ability to adapt program activities to effectively address the challenges of disease elimination. Now it is time to address the remaining challenges that impede the final eradication of brucellosis.

The current status of bovine brucellosis in most of the United States is either at or approaching disease freedom. In 2007, the national brucellosis eradication program reached an all-time low national herd prevalence of 0.0001 percent or one brucellosis-affected herd in approximately one million herds. As of July 10, 2009, all 50 States were Class Free for the disease in domestic cattle herds. The last known focus of *B. abortus* is in wild elk and bison in the Greater Yellowstone Area (GYA). In addition, the risk of spreading brucellosis is now minimal, especially in areas that do not have brucellosis-affected wildlife.

The ultimate goal of the brucellosis program is to establish a national disease-free designation for U.S. domestic cattle and bison and define areas where risks are identified and subsequently mitigated. However, certain surveillance strategies used in the current program, which were instrumental in successfully eliminating brucellosis, are no longer necessary. A new strategy is needed that will allow U.S. Department of Agriculture's Animal and Plant Health Inspection Service (APHIS) Veterinary Services (VS) to effectively demonstrate the disease-free status of the U.S. cattle herd through a national status-based program supported by a national surveillance strategy.

A surveillance strategy that demonstrates disease freedom and includes a risk-based disease management area approach is now appropriate. To implement such a strategy, we must transition the current program, based on States' geopolitical boundaries, to one based on boundaries determined through sound science, epidemiology, and risk assessment.

This document describes a proposed surveillance strategy that moves from a census-based sampling plan originally designed for disease eradication to one that will document national disease freedom, which is more appropriate for the current situation. This strategy will maintain a threshold level of detection at one infected animal per one million animals in the U.S. domestic cattle herd. The initial components of the program are described in detail here, and the program will be adjusted as it matures.

Background

In 2007, APHIS VS' Centers for Epidemiology and Animal Health's National Surveillance Unit (NSU) completed an evaluation of bovine brucellosis surveillance in States that had been Class Free for more than 5 years. The evaluation found redundancies in bovine brucellosis surveillance and provided recommendations for the Federal-State Working Group on National Brucellosis Surveillance Planning to consider, including:

- Reducing slaughter surveillance
- Eliminating brucellosis milk surveillance testing
- Limiting first-point testing (FPT) to States that have not been Class Free for at least 5 years or that have *B. abortus* in wildlife
- Promoting an abortion surveillance system
- Standardizing laboratory testing through laboratory consolidation and using a standardized testing protocol

APHIS VS and the United States Animal Health Association endorsed the recommendations. In 2008-2009, NSU re-evaluated the recommendations related to slaughter surveillance for improving the efficiency and cost effectiveness of the brucellosis slaughter surveillance strategy.

Rationale for Surveillance

Disease surveillance is the ongoing systematic collection and analysis of data and the provision of information that leads to action to prevent and control a disease, usually an infectious one. It is an epidemiological practice that monitors the spread of disease to establish patterns of progression. The main role of disease surveillance is to predict, observe, and minimize the harm caused by outbreaks, epidemics, and pandemics, as well as increase our knowledge as to what factors might contribute to these circumstances. A key part of modern disease surveillance is the practice of disease case reporting.

Surveillance has been a critical component of how the brucellosis program finds new cases of infection that may be transmitted between cattle herds, between cattle and wildlife, or introduced from imports into the United States. When new cases are no longer found, surveillance provides evidence to prove with high confidence that the disease no longer exists in domestic cattle herds, or would be detected quickly if it re-emerged. Today, census-based testing is no longer cost effective because adequate data can be collected less expensively by using a statistical sample of cattle that represents the national population[1].

The prevalence of brucellosis in the United States has been established by sampling slaughter cattle for *B. abortus* infection. We do this by collecting blood samples from at least 95 percent of test-eligible cull adult dairy and beef cattle at State and federally recognized slaughter establishments. Currently, each year of sampling provides greater than 99 percent confidence

[1]Cameron A., Gardner I., Doherr M.G., Wagner B. 2003. Sampling considerations in surveys and monitoring and surveillance systems. In: Animal Disease Surveillance and Survey Systems-Methods and Applications. M.D. Salman, ed. Iowa State Press, Ames, IA.: pp 47-66.

that the prevalence of brucellosis is less than one infected animal per one million animals (0.0001 percent) in the national herd. This is considerably above the international standard of 95 percent confidence. Negative test results accumulated over multiple years provide even higher confidence of disease freedom.

This indicates that the United States has reached a point where the last cases of brucellosis in the national cattle herd are being detected. Of further note, the few recent cases of brucellosis have not been from the general population, but have been directly associated with the GYA.

Purpose and Objectives for Surveillance

The purposes of brucellosis surveillance are to:

- Detect new occurrences of brucellosis in domestic cattle
- Support the U.S. classification as a country free of brucellosis
- Generate information in epidemiological investigations to trace potential sources of infection

This depends on a system that includes reliable sampling, diagnostic testing, and animal identification and recordkeeping to effectively determine the disease's presence, source, and distribution.

Surveillance should meet the following objectives:

- Detect *B. abortus* infection with 95 percent confidence that the prevalence level is no greater than one per million animals
- Document disease freedom status
- Target animals and populations that are more likely to have the disease (animals associated with disease management areas and those exhibiting clinical signs of disease)

Surveillance Streams

Historically, brucellosis surveillance has relied on two major surveillance components or streams—market cattle identification (MCI) activities and brucellosis milk ring testing (BRT). The NSU 2007 evaluation demonstrated significant redundancy and inefficiency in these streams. In fact, the sampling of the slaughter surveillance stream alone allowed the United States to reach the current prevalence with a greater than 99 percent confidence level.

The new brucellosis surveillance strategy will initially rely on market cattle surveillance at slaughter and a diagnostic laboratory-based abortion surveillance system. Additional surveillance information from FPT, BRT, area or herd testing, herd certification, and designated surveillance areas will be supplemental components that further enhance the system in some situations.

Slaughter Surveillance Stream

Rationale. Testing blood samples from breeding-age cattle intended for slaughter is particularly valuable. Brucellosis epidemiology predicts that infected cattle are more likely to be culled because of abortions or failure to become pregnant. Therefore, this group of animals at slaughter is a targeted population with a higher likelihood of being brucellosis-positive than the general population. This means that the prevalence of brucellosis in the national cattle population must be the same or less than the slaughter population. In other words, if the prevalence is shown to be less than one in one million in the targeted population, it is reasonable to conclude that the prevalence in the general population is also less than this benchmark.

Slaughter sampling has the following advantages:

- Most dairy and beef breeding cattle are eventually sent to slaughter.
- Slaughter establishments are convenient points of cattle concentration.
- Blood sample collection from a slaughtered animal is relatively simple.

Slaughter surveillance involves collecting blood samples from each animal along with that animal's identification. The blood samples are shipped to the laboratory and tested for brucellosis. The animal identification on each blood sample enables animal health officials to trace the origin of the animal it came from, if necessary. The greatest deficiency of sampling occurs when a blood sample is collected from a slaughtered animal that has no form of traceable identification. The probability of successfully finding and managing the disease in an infected animal's herd-of-origin is substantially reduced if official identification is unavailable.

Sampling Scheme. Initially, we will use a statistically derived sampling approach[2] based on classical sample size calculations. Samples from approximately 2.9 million cull adult dairy and beef cattle collected in a manner that represents all cattle at slaughter provides 95 percent confidence that there is less than one infected animal per million in the population. This estimate is conservative and does not include any cumulative information. That is, neither the number of animals sampled in the previous year nor the number of years that the United States has been free contributes to this confidence estimate.

[2]Cannon R.M. 2001. Sense and sensitivity—designing surveys based on an imperfect test. Prevent Vet Me 49; pp 141-163.

Laboratory-based Surveillance (Abortion Screening)

Rationale. Cattle that either abort or have other reproductive problems associated with *B. abortus* infection (e.g., weak calves, infertility) can provide valuable surveillance information. Not all of these animals are culled and sent to slaughter; many are sampled and tested at diagnostic laboratories for further investigation. Testing can be conducted on a maternal blood sample, maternal tissues (e.g., placenta or uterine discharge), or aborted fetal tissues. Laboratory submissions are a highly targeted surveillance stream for sexually mature cows, which, due to their reproductive problems, have a higher probability of brucellosis infection than any other population segment. They also provide great value for epidemiological investigations due to the direct link back to the herd-of-origin.

Implementation. The current passive system for detecting brucellosis through this surveillance stream will be enhanced to increase veterinary diagnostic laboratories' participation in disease detection and national reporting of their results. Standardized laboratory protocols will also be an important component for an integrated national laboratory-based surveillance stream. For successful implementation, veterinarians and cattle producers must be made aware of the need for samples.

Supplemental Surveillance Streams

Additional surveillance streams besides slaughter and laboratory surveillance are supplemental since they are not required to statistically demonstrate national disease freedom (e.g., by detecting brucellosis at or above the one per million threshold level); those numbers are supported mainly from slaughter surveillance. Although supplemental testing may contribute little to national status, it may be necessary in situations where brucellosis risk is higher than the rest of the national herd or for specific trade purposes. The NSU 2007 evaluation determined that FPT and the BRT were redundant with slaughter surveillance in States that had Class Free status for more than 5 years. Often, market and dairy cattle are tested repeatedly providing no greater value over the original negative test. Because of these findings, brucellosis surveillance efforts have been refocused to maximize efficiency and cost effectiveness.

Nevertheless, if States or industry continue to perform FPT, BRT, area or herd testing, and herd certification, the test results from these streams can supplement slaughter surveillance as additional evidence of disease freedom and increase the system's ability to detect disease at even lower levels. Many of these surveillance activities will likely be implemented in areas described in brucellosis management plans (described below), particularly to mitigate risk in places that may have a higher-than-average probability of disease introduction.

First Point Testing (FPT). Due to the redundancy with slaughter surveillance, Federal funding will not support FPT in States that have been brucellosis-free for more than 5 years. However, some of these States may choose to continue collecting samples at livestock markets, specifically approved stockyards, buying stations, assembly points, or feedlots receiving cattle directly from farms. These sampling locations enable effective tracing of suspicious cases back to their herd-

of-origin by providing a link to marketing records, as well as further diagnostic testing because the presumptive case remains alive at the initial detection.

Brucellosis Ring Testing (BRT). Due to the redundancy with slaughter surveillance, BRT of milk or cream samples from commercial dairy herds will no longer be federally funded. However, milk samples are an economical means of testing all the cattle that contributed milk to it, enabling a herd-level assessment for infection. Milk samples are usually collected by milk processors who frequently visit each dairy to transport milk to processing facilities. Samples tested at official laboratories, their test results, and the herd identification are entered into a database. Thus, milk surveillance provides effective identification of presumptive cases for further investigation. Data from States that choose to continue BRT can be used to supplement national brucellosis surveillance.

Cattle Movement Testing. Testing for interstate, intrastate, or international movement requirements represents another potential source of surveillance data. This testing is not necessarily targeted toward finding infected cattle and affected herds. However, such testing could help mitigate the likelihood of transmission from undetected affected herds, especially in areas where disease may be present in wildlife.

Herd Certification. Herd certification testing can be an effective herd-level assay for brucellosis. Annual herd certification is not necessarily targeted toward finding affected herds because herds seeking certification are also likely to engage in management practices that reduce their chances of becoming infected (e.g., testing and quarantining imports).

Area Testing. Targeted area herd testing can be highly effective in detecting brucellosis-affected herds in higher prevalence areas. Area herd testing can be cost effective if the methods for selecting herds are epidemiologically sound (e.g., increased potential for disease transmission between cattle and wildlife).

Risk-based Disease Management Areas

In addition to slaughter and laboratory-based surveillance streams, some of the supplemental surveillance streams described above may be used in established disease management areas. Their use could ensure rapid disease detection of affected herds and mitigate against the disease moving outside the management area.

The World Organization for Animal Health (OIE) uses zoning to define distinct subpopulations for disease control and international trade purposes. The brucellosis program will use this zoning concept as a starting point for how to define geographically distinct areas with a specific health status that require certain surveillance, control, and biosecurity measures. VS is currently working with GYA State animal health officials to develop a template and criteria for designating a disease management area.

The specific requirements for supplemental surveillance in these areas, both in domestic cattle and wildlife species, will be determined in coordination with State animal health and wildlife authorities. A combination of area risk assessments, individual herd risk assessments, herd management plans, and effective implementation of mitigation activities will inform surveillance needs for each disease management area.

Laboratory Consolidation and Test and Data Standardization

Laboratory consolidation is a key component to an efficient and effective national brucellosis surveillance program and the testing of bovine brucellosis slaughter surveillance (BBSS) samples. Accomplishing this requires a viable regional laboratory structure for BBSS sample testing. Any adjustments made to the current laboratory structure must:

- Increase cost efficiency
- Increase effectiveness by standardizing the testing protocol
- Maintain testing accuracy and timely result reports

The capabilities of individual laboratories to handle increases and decreases in sample volume, and the changes that might occur to the cost of sample testing due to altered volume, must be evaluated.

Key components of a national surveillance approach include comparable laboratory tests, diagnostic test results, and surveillance data. Data generated from surveillance should support estimating a national herd prevalence and documenting U.S. disease freedom.

Test results must follow a standardized diagnostic protocol so that results from each State or laboratory are comparable. The protocol must maximize the probability of detection and minimize the number of false positive results. Standardized data entry into a national database is necessary to prove that the United States is brucellosis free.

Surveillance Performance

Regular evaluation of the surveillance system is essential for achieving surveillance objectives. An annual assessment will be conducted. Adjustments to sample size numbers, allocation of samples, and other program activities will be recommended as necessary to ensure adequate surveillance.

Monitoring the validity of laboratory diagnostics is also important. Validity hinges on collecting quality samples and accurate test performance. Although it is impossible to objectively evaluate performance of each test performed across all laboratories, regular monitoring of general trends is appropriate for quickly identifying problems. Expected versus actual numbers of screening and confirmatory-test positive samples will be assessed to detect increasing or decreasing trends. The change can then be statistically analyzed to determine if it is by chance alone, relates to laboratory test performance or techniques, or actually represents changes in the status of the tested cattle populations.

Future of Brucellosis Surveillance

Successful implementation of the new national brucellosis surveillance strategy and subsequent evaluation of its performance will direct the future of brucellosis surveillance. Future changes to surveillance could begin after a laboratory-based surveillance stream and risk-based designated surveillance areas are fully implemented. This will provide continuing evidence that brucellosis is absent or controlled in the highest risk cattle populations.

A future option could be to focus on slaughter surveillance sample number calculations based on statistical techniques that consider historical data, e.g., consider sample size based on 2-5 years of accumulated negative test data. Conceptually, this is similar to past requirements for States to be declared free only after collecting 2 or more years of negative data.

Further re-evaluation of brucellosis surveillance should continue as the program proceeds. If surveillance data continue to suggest the United States is free of the disease, that may warrant further reduction in sampling. Options such as periodic surveys (similar to the Canadian system) or reliance on robust laboratory-based surveillance with the support of producer-reported events followed by epidemiological investigation may become viable alternatives to continuous slaughter stream sampling.