National Bovine Brucellosis Surveillance Plan

Veterinary Services

Centers for Epidemiology and Animal Health

National Surveillance Unit

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TABLE OF CONTENTS

Executive Summary

Brucellosis is a contagious disease of livestock and wildlife that has significant consequences for animal and public health and international trade. Bacteria of the genus *Brucella* cause the disease. Brucellosis occurs primarily in cattle, bison, and swine, although cervids, goats, sheep, and horses are also susceptible. In cattle and bison, the specific disease organism of concern is *Brucella abortus (B. abortus).*

The U.S. Department of Agriculture's (USDA) Animal and Plant Health Inspection Service (APHIS) has cooperated with the livestock industry and State animal health authorities since 1934 to eradicate brucellosis from the United States. Through the years, many surveillance strategies have been used to eradicate this disease, including the testing of cows and bulls at slaughter, first-point testing (at livestock markets, shows, sales, buying stations, etc.), and whole herd, on-farm testing. These surveillance strategies have proven successful. By 2007, the national brucellosis program had achieved an all-time low national herd prevalence of less than 0.0001 percent. Since July 2009, Veterinary Services (VS) has officially designated all 50 States as Class Free for bovine brucellosis, despite recent detections in the Greater Yellowstone Area (GYA) States of Idaho, Montana, and Wyoming. While all three of the GYA States remain Class Free, the GYA remains our primary focus for brucellosis in livestock because the disease is endemic in GYA wild elk and bison. There is currently no evidence to suggest that brucellosis has spread outside the GYA.

Even though the program has succeeded in eradicating brucellosis from the U.S. domestic cattle and bison herds, continued surveillance is needed to detect any resurgence or reintroduction of the disease and to prove to our trading partners that the United States is free of it. This national plan describes the baseline surveillance activities required to meet the overarching goals of the national bovine brucellosis surveillance program:

- Detecting *B. abortus* infection with 95 percent confidence that the prevalence level does not exceed 1 infected animal per 100,000 animals. This level is higher than the World Organization of Animal Health (OIE) requires.

- Providing data to document a disease freedom status at that level.

The following lists the performance standards to ensure the goals of brucellosis surveillance are met:

a) The total number of adult cattle and bison sampled at slaughter from inspected U.S. establishments should be sufficient to detect with 95 percent confidence a 0.001 percent or higher prevalence level among the U.S. cattle and bison populations.

b) At least 95 percent of all samples collected within each 12-month period should be of suitable quality for testing, packaged and shipped according to protocol, and be accurately associated with the animal identification collected with the sample.

c) At least 90 percent of the reactors collected at slaughter establishments in each 12-month period should be traceable to the herd of origin within 15 days of notification of non-negative results.

Slaughter surveillance is the main surveillance stream used in this plan, but States and VS may use their discretion to implement targeted surveillance in high-risk areas. Adjustments in the plan may be made to increase the efficiency of the surveillance activities or to target specific higher-risk areas.

1. Introductory Information

Disease Description

Bovine brucellosis is a contagious, infectious, and communicable disease of domestic cattle, usually caused by the bacteria *Brucella abortus.* Brucellosis also affects bison, elk, yak, domestic buffalo, African buffalo, and various African antelope species.

Etiology

Brucellosis results from infection by various *Brucella spp.*, which are gram-negative facultative intracellular coccobacilli (short-rod bacteria). The disease in cattle is caused almost exclusively by *Brucella abortus*, although *B. suis* or *B. melitensis* are occasionally incriminated. Although eight biovars of *B. abortus* have been identified, biovar-1 is most frequently isolated from cattle in the United States. These organisms can remain viable for several months in water, aborted fetuses, manure, wool, hay, equipment, and clothes. Survival is longer when the temperature is low, particularly when it is below freezing.

History and Distribution

Brucella spp. are found around the world. *B. abortus* is found worldwide in cattle-raising regions with some exceptions. *B. abortus* has been eradicated in Japan, Canada, Australia, New Zealand, and several Northern and Central European countries (OIE, 2011a). In the United States, the brucellosis eradication program has historically been an important activity for VS . Economic losses due to decreased animal production and public health risk have been and remain the two major drivers of brucellosis surveillance and eradication activities. In 1934, a campaign to control brucellosis in U.S. cattle was launched to assist the cattle industry during the Great Depression. At that time, a reported 11.5 percent of cattle tested serologically positive for brucellosis. By 1954, a comprehensive State-Federal effort was organized to eradicate brucellosis from cattle, and that campaign has continued to the present. The number of brucellosis-affected cattle herds in the United States has declined substantially since the eradication program began. The prevalence level in 2007 was near zero at 0.0001 percent. Currently, all 50 States, Puerto Rico, and the U.S. Virgin Islands are now designated Class Free for brucellosis. The only known location where brucellosis is still present is the Greater Yellowstone Area (GYA), where there is a wildlife reservoir (bison and elk).

Epidemiology

B. abortus is usually transmitted between animals by contact with the placenta, fetus, fetal fluids, and vaginal discharges from an infected animal. Transmission can occur after an abortion or full-term calving. Animals can become infected by ingestion and through the mucous membranes or broken skin. Although cattle are usually asymptomatic after their first abortion, they can become chronic carriers. The *Brucella* organisms can be shed in the milk of infected animals for a variable length of time, but for many, it can be shed for the life of the infected animal (Merck Veterinary Manual, 2012). The organisms can be transmitted to calves vertically and through contaminated milk. Venereal transmission is rare, but it may occur by artificial insemination. In newly affected unvaccinated cattle herds, infection can spread rapidly, and many abortions may occur. Vaccination is effective in preventing abortion and may prevent infection. Nevertheless, large exposure doses may overwhelm vaccination-induced immunity.

The most likely route for brucellosis to enter disease-free cattle herds, regions, or countries is through an infected animal that is purchased and introduced to the herd. Other means of spread from one herd to another include commingling with infected animals or exposure to contaminated materials such as placentas or fomites.

Clinical Signs

The most frequent manifestation of brucellosis in cattle is abortion, usually during the second half of pregnancy (OIE 2011a; Acha and Zyfres 2003). Other clinical signs include stillborn or weak calves, retained placentas, decreased milk yield (estimated 20 to 25 percent loss), decreased fertility, orchitis, epididymitis, and infertility (Acha and Zyfres 2003). Cows often abort after their first exposure to *B. abortus*. Subsequent parturitions are usually normal, although an estimated 10 to 25 percent of infected cows will abort a second time. Nonpregnant females and bulls are usually asymptomatic. Heifers with latent asymptomatic infection may abort or give birth to infected calves and, therefore, play an important role in maintaining disease in a herd. Calves that acquire the infection vertically or by ingesting contaminated milk may remain serologically negative and show no sign of the disease. Infected bulls may develop systemic signs of infection, including fever, anorexia, and depression. The outcome of infection in cattle depends on age, reproductive and immunological status, natural resistance, route of infection, infectious challenge, and virulence of the infective strain (Carvallo Neta et al. 2010).

Prevention

Brucellosis may be avoided by employing good sanitation and management practices. Use of an approved vaccine (i.e., RB51 in the United States) can increase protection of a herd; Vaccination alone, however, may not prevent herd infection because immunity is not absolute. Good husbandry practices are important in reducing the risk of disease entering a herd and include:

- careful selection of replacement animals;
- isolation of purchased replacements for at least 30 days, followed by a serological test prior to commingling;
- prevention of contact and commingling with herds of unknown status or those with brucellosis;
- laboratory testing to diagnose the cause of abortions, premature births, or other clinical signs;
- proper disposal (burial or burning) of placentas and non-viable fetuses; and
- thorough disinfection of contaminated areas.

2. Purpose and Rationale for Surveillance

Historically, brucellosis surveillance and related activities were conducted with the goal of disease eradication. With a near-zero prevalence level in the domestic U.S. cattle and bison populations, the focus in surveillance activities is shifting to reflect this very low prevalence. Brucellosis surveillance should meet the following goals:

- Detect *B. abortus* infection with 95 percent confidence should the prevalence level exceed 1 infected animal per 100,000 animals (or 0.001 percent); and
- Provide data to document disease freedom at that level.

Current OIE standards to qualify for disease-free status require the United States to demonstrate that the rate of brucellosis infection does not exceed 0.2 percent of the cattle herds in the country (OIE, 2011b). To meet this, the United States needs to conduct surveillance at a level that would detect with at least 95 percent confidence whether brucellosis is present in 1,900 or more herds. Surveillance to detect at 0.001 percent ensures the United States' ability to meet the OIE requirement. The current U.S. combined cattle and bison population is 41 million animals (USDA-NASS, 2012). Accordingly, a 0.001 percent annual infection rate would correspond to infection in *at most* 410 separate herds (0.04 percent of the 950,000 herds in the United States) if each herd had only 1 animal infected (0.00001* 41 million = 410 animals). Therefore, this surveillance strategy exceeds the international standard of detecting whether brucellosis is present in more than 0.2 percent of U.S. herds.

Designated surveillance areas (DSAs), such as those defined for the affected areas in the GYA, have separate targeted surveillance and mitigation activities because of periodic spillover from wildlife disease reservoirs. The surveillance requirements for a DSA depend on various epidemiological and ecological factors such as the prevalence of the disease in the wildlife populaton, risk of contact with domestic herds, geographic features, and environmental factors that influence risk to domestic cattle and bison. Because of these differences, this plan does not specifically cover surveillance efforts in DSAs.

The rationale for conducting surveillance for bovine brucellosis includes the following:

- *Economic Impact on Industry*: Brucellosis has cost the livestock industry billions of dollars in direct losses such as reduced beef and milk production and the expense of eradication efforts. Analysts estimate that every dollar spent on eradication activities saves $7 that would otherwise be lost because of infection (Seleem et al. 2010). The cumulative reduction of brucellosis infection in the U.S. cattle herd since the brucellosis eradication program was implemented more than 50 years ago has resulted in an increased supply of both beef and milk.

- *Public Health Concern*: Brucellosis is a zoonotic disease; therefore, control and prevention of brucellosis in animals is essential to reduce human risk. *B. abortus, B. melitensis,* and *B. suis* are highly pathogenic for humans (OIE, 2011). In humans, brucellosis (or undulant fever) presents as a nonspecific flu-like illness, and clinical signs range from mild to severe. People can become infected by consuming unpasteurized dairy products containing the bacteria or through direct contact with contaminated tissues associated with calving or abortion from infected cattle. Humans can also become infected through inhalation of infectious aerosolized organisms. Because of this characteristic and the nonspecific nature of the initial symptoms in people, *B. abortus, B. melitensis,* and *B. suis* are considered select agents by both APHIS and the U.S. Centers for Disease Control and Prevention (CDC). Brucellosis is also considered an occupational disease for people who work with infected animals, particularly farm workers, veterinarians, ranchers, and meatpacking employees.

3. Surveillance Objectives

The objectives of national brucellosis surveillance include:

- detecting brucellosis in domestic cattle and bison;
- estimating the magnitude of brucellosis infection (i.e., prevalence);
- measuring progress toward regulatory goals;
- providing metrics to aid in evaluating compliance with program standards; and
- giving stakeholders and decision-makers timely and relevant actionable information.

These objectives will be met through slaughter surveillance and targeted surveillance.

Slaughter Surveillance

Slaughter surveillance will continue to be the main surveillance stream used to meet the objectives. Slaughter surveillance consists of the collection of blood samples from cattle 2 years of age or older that are capable of reproduction. Sampling will be conducted at select federally inspected slaughtering establishments. VS will select the slaughterhouses annually to ensure that sampling adequately represents the national herd. Approved brucellosis laboratories will test the samples using official diagnostic tests. (Refer to the appendix for more information on the slaughter surveillance sampling strategy.)

Targeted Surveillance

VS and State animal health officials may implement additional targeted surveillance activities in areas deemed to be higher risk. This list includes those already in place, as well as examples of targeted surveillance activities that are being piloted or planned.

- On-farm surveillance: This surveillance stream includes samples collected by federally accredited veterinarians from cattle or bison that present for reproductive issues, such as aborted fetuses or failure to breed.
- Livestock market surveillance: This surveillance stream includes targeting sampling at collection points by federally accredited veterinarians from cattle or bison that present for reproductive issues, such as aborted fetuses or failure to breed.
- Enhanced passive surveillance (EPS): EPS is non-disease-specific and is designed to detect anomalies in animal health that may warrant further investigation. In addition, EPS may provide a means for a specific diagnosis through the collection and analysis of specific body system associated clinical signs (i.e., syndromes) in animal populations.
    - Examples of EPS activities related to brucellosis surveillance being piloted include:
        - *Livestock market surveillance*: This surveillance stream includes both recorded observational data and samples collected by accredited veterinarians from domestic cattle or bison that present for reproductive issues such as aborted fetuses or failure to breed.
        - *Laboratory-based surveillance*: Veterinary diagnostic laboratories already screen for brucellosis in samples submitted by private practitioners from cattle that have aborted; this screening provides additional active surveillance. A pilot is planned to encourage more private practitioners to submit samples from open cattle and cattle that have aborted. If successful and implemented on a larger scale, this EPS activity will

increase the number of diagnostic tests performed, thereby increasing confidence of detecting infection in domestic cattle and bison.

- Import/export-related surveillance: This surveillance stream includes samples collected from other higher-risk animals or herds, including those with cattle and bison that were imported from countries that are not free of brucellosis. Accredited veterinarians are currently testing some of these high-risk animals and this may be enhanced at the discretion of VS and State animal health officials. Also, the required testing of animals exported from the United States provides additional active surveillance.

4. Expected Outcomes

Implementation of this national brucellosis surveillance plan is expected to produce several important outcomes. One outcome is the detection of brucellosis-infected domestic cattle and bison in the United States at a prevalence level of 0.001 percent or higher. Detection at this low level ensures actions can be taken to eliminate infection from the national herd, as described in the Bovine Brucellosis Uniform Methods and Rules (UM&R). In addition, the detection of affected herds may signify high-risk areas that warrant targeted surveillance. Another expected outcome is to meet or exceed the internationally accepted surveillance activities recommended by the OIE; such an outcome would facilitate trade by assuring our trading partners that our domestic cattle and bison and their products are free of this disease. Finally, decision-makers can use the data and other information generated to adjust future surveillance activities to increase the effectiveness and efficiency of the brucellosis program and to guide future regulatory activities.

5. Stakeholders and Responsible Parties

- National Surveillance Unit (NSU): Surveillance planning and evaluation
- VS National Center for Animal Health Programs (NCAHP), regional staff, and the National Veterinary Services Laboratories (NVSL): Surveillance planning, implementation, and oversight; training; communication
- VS regional staff, Area Veterinarians-in-Charge (AVICs), State animal health authorities: Surveillance implementation and communication with local producers and industry
- All sectors of the cattle industry, including producers and producer organizations, market operators, marketing organizations, processors, and processor organizations
- Animal health officials and organizations, including the United States Animal Health Association (USAHA)
- Private practitioners who first suspect and diagnose brucellosis
- State government entities, including departments of agriculture (or equivalent), departments of natural resources (or equivalent), and divisions of wildlife
- Veterinary diagnostic laboratories that test samples and report results
- USDA Food Safety and Inspection Service
- U.S. taxpayers, who ultimately fund brucellosis surveillance and benefit from disease freedom and minimized public health risk
- Foreign trading partners

6. Population Description

The targeted population for brucellosis surveillance is adult domestic beef and dairy cattle and commercial bison in the continental United States. Approximately 41 million cows that have calved (dairy and beef) and bulls over 500 pounds were present on U.S. farms as of January 1, 2012 (Table 1; USDA-NASS, 2012). The U.S. cattle industry consists of approximately 950,000 herds with breeding cows (USDA-NASS, 2010). In addition, there are 198,234 bison on 4,500 operations in the United States (USDA-NASS, 2007). The western half of the United States contains the majority of beef herds; the eastern half contains the majority of dairy herds. The majority of beef operations have from 1 to 29 head of cattle while the largest percentage of inventory is in herds containing 100 to 499 head. The largest number of dairy operations also contains 1 to 29 head but the largest percentage of dairy cows is in herds with 2,000 head or more (Table 2).

Table 1. Number of cattle in States as of January 1, 2012 by length of time the State has been Class Free (NASS 2012)

Length of Time Class Free	Beef Cows That Have Calved	Milk Cows That Have Calved	Bulls 500 Lbs. Or Over	TOTAL
11 or more years	16,291,900	7,820,500	1,194,000	25,306,400
6-10 years	6,587,000	373,000	398,000	7,358,000
1-5 years	7,004,000	1,036,000	460,000	8,500,000
TOTAL	**29,882,900**	**9,229,500**	**2,052,000**	**41,164,400**

Table 2. Number of cattle operations and percentage of inventory by industry (beef and dairy) and operation size (NASS 2011)

Beef Cow Operations (# Head in Operation)	Number of Operations	% Of Inventory (# Head)		Dairy Cow Operations	Number of Operations	% Of Inventory (# Head)
1-29	583,000	27.7		1-29	19,400	1.6
50-99	81,000	17.4		30-49	10,100	4.3
100-499	64,200	38.2		50-99	14,800	11.2
500-999	4,390	9.1		100-199	8,300	11.9
1,000-1,999	1,080	4.3		200-499	4,000	12.5
2,000-4,999	280	2.1		500-999	1,650	12.3
5,000+	50	1.2		1,000-1,999	950	13.7
--	--	--		2,000+	800	32.5
TOTAL	**734,000**	**100**		**TOTAL**	**60,000**	**100**

7. Case Definition

Cattle and bison with brucellosis can be difficult to detect because bulls and non-pregnant females are usually asymptomatic and rates of abortions in pregnant cattle decrease after the first aborted pregnancy. Brucellosis should always be considered in all cattle abortions, particularly when multiple abortions (abortion storms) occur in a herd. Suspect cattle or bison exhibiting one or more of these signs warrant testing:

- abortion,
- reduction in milk yield,
- stillborn or weak calves,
- increased frequency of retained placentas, or
- testicular enlargement or abscesses.

An animal may be suspected for brucellosis based on non-negative response to an official brucellosis screening test.

Animal Classification

Suspect

Cattle and/or bison are classified as suspects when their blood serum has been subjected to official tests and the test results suggest infection but are inconclusive. If bacteriologic methods to cultivate *Brucella* from blood, milk, or tissues were used, they did not yield field-strain *Brucella*.

Reactor
Cattle and/or bison are classified as reactors when their blood serum has been subjected to official tests and the test results indicate that the animal has been exposed to and infected with *Brucella*. Cattle and/or bison are also classified as reactors in the absence of significant serologic test results when other diagnostic methods, such as bacteriologic methods, result in the recovery of field-strain *Brucella* organisms, a significant rise in the serologic titer occurs, or when other epidemiologic evidence of infection is demonstrated.

Negative
Cattle and/or bison are classified as brucellosis-negative:

1. when their blood serum has been subjected to official serologic tests and the test results fail to disclose evidence of *Brucella* infection; and
2. if blood, milk, or tissues are subjected to bacteriologic methods to cultivate field-strain *Brucella* but none are recovered.

Laboratory Criteria for Diagnosis
A suspect or reactor animal is identified using official serologic tests, per Title 9 *Code of Federal Regulations* (CFR) part 78.

When a suspect or reactor animal is identified, tissue and/or milk may be further evaluated to isolate, identify, genotype, and establish the pathogenicity of the organism. NVSL performs these subsequent tests.

8. Data Sources
In conjunction with data collected under this brucellosis surveillance plan, VS and State animal health officials may deem it appropriate to collect additional surveillance data. This can include data from source and at-risk populations through testing, movement controls, slaughter surveillance, or other appropriate risk-mitigating management practices.

Slaughter Surveillance Data
Title 9 CFR parts 78, 71.21, and 310.2 pertain to the collection of samples and/or official identification. The individual animal identification should also link to marketing records (e.g., invoices and test charts) to support the trace of tested cattle back to their herds of origin. Test results are generated at approved laboratories and the data are maintained in each laboratory's record system such as the Laboratory Information Management System (LIMS) or some other database. Laboratories approved to test brucellosis slaughter samples under this plan will provide testing data to State and Federal animal health officials, who generally keep the data in a State database as well as the VS Surveillance Collaboration Services (SCS) database.

Targeted Surveillance Data
In addition to the data that VS collects at slaughter, States may collect data from targeted surveillance activities as part of their animal health plans. These stakeholders currently keep much of this data in various databases (Table 3).

Table 3. Data sources for brucellosis surveillance in the United States

Data Stream	Data Source
Slaughter surveillance	• Diagnostic laboratory database (e.g.,LIMS) • State animal health database • Federal database (e.g., SCS) • Industry database such as slaughter establishment database
On-farm and livestock market surveillance	• VS-SCS-MIM data repository • State animal health database • VS AWBDS system
EPS livestock markets	• State animal health database • Spreadsheets submitted to NSU • SCS
Laboratory-based stream (abortion screening)	• Diagnostic laboratory database (e.g., LIMS) • State animal health database

a) On-farm and livestock market surveillance: Data from brucellosis test charts are entered into State databases either manually or via mobile information management (MIM) hand-held devices. Required data are then uploaded from State databases into the VS Automated Web-Based Data Submission (AWBDS) System or the data are entered directly into SCS.
b) EPS livestock market surveillance pilot: The State animal health official collects data from these pilot projects weekly or as defined in the cooperative agreement workplan and submits the data to NSU for analysis and reporting. NSU will enter the data into SCS.
c) Laboratory-based surveillance (abortion screening): Currently, all data associated with abortion screening are held within each approved laboratory's record-keeping database (e.g., LIMS). Future pilot EPS-related laboratory surveillance data will be submitted to VS as defined in each cooperative agreement workplan.
d) Export-import testing data: Records of export-import testing are maintained in the each approved laboratory's record-keeping database (e.g., LIMS).

9. Sampling Methods

Slaughter Surveillance

According to a statistically-based sampling approach (Cannon, 2001), approximately 350,000 blood samples collected completely at random from the population of adult cull cows, bulls, and bison at slaughter would be adequate to detect with 95 percent confidence 1 infected animal in 100,000 animals (or 0.001 percent) in the *slaughter population*, assuming a testing regime with 83 percent sensitivity (USDA-APHIS, 2007). Because brucellosis-infected animals are more likely to be culled, one would expect this number of samples to be equivalent to a much higher number from the healthy (bred) population. However, collecting only 350,000 samples from this population still requires continual resources and time commitment. Attempting to sample completely at random is not possible, as this would disrupt slaughter establishment operations.

Partial sampling in any form would have the same effect on many establishments. Because of these limitations, NSU, NCAHP, and regional staff will establish the target number of samples that will adequately represent the national herd. As part of this planning, VS will evaluate slaughter establishments, as well as the sampling scheme at each establishment, to ensure sampling represents all domestic cattle and bison herds presented for slaughter. Slaughter establishments will be selected based on their geographic distribution across the country as well as the diversity of States from which they receive adult cull cows, bulls, and bison. Target sample numbers may increase or decrease each year based on an analysis of the previous year's data and historical surveillance data.

Targeted Surveillance

Samples will be collected from targeted surveillance efforts that are specific to the surveillance streams or high-risk area. This may include sampling animals before they leave a DSA, testing open cattle or those known to have aborted a fetus (seen on-farm or at a market), and others. The sampling methods will be described in specific plans that are beyond the scope of this national plan.

10. Data Analysis and Interpretation

Numerous groups within VS analyze data. This includes national brucellosis staff, regional and area office personnel, designated brucellosis epidemiologists (DBEs), and Centers for Epidemilolgy and Animal Health (CEAH) personnel.

11. Data Presentation and Reports

States and Tribes are required to submit annual reports to the national brucellosis staff for monitoring. Regional epidemiologists and staff from NCAHP and CEAH will compile cattle slaughter data from the selected Federal slaughter establishments to provide reports on the status of surveillance activities throughout the United States.

12. Implementation, Budget, and Evaluation

Surveillance System Implementation

VS intends to begin the implementation of this national surveillance plan in FY 2013. VS may be unable to implement certain elements of the plan immediately.

Resources

The VS brucellosis program is now funded under a cattle health commodity-specific line item rather than a brucellosis program line item. This line item provides flexibility to direct funding to cattle programs where the funding is most needed, and the line item should provide adequate funds to meet the brucellosis program's goals and objectives.

Human resources essential for the success of the brucellosis program include national brucellosis staff, regional epidemiologists, VS area office staff, DBEs, VS and State animal health field personnel, and NVSL and CEAH personnel. Additional external resources include select State diagnostic laboratories that are approved to perform the official tests.

Surveillance Plan Performance Metrics

Performance metrics provide assurance that surveillance activities are effectively and efficiently meeting the national surveillance program goals. The performance metrics for national brucellosis surveillance are:

a) The total number of adult cattle and bison sampled at slaughter from inspected U.S. establishments should be sufficient to detect with 95 percent confidence a 0.001 percent or higher prevalence level among the U.S. cattle and bison population.

   The Strategy for National Brucellosis Slaughter Sampling (appendix) describes how the detection threshold meets surveillance goals. Considering reproductive problems associated with brucellosis and that animals with reproductive problems are likely to be culled from a herd, it follows that infected animals are more likely to be culled. This subpopulation of cull cows (dairy and beef), bulls, and bison forms a target population with a higher likelihood of having brucellosis-positive animals than the general population. Using samples collected from this targeted population allows inference regarding the prevalence of brucellosis in the U.S. domestic cattle and bison population. If the prevalence is shown with 95 percent confidence to be less than 1 in 100,000 animals per year in the targeted (i.e., higher-risk) population, it is reasonable to conclude with the same level of confidence that the prevalence in the general population is equal to or lower than this 1 per 100,000 benchmark.

b) At least 95 percent of all samples collected within each 12-month period should be of suitable quality for testing, packaged and shipped according to protocol, and be accurately associated with the animal identification collected with the sample.

   The success of the slaughter surveillance program relies on the collection, packaging, and shipping of all samples from this targeted population according to slaughter surveillance procedures (see Slaughter Surveillance Procedures Manual) to ensure they arrive at the laboratory in testable condition. Equally important, each blood sample must accurately correlate with identification devices to ensure the proper identification of any infected animals. The proper identification of infected animals will allow traceback to the herd of origin for further testing and will prompt removal of additional reactor animals when appropriate.

c) At least 90 percent of the reactors identified through samples collected at slaughter establishments in each 12-month period should be traceable to the herd of origin within 15 days of notification of non-negative results.

   Another key to the success of the surveillance program is the ability to efficiently and effectively trace potential infected animals to their herd of origin. This reduces the risk of spread to other herds and assures trade partners of the disease-free status of the other animals in the national herd.

Surveillance System Evaluation

The brucellosis surveillance system should be evaluated regularly to determine how well the system fulfills its stated goals and meets accepted standards. The evaluation process will identify system strengths and areas for improvement. This surveillance plan should be evaluated within 2 to 3 years of its implementation and periodically thereafter.

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List of Acronyms Used

APHIS	Animal and Plant Health Inspection Service
AVIC	Area Veterinarian-in-Charge
AWBDS	Automated Web-Based Data Submission System
BSAS	Body System Associated (Clinical) Signs
CDC	Centers for Disease Control and Prevention
CEAH	Centers for Epidemiology and Animal Health
CFR	Code of Federal Regulations
DBE	Designated Brucellosis Epidemiologist
DSA	Designated Surveillance Area
EPS	Enhanced Passive Surveillance
FSIS	Food Safety and Inspection Service
GYA	Greater Yellowstone Area (includes areas of Idaho, Montana and Wyoming)
LIMS	Laboratory Information Management System
MIM	Mobile Information Management
NASS	National Agricultural Statistical Service
NCAHP	National Center for Animal Health Programs
NCIE	National Center for Import and Export
NSU	National Surveillance Unit
NVSL	National Veterinary Services Laboratories
OIE	World Organization for Animal Health
SCS	Surveillance Collaboration Services
UM&R	Uniform Methods and Rules
USAHA	United States Animal Health Association
USDA	U.S. Department of Agriculture
VS	Veterinary Services
VSPS	VS Process Streamlining

Appendix: Brucellosis Slaughter Surveillance Sampling Strategy, FY2013

Background

The national brucellosis eradication program has successfully reduced the prevalence of brucellosis in domestic cattle and bison to virtually zero in all States. The focus of the national brucellosis surveillance has changed from eradication to documenting disease freedom. Since 2006, the program has undergone several evaluations (USDA-APHIS, 2007a; USDA-APHIS, 2009) and numerous changes (9 CFR 78, 2010; John Clifford memo, 2011) in this direction. It should be noted that the Greater Yellowstone Area (GYA) has additional surveillance and mitigation plans because of the presence of infected wildlife that serve as disease reservoirs, resulting in periodic spillovers.

The goals of the updated national brucellosis surveillance plan are to meet World Organization for Animal Health (OIE) standards for disease freedom and to detect brucellosis if there is a recrudescence or reintroduction. To be considered free of brucellosis, international standards require a country to conduct surveillance at a level sufficient to detect brucellosis if it is present in more than 0.2 percent of the country's herds (OIE, 2011). To meet this, the United States needs to conduct surveillance at a level that would detect the presence of brucellosis if it was present in 1,900 or more herds with at least 95 percent confidence.

Slaughter surveillance is currently the major component of the national brucellosis surveillance plan. The purpose of this document is to describe revisions to the slaughter surveillance sampling strategy that will meet the OIE standards for disease freedom and detect brucellosis in the U.S. domestic cattle and bison population if there is recrudescence or reintroduction of disease.

Population Description and Characteristics

The population at risk for brucellosis is adult beef and dairy cattle and commercial bison in the continental United States. According to the USDA's National Agricultural Statistics Service (NASS), approximately 41 million cows that have calved (dairy and beef) and bulls over 500 lbs. were present on U.S. farms as of January 1, 2012 (USDA-NASS, 2012). The U.S. cattle industry consists of approximately 950,000 herds with breeding cows (USDA-NASS, 2010). There are 198,234 bison on 4,500 operations in the United States (USDA-NASS, 2007).

In December 2010, an interim rule (9 CFR 78, 2010) was published, providing for a national brucellosis surveillance plan in lieu of the traditional State census-based sampling originally designed for disease eradication. The goal of the new plan is to conduct slaughter surveillance that represents and demonstrates the disease-free status of our national domestic cattle and bison herd. Additional surveillance requirements remain in place for States that have not been Class Free for brucellosis for 5 or more years or that have identified brucellosis in a wildlife population.

Sampling Streams

In the United States, there are four sampling streams that would enable detection of infected cattle: slaughter sampling, diagnostic testing of samples submitted by private practitioners, testing of cattle being moved interstate, and enhanced surveillance in the GYA (e.g., change of ownership and market testing). Although each of the four streams listed above provides

information about the status of brucellosis in the domestic U.S. cattle and bison, this document focuses solely on slaughter surveillance sampling to meet the surveillance objectives.

Clinical signs for brucellosis include abortion, stillborn or weak calves, retained placentas, decreased milk yield, testicular abscesses, arthritis, and infertility (Radostits et al., 2000). It is estimated that 26.3 percent of culled dairy cows are culled because of reproductive problems (USDA-APHIS, 2007b), and 33 percent of culled beef cows are culled because they are open or have aborted (USDA-APHIS, 2008). From this, we can infer that brucellosis-infected animals are much more likely to be culled. Therefore, the subpopulation of cull cows (dairy and beef), bulls, and bison provides a targeted population with a higher likelihood of having brucellosis-infected animals than the general population. By sampling this targeted population, inferences regarding the prevalence of brucellosis in the U.S. domestic cattle and bison population can be made. If the prevalence is shown to be less than 1 infected animal in 100,000 animals per year with a 95 percent confidence in the targeted (i.e., higher-risk) population, it is reasonable to conclude with the same level of confidence that the prevalence of brucellosis in the general population is lower than one infected animal per 100,000 animals.

Slaughter Sampling Strategy

A surveillance strategy that has a high level of confidence in detecting at least one infected animal in 100,000 animals per year meets the surveillance standards set by OIE as well as detect disease at relatively low prevalence. We have determined that a detection level of one infected animal out of 100,000 animals per year provides high confidence in meeting our new national surveillance goals. The current U.S. cattle and bison population is 41 million animals (USDA-NASS, 2012). Accordingly, a 0.001 percent annual infection rate would correspond to infection in *at most* 410 separate herds (0.04 percent of the 950,000 herds in the United States) if each herd had only one animal infected (0.00001* 41 million = 410 animals). This greatly exceeds international standards of detecting brucellosis if more than 0.2 percent of U.S. herds (or 1,900 herds) were infected. Our detection level also allows time for implementation of mitigation measures should brucellosis re-emerge. This is because of the slow spread of this disease; for example, since 2004, only three secondary herds were identified from 23 index cases with an average of less than five infected animals per herd (Personal communication, VS Regional Epidemiologist, 2012). To meet our national brucellosis surveillance goals, we need to collect an adequate number of samples from the slaughter surveillance stream within a fixed period of time. The samples collected must be selected from the national domestic cattle and bison population, as well as all geographic regions of the United States. Maintaining a sustainable, quality slaughter sampling strategy requires a sampling design that minimizes disruption of slaughter establishment operations.

According to a statistically-based sampling approach (Cannon, 2001), approximately 350,000 blood samples collected completely at random from the population of adult cull cows, bulls, and bison at slaughter would be adequate to detect 1 infected animal in 100,000 animals in the *slaughter population* with 95 percent confidence, assuming a testing regime with 83 percent sensitivity (USDA-APHIS, 2007a). Because brucellosis-infected animals are more likely to be culled, one would expect this number of samples to be the equivalent of a much higher number from the healthy (bred) population. However, collecting only 350,000 samples from this population still requires the continual presence and availability of resources and time commitment and thus would fail to decrease collection costs. Attempting to sample completely at

random could disrupt slaughter establishment operations. Partial sampling in any form would have the same effect on many establishments. For these reasons, Veterinary Services has evaluated slaughter establishments to sample, as well as the sampling scheme at each establishment, with the objective of determining the most efficient strategy to obtain an adequate number of samples representative of all domestic cattle and bison herds presented for slaughter. Slaughter establishments were selected based on their geographic distribution across the country as well as the diversity of States from which they receive adult cull cows, bulls, and bison. Nonetheless, there are many uncertainties in cattle movement and the populations of cull animals at specific plants, so a sample number of approximately 1 million blood samples (or approximately three times the number of *random* samples required) was chosen for collection in FY 2013 to ensure representativeness and adequate surveillance.

The detection level and confidence described above is predicated on a single year of sampling. The negative slaughter surveillance testing accumulated in prior years also contributes to knowledge about national prevalence estimates in the current year. This historical information, along with data provided by the other surveillance streams, provides further evidence to support the determination that the prevalence of brucellosis in the national domestic cattle and bison population is less than the one per 100,000 detection level.

Summary

The recent and ongoing reduction in brucellosis slaughter surveillance sampling signifies a shift in the national brucellosis surveillance paradigm and reflects the shift in goals from disease eradication to detection of re-emergence and demonstrating the disease-free status of U.S. domestic cattle and bison herd. The new sampling strategy also reflects a level of surveillance adequate to detect recrudescence or reintroduction of brucellosis. This sampling strategy will be evaluated during the year to ensure that it meets the national brucellosis surveillance goals and provides for representative samples. Given the characteristics of the disease, the available historical slaughter surveillance data, and the non-random surveillance streams, this targeted slaughter surveillance sampling strategy more than ensures detection of 1 infected animal per 100,000 animals with 95 percent confidence. This slaughter surveillance sampling strategy may be revised in FY 2014 as we continue our efforts to improve the efficiency and cost-effectiveness of the brucellosis surveillance program.

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