

REPORT OF THE COMMITTEE ON BRUCELLOSIS

Chair: Glenn Plumb, Yellowstone National Park, WY

Vice Chair: Claude Barton, Nashville, TN

John B. Adams, VA; J Lee Alley, AL; Keith E. Aune, MT; Carter Black, GA; Richard E. Breitmeyer, CA; Becky L. Brewer-Walker, OK; Marcus Bridges, MT; John Chatburn, ID; Max E. Coats, Jr., TX; Thomas F. Conner, OH; Walter E. Cook, WY; Ed Corrigan, WI; Donald S. Davis, TX; Mark L. Drew, ID; Anita J. Edmondson, CA; Robert G. Ehlenfeldt, WI; Philip H. Elzer, LA; Steven R. England, NM; Donald E. Evans, KS; Dave E. Fly, NM; James M. Foppoli, HI; Tony G. Frazier, AL; Bob Frost, CA; Frank Galey, WY; Tam Garland, MD; Robert F. Gerlach, AK; Arnold A. Gertonson, CO; Michael J. Gilsdorf, DC; L. Wayne Godwin, FL; William L. Hartmann, MN; Gregg Hawkins, TX; Steven G. Hennager, IA; Bob R. Hillman, TX; E. Ray Hinshaw, AZ; Sam D. Holland, SD; Majon Huff, CO; Dennis A. Hughes, NE; David L. Hunter, MT; Jon G. Johnson, TX; Susan J. Keller, ND; Terry L. Klick, OH; Terry J. Kreeger, WY; Maxwell A. Lea, Jr., LA; Thomas F. Linfield, WY; Jim R. Logan, WY; Laurent O'Gene Lollis, FL; Phillip M. Mamer, ID; Bret D. Marsh, IN; Barbara M. Martin, IA; Chuck E. Massengill, MO; George L. Merrill, NY; Andrea Mikolon, CA; Henry I. Moreau, LA; Rick R. Nabors, TX; Steven C. Olsen, IA; Elizabeth J. Parker, DC; Janet B. Payeur, IA; Valerie E. Ragan, MD; Thomas J. Roffe, MT; Shawn P. Schafer, MN; David D. Schmitt, IA; Marilyn M. Simunich, ID; Robert C. Stout, KY; Paul L. Sundberg, IA; George A. Teagarden, KS; Kenneth J. Throlson, ND; James A. Watson, MS; Gary M. Weber, MD; Diana L. Whipple, IA; Margaret A. Wild, CO; Richard D. Willer, AZ; Larry L. Williams, NE; Taylor Woods, MO; Glen L. Zebarth, MN.

The Committee met on Wednesday, October 24, 2007 from 7:30 a.m. to 12:30 p.m. at John Ascuaga's Nugget Hotel, Reno, Nevada. A total of 117 individuals were in attendance of which 52 were Committee members and 65 were guests. The meeting was chaired by Glenn Plumb, National Park Service, and there were 22 scientific presentations, reports, resolutions, and recommendations presented to the Committee for consideration.

Claude Barton, gave a brief review of the 2006 meeting in Minneapolis, Minnesota, and reported on one Resolution and one recommendation from that meeting. The response from United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS), Veterinary Services (VS) to both was positive.

Phillip Elzer presented the report of the Scientific Advisory Subcommittee on Brucellosis, as follows.

Report of the Scientific Advisory Subcommittee on Brucellosis

Chair: Philip Elzer

Subcommittee Chair Phillip Elzer, Brucellosis Researcher, Louisiana Annual State University (LSU), convened the Subcommittee at 10:00 a.m., October 23, 2007 during the 111th Meeting of the United States Animal Health Association (USAHA). Subcommittee members are Keith Aune, Don Davis, Phillip Elzer, Don Evans, Barb Martin, Steve Olsen, Jack Rhyon, and Gerhard Schurig. There were no scientific issues referred to the Subcommittee during the year. If needed, further actions will be taken at a later date. Members present were Davis, Elzer, Martin, and Olsen. There were 39 visitors also in attendance.

Geetha Srinivas, United States Department of Agriculture (USDA), Animal and Plant Health Inspection Services (APHIS), Veterinary Services (VS), Center for Veterinary Biologics (CVB), gave a presentation outlining procedures and requirements for approval of new technologies, including needle-free delivery systems for vaccinations. The presentation included considerations for safety and efficacy using the needle-free system compared to the currently approved vaccination method.

The Subcommittee did not make a formal recommendation regarding this new technology. However, it should be pointed out that this system currently would be considered off label usage of the vaccine and therefore animals vaccinated using this method would not be considered to be officially vaccinated in accordance with the Brucellosis Uniform Methods and Rules (UMR).

Terry Kreeger, Wyoming Game and Fish Department, gave a presentation updating the pilot brucellosis test and removal project for elk at the Muddy Creek feed-ground. This project is intended to

measure the effect of test and removal of sero-positive animals on the prevalence of brucellosis in elk at this feed-ground. He discussed plans for expanding the program in 2008. The Subcommittee looks forward to the results of 2008.

Pauline Nol, VS-APHIS-USDA gave a brief presentation entitled, Immunologic Responses and Protection in Elk Vaccinated with *Brucella abortus* Strain RB51, over-expressing superoxide dismutase (SOD) and wboA and challenged with virulent *Brucella abortus*. Although there was some evidence of immune response, the results were inconclusive and the number of animals in the study was low. The view of the Subcommittee is that more study in this area is needed.

Chuck Massengill, Missouri Department of Agriculture, presented a request for a recommendation to change the cut-off values for the fluorescence polarization assay (FPA) brucellosis serologic test. Due to program changes and potential budget reductions, the Subcommittee recognizes that there is a need for more efficient testing standards. Therefore, the Subcommittee recommends that the Chair of the Committee on Brucellosis put forth a formal charge to the Brucellosis Scientific Advisory Subcommittee to evaluate FPA data in regard to a change in the current cut-off value. Further, the Scientific Advisory Subcommittee requests that the Chair of the Committee on Brucellosis communicate with USDA-APHIS-VS the need to gather and compile FPA results sufficient to support this effort.

The Scientific Advisory Subcommittee Report was accepted by the Committee.

The Feral Swine Subcommittee on Brucellosis and Pseudorabies Report was delivered to the Committee by Carter Black and Joseph Corn, as follows.

Report of the Feral Swine Subcommittee on Brucellosis and Pseudorabies

Co-Chairs: Carter Black
Joseph Corn

The Subcommittee was called to order by the Chair at 1:00 p.m. on Monday, October 22, 2007. There were 49 attendees, including eight members of the Subcommittee. Reports were provided on feral swine issues relating to brucellosis and pseudorabies.

Joseph L Corn, Southeastern Cooperative Wildlife Disease Study (SCWDS), University of Georgia, provided a report on development of the National Feral Swine Mapping System (NFSMS). SCWDS produced nationwide feral swine distribution maps in 1982, 1988 and 2004 by working directly with state and territorial natural resources agency personnel. In 1982, there were 17 states reporting feral swine in a total of 475 counties. In 2004, there were 28 states reporting feral swine in 1014 counties. With support from United States Department of Agriculture, (USDA) Animal and Plant Health Inspection Service (APHIS) Veterinary Services (VS) SCWDS has now developed the NFSMS, an interactive data collection system to be used to collect and display real time data on the distribution of feral swine in the United States. The real time feral swine distribution maps will be produced using data collected from state and territorial natural resources agency personnel and from USDA-APHIS-Wildlife Services (WS). The real time map will be available to be viewed by the public on the NFSMS home page. Distribution data submitted by agency personnel will be evaluated by SCWDS on a continual basis, and the real time distribution map updated with verified additions on a monthly basis. Feral swine populations included in the map will be those determined to be established and breeding. Updated maps will be available to be viewed and downloaded from the website.

Additionally, Corn provided a report on disease exposure in feral swine populations geographically associated with high densities of transitional swine premises and commercial swine production. Surveys for evidence of exposure to pseudorabies virus (PRV), *Brucella suis*, swine influenza virus (SIV, human-like H1N1, reassortant type H1N1, H1N2-like H1N1 and H3N2), porcine circovirus 2 (PCV 2), and porcine respiratory and reproductive syndrome virus (PRRSV) in feral swine were conducted in areas where feral swine were geographically associated with high densities of transitional swine premises in South Carolina and in areas where feral swine were geographically associated with high densities of commercial swine production in North Carolina. These areas were identified using overlays of maps of the distribution of feral swine in the United States, maps of the distribution of transitional swine premises in South Carolina, and county-level maps of the distribution of commercial swine premises in North Carolina.

Tom Ray, North Carolina Department of Agriculture and Consumer Services, gave an update on feral swine programs in North Carolina. Of the 10 largest hog producing counties in the United States, eight of these are in North Carolina. Swine inventories are more than nine million with the vast majority located in the eastern third of the state. Feral swine have been found in 84 of the 100 counties in the state. In addition to surveillance sampling by USDA-APHIS-WS and SCWDS in Eastern North Carolina, sampling has occurred in other parts of the state, particularly in and around the Great Smokey Mountains National Park. Sampling over the past three years has shown no positive samples for PRV, *Brucella suis* or classical swine fever (CSF) in the eastern third of the state where the vast majority of North Carolinas' commercial swine industry is located. A small number of PRV positive samples have been found in Western North Carolina and the number is increasing. Because feral swine are the greatest risk for spreading PRV and swine brucellosis (SB) to the commercial swine industry, an objective-based surveillance plan, or hazard analysis critical control points (HACCP), is suggested, based on a sound, reliable epidemiological investigation of prevalence, statistical sampling and incidence rates, combined with education/outreach and regulatory involvement.

Troy Bigelow, gave an update on VS programs related to feral swine. Feral swine continue to be a threat to domestic swine. They, being carriers of PRV and brucellosis, have transmitted these diseases to herds where exposure to feral swine is allowed. This presentation reviews the number of indemnified herds due to feral or potential feral swine exposures and discusses possible ways to modify the regulations to account for different risks in different states. HACCP is a systematic thought process used as the regulatory background in other agencies to mitigate risks. HACCP principles, if adopted could be used to mitigate risks of PRV and swine brucellosis from entering the commercial compartment. The HACCP principle will be discussed as a way to protect the commercial compartment of possible risks.

Seth Swafford, gave an update on WS activities related to feral swine. As part of an intra-agency initiative, WS has continued to partner with VS to design and implement a nationwide surveillance approach regarding sampling feral swine for CSF. As an equally important component, these agencies have included monitoring for SB and PRV over the last three years in feral swine populations. This has been possible only with support provided by state departments of agriculture and state wildlife agencies. This approach has truly become an inter-agency effort and represents one of the largest coordinated wildlife disease surveillance efforts implemented by WS. Information provided below is a general compilation of activities conducted between October 2006 and September 2007 and the planned approach for the following year. The inter-agency effort involved sampling 2029 feral swine from 20 States as one surveillance stream to support a comprehensive swine disease surveillance program. CSF surveillance remains the emphasis of the effort and is based on serological analyses performed by VS Foreign Animal Disease Diagnostic Laboratory (FADDL), Plum Island, New York. CSF was not detected in any of the samples collected during the sampling period. Surveillance for SB and PRV is also serologically based, samples are analyzed at state or university laboratories. This is an important distinction between the two components of the effort, foreign animal disease surveillance and endemic disease monitoring, and establishes the local experts as the leading authorities. SB and PRV was detected in many, but not all, local populations of feral swine. Data are presented from three states, Oklahoma, Florida, and South Carolina, to highlight the disparity between apparent sero-prevalence findings in feral swine. These states are used only to highlight the differences between apparent sero-prevalence findings and are not meant to implicate these states in any way. Apparent sero-prevalence of SB and PRV in feral swine from these states ranged from 0.6 percent to 19.0 percent and 3.8 percent to 26.5 percent respectively. These findings document the large degree of variability in which SB and PRV circulate in feral swine populations. Monitoring endemic diseases in feral swine should continue as a long term objective to establish baseline data, monitor for epidemics in feral swine which could increase risk to domestic swine, aid in response and eradication if necessary, and leverage information and education to local communities. The inter-agency cooperative has planned to sample approximately 2,100 feral swine in 30 States during the next sampling period.

Ned Hahn, College of Veterinary Medicine, University of Illinois, reported on, Feral Pig PRV: What is in your Neighborhood? The overlap of feral and domestic swine herds and the traffic among

transitional herds and shooting preserves poses a high risk of reintroduction of PRV to commercial herds. There are DNA markers in the PRV that will assist in identifying the source of infection. Pinpointing the source of infection will dictate appropriate management changes needed to mitigate the risk. Improved preparedness presents confidence to the world that our nation can handle this persistent reservoir of infection. The risk of infection of domestic swine from the feral reservoir will not diminish. The route of transmission can occur by oral as well as venereal routes and marker technology can differentiate viruses to establish sources of infection.

There was a discussion on the status of transitional herds. This will require more discussion as the nation moves toward World Organization for Animal Health(OIE) Free status.

The Subcommittee Report was unanimously accepted by the Committee.

Debra A. Donch, Arnold A. Gertonson, and Jack C. Rhyon, VS-APHIS-USDA, presented the Fiscal Year (FY) 2007 Annual Report of the National Cooperative Brucellosis Eradication Program. During the year a single brucellosis affected cattle herd was disclosed in the Brucellosis Class Free State of Montana. No new affected herds were disclosed during the year in Texas, the single remaining Brucellosis Class A State. A pre-review for Class Free status was conducted in Texas during the year. Regulatory administrative requirements for advancement of Texas to Brucellosis Class Free Status were initiated and in progress as FY 2007 came to a close. The complete text of the 2007 National Status Report is included in these proceedings.

Alfredo Gutierrez gave the brucellosis status report for Mexico. He reported that the Mexico Norm (program standards) and other animal health regulations have been reviewed and are in the process of being updated. The goal for the coming year is for Sonora, Yucatan, and Lower Baja states to become brucellosis free and all the border states being in the eradication phase. Gutierrez reviewed serologic testing and vaccination data for the year. The number of human cases of brucellosis continued to decline, with approximately 1,600 cases having been reported during the year.

The Texas Brucellosis Report was given by Bob Hillman, Executive Director, Texas Animal Health Commission (TAHC). The State of Texas is the only State in the United States which has not yet achieved Brucellosis Class Free Status. Cattle producers, market operators, veterinarians, and animal health officials have worked long and hard to qualify Texas for Class Free Status. By 1990 the number of affected herds discovered in the State had been reduced to five-hundred and twenty five. By 1994, the number of affected herds had been reduced to one-hundred and eighty-one, and on March 28, 1994, Texas achieved Brucellosis Class A Status. From 1990 to the present time Texas aggressively pursued all of the components of the brucellosis program and there was a continuous decrease in the number of affected herds discovered in the state. Producers, market operators, veterinarians and animal health officials continued vigorous efforts to eliminate the disease.

The pathway has not been easy. The state neared zero affected herds several times only to find additional infection. In an effort to assure that animal health officials were doing all of the tasks necessary to eliminate brucellosis, the TAHC, in early 2006 formed a Brucellosis Eradication Working Group to review the state's brucellosis program and make recommendations that could assist achievement of Class Free Status. The working group made a number of recommendations to the Commission. Foremost among these was the recommendation to aggressively pursue Class Free Status for the State of Texas. Other recommendations included: strategic vaccination of heifers, alternative methods to achieve vaccination, identification of non-vaccinated heifers, continuation of first-point testing, testing of higher risk herds, improved recordkeeping to assist in trace-back, and dissemination of information about the need for the support of the cattle industry segments to complete the eradication effort in Texas. The last affected herd identified in the state was detected in August 2005, in Hardin County, Texas. The herd consisted of 24 cattle. Only one infected animal was discovered in the herd. The herd was tested as recommended by the Brucellosis Uniform Methods and Rules and as required by TAHC regulations. The herd was released from quarantine in August 2006.

At the time of release of the last quarantined herd, animal health officials in Texas believed that the state had met all of the requirements for classification of the State to Brucellosis Class Free Status. The Executive Director and the Area Veterinarian-In-Charge requested a Brucellosis Class Free pre-review by USDA. This review was conducted from July 30 through August 3, 2007. The review team was

led by Arnold Gertonson. Texas awaits the report from the review team. Texas animal health officials strongly believe that the State meets all of the requirements for Class Free Status. However, they remain committed to making any corrections or adjustments to the Texas Brucellosis Program that may be necessary to achieve classification to Class Free Status.

The Yellowstone National Park Status Review was presented by Rick Wallen, Wildlife Biologist and Glenn Plumb, Chief of Natural Resources, Yellowstone National Park. Yellowstone National Park is active in implementing the Interagency Bison Management Plan (IBMP). The IBMP is a brucellosis risk management program focused primarily on reducing the probability of wild bison commingling on common ranges used by domestic livestock. The IBMP is cooperatively implemented with USDA-APHIS-VS, U.S. Forest Service, Montana Department of Livestock, and Montana Department of Fish, Wildlife and Parks. The action plan has been in place since December 2000. Seasonal climate variability is a significant ecological driver in the Yellowstone ecosystem causing all native ungulate populations to shift from high elevation summer ranges to lower elevations as snow accumulates in the mountains. The majority of the bison population uses ranges within the park on a year around basis. Portions of the population migrate variable distances, in response to population density and winter severity, to find suitable winter habitats to survive the long cold winters. Bison tend to migrate later than other species and in some years migratory movements outside the National Park can be up to 30 percent of the population. Some bison winter range outside the park overlaps with livestock range. To reduce the risk of brucellosis transmission from wild bison to domestic livestock, interagency partners actively haze bison away from livestock and when necessary capture and cull portions of the wild bison population. These actions keep the wild bison population within the primary conservation area established by the IBMP. The active management period generally runs from October through the winter and ends in June when the bison population returns to high elevation summer range.

During winter 2006-2007, risk management activities were successful in preventing brucellosis transmission from Yellowstone bison to livestock. One hundred twenty five hazing events were conducted to keep bison within the primary conservation area. Nine individual bison were culled because they persistently moved outside the conservation area onto spring livestock ranges. Yellowstone National Park continues to evaluate the feasibility of remote vaccination of the bison population. An ongoing environmental impact study is showing that the current program to vaccinate young (non reproducing) bison only during years when risk management operations capture and release individuals will do little to reduce disease prevalence. Uncertainty about the duration of vaccine protection, the effects of vaccinating pregnant animals and the comparability of experimental trials with expected results in wild populations are driving new efforts to initiate field studies in association with an expanded vaccination program that was directed in the 2000 management plan.

Wildlife, domestic animals and humans share a large and increasing number of infectious diseases. The continued globalization of society, human population growth, and associated landscape changes will further enhance interfaces between wildlife, domestic animals, and humans, thereby facilitating emergence and resurgence of infectious diseases. Further, habitat loss and other human-caused stresses on ecosystems have reduced the ability for many wildlife populations to recover following declines. The increasing challenges of zoonotic diseases has given new attention to the century-old concept of "the one medicine" because of the need to address these diseases across species if their economic, social and other impacts are to be effectively minimized. The wildlife component of this triad has received inadequate focus in the past. Disease emergence and resurgence has reached unprecedented importance for the sustainability of desired population levels for many wildlife populations and for the long-term survival of some species. At Yellowstone National Park, the following wildlife diseases are currently, or have the potential to, determine the outcome of the park's conservation mandate: brucellosis (bison and elk), hantavirus (small mammals), Whirling Disease (trout), West Nile Virus (birds), chronic wasting disease (elk and deer), Johne's disease (bison), and high pathogenic avian influenza (waterfowl and mammals). In response, Yellowstone National Park formed a new partnership with Montana State University and the University of California-Davis Wildlife Health Center in 2007 to create the Yellowstone Wildlife Health Program (YWHP), a long term research program focused on understanding and solving priority wildlife health problems in Yellowstone National Park.

With government and private sector funding, the YWHP will design and implement a long term wildlife health assessment program to monitor and evaluate wildlife diseases and health indicators; a subcomponent of the Vital Signs Monitoring Program; design and implement a disease surveillance program for priority wildlife disease threats; manage and conduct research on urgent and emergent

wildlife disease and ecosystem health issues; prioritize and offer competitive grants for research projects pertaining to wildlife disease and health assessment; provide on-site wildlife veterinary services, including veterinary support for animal handling activities and disease outbreak investigation, including field evaluation, necropsy and specimen sampling; establish and manage an on-site wildlife disease diagnostics and research field laboratory; and facilitate graduate and post-doctoral research projects on wildlife disease and health.

The YWHP operational design includes Program Coordinators – each of the three principle program partners designated a program coordinator. It is the responsibility of the Program Coordinators to coordinate research and facilitate cooperative efforts involving the three institutions and other program partners. The YWHP will establish a Scientific and Stakeholder Advisory Committee to provide guidance to the program; provide a forum for scientific issues and assess the relevance and priority of research efforts among various research and stakeholder communities; Resident Ecosystem Health Field Director—a wildlife veterinarian/ecosystem health specialist will be based in the park to manage the Wildlife Health Program and to provide wildlife veterinary support services. The program may hire additional researchers and staff as needed if funding is available; Competitive Grants Program for Wildlife Health Research—to involve the best scientists and to include pre-existing regional expertise, the program will annually award grants through a competitive grants program to address both urgent and long term ecosystem health issues including evaluating vital signs and protocols. Proposals to the competitive grants program will be reviewed and selected by the advisory committee with the assistance of external reviewers; and Graduate and Post-Doctoral Field Research Element—this program element will facilitate research by graduates and post-doctorate researchers to tackle priority wildlife health research projects in the Park.

Walt Cook, Wyoming State Veterinarian, gave the Wyoming Status Review. The State of Wyoming reached the one year mark of being brucellosis-free in September. State and Federal agencies as well as producers and sale barns continue efforts aimed at reducing the risk of introducing brucellosis in the State's livestock. Early in 2007, Dwayne Oldham resigned as State Veterinarian for Wyoming. Walter Cook was hired as his replacement and will work out of Cheyenne. Jim Logan was then hired as Assistant State Veterinarian to work out of Riverton. Logan's primary responsibilities will be overseeing the state's brucellosis and scrapie progra From October 2006 through September 2007, Wyoming tested 121,456 cattle for brucellosis. None were classified as reactors. Six were classified as suspects and appropriate actions taken. Over the same time period 177,019 cattle were vaccinated. This included calf-hood vaccinates, adult vaccinates and booster vaccinates. A few slaughter suspects were traced back to Wyoming. One resulted in a whole herd test with all being negative. Other suspect cases were resolved without whole-herd testing.

In November 2007, state and federal personnel will conduct an annual test of three herds that are in the area of the original cases that occurred in 2003-2004. This will include testing of approximately 1,200 cattle. These cattle herds are also booster vaccinated every two years. Wyoming received some cattle from Montana that had been in brief contact with infected cattle. We have successfully traced most of these; one herd is still under quarantine to be tested this December when the cattle return from summer grazing. We are continuing tracing efforts on the unaccounted few that remain. The State of Wyoming has requested a brucellosis program review which we expect to occur sometime in 2008. The Wyoming Livestock Board has also adopted new brucellosis rules. These rules have reduced some testing requirements, but still require testing of all breeding cattle sold through a Wyoming auction market and also require change of ownership testing for most test-eligible cattle from an identified area in which contact with infected elk is considered possible.

The Wyoming Governor's Brucellosis Coordination Team continues to follow and provide recommendations aimed at reducing the risk of brucellosis transmission from wildlife to cattle. Among the recommendations made by this group are the development of cattle herd management plans, elk brucellosis management action plans, and a pilot test and slaughter program for feed-ground elk. The Wyoming Livestock Board and VS personnel have worked with producers to develop 155 cattle herd plans. Herd plans are voluntary and individualized based on the individual herd exposure to potentially infected wildlife. They represent an obligation of the producer to take certain steps to minimize the risk of transmission to their cattle and include surveillance measures for herds with potential wildlife contact.

Several herd plans call for periodic adult booster vaccination with Strain RB51. One producer, who vaccinated 281 pregnant, seronegative, cattle on November 12, 2006, documented multiple abortions, and other fetal/calf losses. A total of 20 (7.12 percent) booster vaccinated cows were found to

have aborted, given birth to a weak calf or otherwise failed to deliver a healthy calf. Abortions were documented beginning February 10 and ending on April 3, 2007. Seven fetuses/tissues were sent to the Wyoming State Veterinary Laboratory and/or the National Veterinary Service Laboratory. All had lesions consistent with bacterial infection, pneumonia and Strain RB51 *Brucella abortus* was cultured from five fetuses; an additional fetus was culture negative, but a positive polymerase chain reaction (PCR) for RB51 was obtained at Wyoming State Veterinary Laboratory. There may be confounding factors involved in this herd. For instance, the herd had existing problems with bovine viral diarrhea (BVD), and eight cattle that aborted and were bled had titers to BVD. Adult cattle on other premises with herd plans (approximately 1,000 head) also were booster vaccinated using the same vaccine serial and dose and no problems were associated with the vaccination in those animals.

The Wyoming Game and Fish Department has completed Brucellosis Management Action Plans for all seven elk herds in Northwestern Wyoming. These plans require wildlife management aimed at minimizing risk of brucellosis transmission from elk to livestock. The Wyoming Game and Fish Department is in the process of developing plans for Wyoming's two wild bison herds as well. In the winter of 2006, the Wyoming Game and Fish Department began a test and slaughter of elk on the Muddy Creek feedground. That year, 158 test eligible females were trapped; 58 (37 percent) of these elk were seropositive and sent to slaughter and culture. Eighteen (32 percent) of the seropositive elk were culture positive. The project continued during the winter of 2007 with the capture of 79 test eligible female elk; 13 (16 percent) of which were seropositive and eight (62 percent) of seropositive were culture positive. Interestingly, four elk that were captured and tested negative in 2006 had seroconverted in 2007 and three (75 percent) of these were culture positive. Current plans expand the test and slaughter program; a trap has been built on Fall Creek feedground and the Department plans to trap there this winter (2008) in addition to trapping on Muddy Creek again. The following year they expect to trap on Scab Creek feedground in addition to the other two. I thank Brandon Scurlock of the Wyoming Game and Fish Department for the data on the elk test and slaughter program and Tom Linfield of VS-APHIS-USDA for data on fetal loss associated with booster vaccination.

The Montana Status Review was given by Martin Zaluski, State Veterinarian, Montana Department of Livestock. Montana experienced its first case of brucellosis in cattle since regaining its Class-Free Status in 1985. The index animal was a three-year old beef cow that was given as a wedding present from an individual ranching in Emigrant, Montana to daughter and son-in-law ranching in Bridger, Montana. The animal aborted as a two-year old within a month of arriving in Bridger, and then again as a three-year old. She was subsequently sold through a sale in Billings, Montana for use as an embryo transfer recipient. During export testing, she was found to be a brucellosis reactor, and further testing revealed six additional reactor animals in the index herd.

Epidemiological investigation revealed that exposure most likely occurred from elk co-grazing and co-mingling at the Emigrant herd, however, fingerprinting (hoofprinting) of the brucella strain was not conclusive. Montana is enhancing surveillance by two methods. First, Montana Department of Livestock (MDOL) is working with Montana Fish Wildlife and Parks to increase surveillance (blood and tissue) of hunter harvested elk in the area directly north of Yellowstone National Park. Second, MDOL is working with VS to assess the risk of brucellosis in the Greater Yellowstone Area (GYA) herds, and to enhance the number of herds that have herd plans which includes brucellosis testing as well as adult brucellosis vaccination.

John Chatburn, Idaho Department of Agriculture, and Phil Mamer, Idaho Department of Fish and Game provided the Idaho Brucellosis Report.

Idaho regained Brucellosis Class Free Status during the summer of 2007. The states surveillance and elk/cattle mitigation efforts are focused on a high risk area in eastern Idaho that is adjacent to Yellowstone National Park and the state of Wyoming. Individual, site specific, Brucellosis Action Management Plans have been developed for the 15 high risk herds identified in the high risk area. These plans are developed jointly between the rancher, Idaho State Department of Agriculture (ISDA), and the Idaho Department of Fish and Game (IDFG). The plans include mitigation actions provided by the rancher as well as the two state agencies. ISDA and IDFG are working with all of the ranches in the high risk area that were not identified as high risk herds to develop additional Brucellosis Action Management Plans. The plans for the remaining herds should be completed by the summer of 2008. The efforts required to regain Idaho's Brucellosis Class Free Status were substantial. However, the cooperation, team work, and dedication exhibited by Idaho's cattle industry ISDA and IDFG have been nothing short of monumental.

Maintaining Idaho's Class Free Status will require even more cooperation and vigilance in the foreseeable future.

John Clifford, Deputy Administrator, VS-APHIS-USDA, spoke on the Proposed Changes to the National Brucellosis Surveillance Program. Clifford introduced this section of the Committee agenda by referring to the expected achievement, within the near future, of Brucellosis Class Free Status for brucellosis in livestock throughout the United States. Dr Clifford stated that the status of animal brucellosis in the country, coupled with declining fiscal resources and improved technology necessitates a review of the national brucellosis surveillance program. About a year ago a Federal-State Working Group on National Brucellosis Surveillance Planning was established to do an in-depth review of brucellosis surveillance as it exists today and what the needs will be in the future. The complete text of the following three presentations listed below are included in these proceedings.

- **Proposed National Brucellosis Surveillance Plan**
David Cummings, VS-APHIS-USDA, Planning and Strategy Staff
This presentation was a time specific paper that gave an in-depth overview of the issues associated with the current brucellosis surveillance program, as well as needs and options for surveillance in the future.
- **Proposed Brucellosis Laboratory Consolidation Plan**
Bob Brady, VS-APHIS-USDA, Area Epidemiologist (New England)
This presentation outlines the findings of the committee within the surveillance working group that was responsible for developing a plan for restructuring the brucellosis laboratory system. This included the identification of laboratories, personnel, fiscal issues associated with brucellosis surveillance and a national plan for consolidating these laboratories.
- **Proposed Brucellosis Laboratory Testing Standardization Plan**
Eric Ebel, Food Safety Inspection Service (FSIS) USDA
This presentation dealt with the crucial importance of the serologic test sensitivity and specificity of the diagnostic protocol in estimating the prevalence of brucellosis in the national livestock herd, and the need for this estimate to be done at least annually.

After completion of the above three presentations, the Committee was divided into three discussion groups to consider the issues that were presented on brucellosis surveillance and to develop resolutions and/or recommendations for consideration by the Committee. The discussion group on the proposed adjustments to standardized serology protocols proposed that the Committee Chair prepare and send a letter of recommendation to the Brucellosis Laboratory Restructuring Committee to ensure that the following points of concern are included in the standardization plan. There was widespread support for a standardization protocol for serological testing, including support for the proposed screening and confirmatory tests. There was additional concern about how long it would take for some individuals to become comfortable with using only three tests and how decision makers would fund the additional testing needed to meet their needs.

The Committee approved a recommendation to the Brucellosis Laboratory Restructuring Committee that training and preparation for implementation be provided prior to phasing out the old system. The Committee also recommended that the Brucellosis Laboratory Restructuring Committee include the following considerations to ensure quality of samples and management of information.

1. Establish standards to describe the quality of acceptable samples needed for testing
2. The plan should account for appropriate time lines for submitting samples and for subsequent retesting if a trace block is necessary
3. Individual animal identification should be a part of the standardization plan to improve record keeping and retracing of initial samples collected
4. The time period for community results book through the testing system should be established for efficient decision making.
5. Consider the value in keeping records of both negative and positive test results

There was a total of seven Resolutions proposed to the Committee. These Resolutions were approved by the Committee and forwarded to the Committee on Nominations and Resolutions.

STATUS REPORT – FISCAL YEAR 2007 COOPERATIVE STATE-FEDERAL BRUCELLOSIS ERADICATION PROGRAM

Debbi A. Donch
National Brucellosis Epidemiologist and National Program Manager

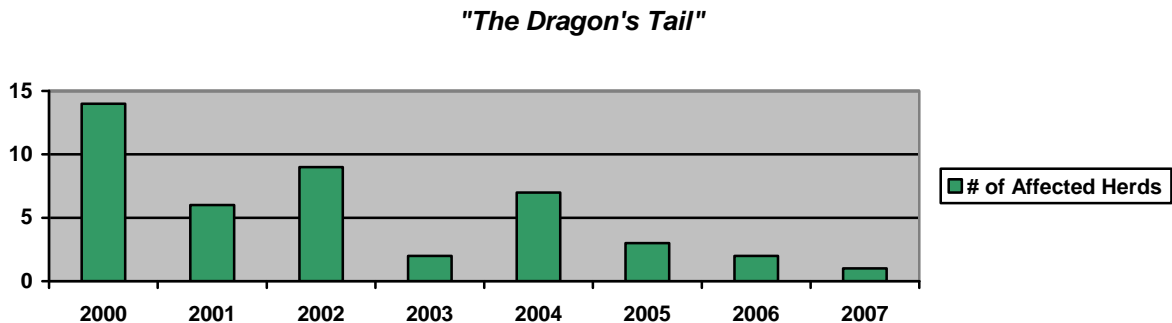
Arnold A. Gertonson
GYA Brucellosis Activities Coordinator

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Fiscal Year (FY) 2007 exemplified the “tail of the dragon,” a maxim often used to describe the steadily declining prevalence of brucellosis affected cattle herds in the final years of eradication efforts. A single brucellosis affected cattle herd was disclosed in a Brucellosis Class Free state while no new brucellosis affected cattle herds were disclosed in the single Brucellosis Class A state. With final eradication imminent, maintaining effective and efficient surveillance is a program priority. FY 2007 program activities have focused on developing effective brucellosis surveillance and assessing ways to restructure the nation’s brucellosis laboratory system for greater efficiency. Additional program activities continued to focus on furthering cooperative efforts to develop concepts to eliminate brucellosis from the Greater Yellowstone Area (GYA).

One new brucellosis affected cattle herd was disclosed in FY 2007. This compares to two new brucellosis affected cattle herds disclosed in FY 2006, three new brucellosis affected cattle herds disclosed in FY 2005, seven new brucellosis affected cattle herds disclosed in FY 2004, two new brucellosis affected cattle herds disclosed in FY 2003, nine new brucellosis affected cattle herds in FY 2002, six in FY 2001, and fourteen in FY 2000 (Figure 1). The FY 2007 brucellosis affected cattle herd was disclosed in May 2007 in the state of Montana, a state which has been classified as Brucellosis Class Free since June 3, 1985. The affected herd was depopulated with indemnity. Montana successfully completed the herd depopulation and epidemiologic investigation, including all required testing, within sixty days, thereby maintaining Class Free State classification.

Figure 1.



The single brucellosis affected cattle herd disclosed in the state of Montana in mid-May 2007 was disclosed on a test of animals intended for interstate movement. One reactor-titered animal was identified and traced to the herd of origin. The herd of origin was tested, disclosing six additional reactor animals. Bacteriologic culture results on the initial reactor animal revealed *Brucella abortus* Biovar 1. The herd of origin was held under quarantine and depopulated with indemnity in mid-July 2007, meeting the sixty day depopulation requirement for a Class Free State to maintain class free status. In addition, all adjacent herds, potential source herds, contact herds, and area herds were tested and placed on herd plans within the required sixty day period to maintain class state status. Approximately 3,200 head of

cattle in approximately 25 herds were tested as part of this brucellosis affected herd epidemiological investigation. No additional brucellosis affected herds were disclosed.

Throughout 2007, Texas maintained diligent brucellosis surveillance activities while conducting an in-house review of previous brucellosis affected herd investigations and high-risk areas. First-point testing has been a key component of brucellosis surveillance activities in Texas. Upon completing their self-assessment, Texas formally submitted application to advance to Class Free Status in June 2007. A pre-Class Free review conducted in Texas the week of July 29 to August 4, 2007 evaluated Texas's brucellosis program to confirm that all requirements to advance to Class Free Status have been met. Regulatory activities to advance Texas to Class Free Status were initiated and in progress as FY 2007 came to an end.

A Brucellosis Surveillance Planning Working Group was convened in FY 2007 and tasked with drafting a proposed future brucellosis surveillance plan based on the findings and recommendations of the National Surveillance Unit evaluation of current bovine brucellosis program surveillance activities conducted in FY 2006. The Brucellosis Surveillance Planning Working Group is composed of eighteen members, including four state veterinarians. In drafting a proposed plan, the working group focused on reducing redundancies in surveillance testing and addressing imbalances in surveillance in lower risk states, while maintaining effective and cost efficient surveillance. The working group held discussions with key industry partners and members of the National Assembly to better understand impacts and concerns relative to changes in brucellosis surveillance activities. A draft of a proposed surveillance plan was presented to the VS Management Team and is being presented for further discussion during this year's USAHA Committee on Brucellosis meeting.

A Brucellosis Laboratory Restructuring Committee, consisting of state and federal animal health officials and laboratory personnel, was convened in FY 2007. This Committee was tasked with drafting a proposal for a regional brucellosis laboratory concept for brucellosis surveillance testing. The objectives are to increase the cost effectiveness of brucellosis surveillance testing while maintaining testing effectiveness and timely reporting of test results. The Committee sent a questionnaire to the eighty-two laboratories currently approved to conduct serological testing for brucellosis to garner information on testing capacity, cost of testing, and laboratory funding. Assessing and comparing this information has proved to be a complex endeavor. Laboratories have been a key component of the national brucellosis eradication program. The Committee continues to work to develop a set of criteria for selection of regional brucellosis laboratories that will meet the needs of all states and maintain the integrity of the national brucellosis surveillance program.

The Brucellosis Program delivered two annual training courses in FY 2007 – the Basic Brucellosis Epidemiology course and the Designated Brucellosis Epidemiologist (DBE) Refresher training course. The Basic Brucellosis Epidemiology course, held in March 2007 in Austin, Texas, was attended by 35 state and federal veterinary medical officers and animal health technicians and four state and federal animal health officials from Mexico. The Basic Brucellosis Epidemiology course is a three-day training event, with instructor-led lectures, facilitated discussions, practical exercises, and laboratory demonstrations. The purpose of the course is to provide training in the principles of the brucellosis eradication program, including the organism, the disease as it occurs in various species of animals, and detailed epidemiological considerations necessary to effect the efficient and rapid eradication of brucellosis. The Designated Brucellosis Epidemiologist Refresher training, held in May 2007 in Bozeman, Montana, was attended by 55 state and federal veterinary medical officers. This training partnered with fourteen experts from state and federal wildlife agencies and focused on brucellosis in wildlife in the GYA.

Brucellosis in the Greater Yellowstone Area (GYA)

A Greater Yellowstone Interagency Brucellosis Committee (GYIBC) Memorandum of Understanding (MOU) draft, agreed to by the United States Departments of Agriculture and the Interior has been forwarded to the Governors of Idaho, Montana and Idaho for their signatures. The Grand Teton National Park (GTNP)/National Elk Refuge Bison (NER) Elk Management Plan and Environmental Impact Statement (EIS) final report and Record of Decision has been issued. The plan is to reduce the number of bison from approximately 1,200 to 500 head and to reduce the number of elk to approximately 5,000 head. The Interagency Bison Management Plan (IBMP) cooperating agencies made several adaptive management changes for 2007. These include strategic hazing in Zone 2 on public lands, increased

tolerance of bison bulls in Zone 2 during certain times of the year, bison hunting in Zone 2, and a clarification of the 3,000 bison population number as a management trigger rather than a Yellowstone National Park (YNP) population objective or target. Adaptive management changes for operations in the IBMP can be made with the concurrence of all of the IBMP cooperating agencies. Montana issued 140 bison hunt permits last year, resulting in 31 bison successfully taken during the hunt. The Nez Perce tribe also successfully hunted six bison. Montana will issue 40 bison hunt permits in a drawing this year (2007) and 40 bison hunt permits will be issued to Native American tribes.

VS personnel assisted IBMP bison management operations. Hazing operations (125) were performed during this past year. Capture operations resulted in the capture of 57 bison on lands adjacent to the west boundary of the park. These bison were hauled to the north side of park and released into YNP. The GYA states (Idaho, Montana, and Wyoming) are continuing, in consultation with APHIS-VS, with development and implementation of individual livestock herd and individual elk herd unit plans to mitigate potential transmission of brucellosis from elk or bison to cattle. Idaho completed and implemented herd plans in 2006. Montana has completed its survey of livestock herds in the GYA and is performing a risk analysis of the individual livestock herds to determine management actions for inclusion in the individual livestock herd plans. Montana is also reviewing its elk herd unit plans. Wyoming has a larger number of livestock herds and elk units in the area of concern. Wyoming is currently surveying livestock herd owners and developing individual livestock herd plans in the area of concern. Wyoming has completed individual elk herd plans for the seven elk herd units of concern. Wyoming is also continuing statewide elk herd brucellosis surveillance using hunter collected blood samples. Wyoming is continuing a five year elk brucellosis test and removal of brucellosis sero-positive elk pilot project at its Muddy Creek feed-ground. This project was initiated in 2006. Data gathered from this project will be evaluated to determine if test and removal will significantly reduce brucellosis sero-prevalence in those elk herds. The study of fluorescent polarization assay (FPA) and buffered acidified plate antigen (BAPA) tests to determine their suitability for brucellosis testing elk sera is ongoing. Three state laboratories are working with NVSL to determine repeatability of test results. The study is expected to be completed in 2007.

APHIS-VS personnel attended Wyoming Brucellosis Coordination Team, Greater Yellowstone Interagency Bison Committee, IBMP, United States Animal Health Association (USAHA) regional and national meetings, state and local meetings of ranchers, and meetings of other stakeholders to provide technical assistance and to make presentations when requested. Veterinary Services continued activities and involvement in several projects aimed at assessing potential effective brucella control strategies for affected wildlife populations. These on-going developmental projects include the following studies:

- Bison Quarantine Feasibility Study (BQFS): There are currently 37 two and three-year-old cows and eight males in Phase II of the BQFS. Phase II of this study will evaluate the likelihood that latent disease expression will be demonstrated during the first pregnancy. Phase I animals that remained test negative, advanced into Phase II quarantine protocols and were bred. The goal of the Phase II quarantine protocols is to determine if and how latent brucellosis infection is expressed during the stress of pregnancy. To date, no animals in this study have sero-converted in 2007. Many two and three year old females in the study are in early pregnancy. If latent infection does not become evident at parturition, some cows and their calves should be eligible for soft release (release into fenced pasture for continued surveillance at the sight of intended full release) next fall/winter. A new cohort of calves is anticipated this winter (Phase III).
- Brucellosis vaccine in elk: In a study last year, elk received engineered RB51 by injection and oral administration. No abortions were seen in these elk and there was less tissue colonization than controls on challenge with Strain 2308. A further study focusing on an oral prime and an oral boost in elk will begin this winter (2007).
- Development of non-lethal methods to eradicate brucellosis from GYA wildlife:
 - Gonacon™, a GnRH immunocontraceptive vaccine, has shown efficacy in bison for three years following a single administration of this vaccine. Immunocontraceptive studies are ongoing in elk. So far, results appear to be similar as those observed in the bison.
 - Studies on rifampin treatment of brucellosis are ongoing in cattle, goats, and mice.
- Serologic differentiation of brucellosis and infection with *Yersinia enterocolitica* strain 0:9 in elk: A study to determine if infection with *Yersinia* can reliably be differentiated from infection with *Brucella abortus* by western blot and ELISA tests is on-going.

Brucellosis Program Surveillance Activities

The following surveillance statistics for the cattle brucellosis eradication program is based on data available as of October 15, 2007. Normal data reporting time allowances for states to gather and submit monthly data preclude ascertainment of all data for FY 2007.

FY 2007 began with 48 States and three Territories classified Brucellosis Class Free, and two states classified Brucellosis Class A Status. FY 2007 ended with 49 States and three Territories classified Brucellosis Class Free Status. The two states classified as Class A at the beginning of FY 2007 were Texas and Idaho. After successfully completing all program regulatory requirements, Idaho successfully regained Class Free Status July 23, 2007. Idaho had initially attained Class Free Status in February 1991, however pursuant to the disclosure of two brucellosis affected herds in November of 2005, Idaho's status was downgraded to Class A Status in January 2006. The state of Texas achieved Brucellosis Class A classification in August 1994. The last brucellosis affected herd in Texas was disclosed in August 2005, placed under hold order and subjected to the required herd testing protocol. The final negative herd test was conducted in September 2006. During the first half of FY 2007, Texas conducted additional epidemiological evaluations in high-risk areas before submitting application for Class Free Status.

Figure 2.

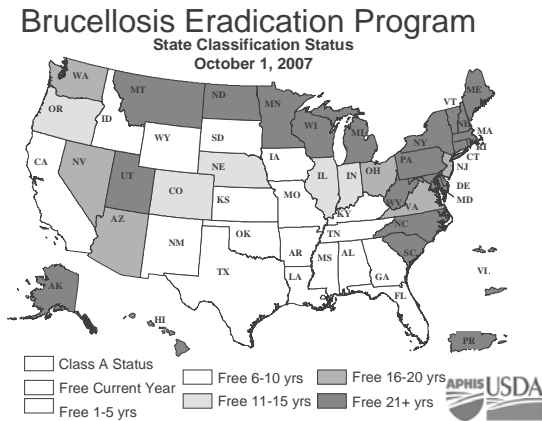
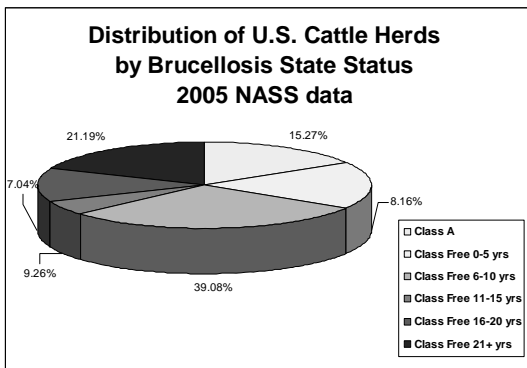


Figure 3.



Cattle inventories in the U.S. at the end of FY 2007 are distributed as follows: 14.52 percent of all cattle and 15.27 percent of all cattle herds are located in the Brucellosis Class A state; 8.35 percent of all cattle and 8.16 percent of all cattle herds are located in states that have held Brucellosis Class Free Status for five years or less; 40.23 percent of all cattle and 39.08 percent of all cattle herds are located in states that have held Brucellosis Class Free Status for six to ten years; 13.26 percent of all cattle and 9.26 percent of all cattle herds are located in states that have held Brucellosis Class Free Status for

eleven to fifteen years; 5.70 percent of all cattle and 7.04 percent of all cattle herds are located in states that have held Brucellosis Class Free status for sixteen to twenty years; and 17.94 percent of all cattle and 21.19 percent of all cattle herds are located in states that have held Brucellosis Class Free Status for more than twenty years.

The national herd prevalence rate for bovine brucellosis was 0.0001 percent in FY 2007. One brucellosis affected cattle herd was disclosed in FY 2007. This herd was disclosed on a herd test of animals intended for interstate movement. Per the Brucellosis Emergency Action Plan (BEAP) recommendation, the brucellosis affected herd was depopulated with indemnity and a thorough epidemiologic investigation was completed disclosing no additional brucellosis affected herds. In addition, trace exposed test negative cattle were depopulated and indemnified as well.

Maintaining Brucellosis state status focuses on continual surveillance activities. Two primary surveillance activities are conducted for bovine brucellosis, market cattle identification (MCI) testing and brucellosis milk surveillance testing (BMST). During FY 2007, APHIS tested approximately 7.995 million head of cattle under the MCI surveillance program. Brucellosis program standards require testing of a minimum of 95 percent of all test-eligible slaughter cattle. In FY 2007, approximately 96.40 percent of all test-eligible slaughter cattle were tested. First-point testing at livestock markets is required in Brucellosis Class A states. Several Brucellosis Class Free States continue to conduct first-point testing at markets to facilitate interstate movement of cattle and enhance surveillance activities. Brucellosis program standards require a minimum of 90 percent successful traceback of all MCI reactor cattle and a minimum of 95 percent successful case closure. In FY 2007, approximately 97.87 percent of all MCI reactors were successfully traced and investigated resulting in successful case closures. Approximately 835,200 additional head of cattle were tested on farms or ranches during FY 2007, bringing the total cattle tested for brucellosis in FY 2007 to approximately 8.831 million head. BMST surveillance is conducted in all commercial dairies – a minimum of two times per year in Class Free States and a minimum of four times per year in Class A States. Suspicious BMSTs are followed up with an epidemiologic investigation. Herd inventory data reported on individual state annual reports reveals there were approximately 62,500 dairy operations in the U.S in FY 2007. Approximately 142,700 BMSTs were conducted in FY 2007; approximately 126 of those BMSTs yielded suspicious results after repeat screening (repetitive BRT and/or HIRT). All suspicious BMSTs in FY 2007 were confirmed negative by subsequent epidemiologic investigations and additional herd testing.

There were approximately 4.212 million calves vaccinated for brucellosis in FY 2007. The national calfhooD vaccination policy recommends proper calfhooD vaccination in high risk herds and areas and whole herd adult vaccination when appropriate in high risk herds and areas. Elimination of mandatory vaccination in all states is also recommended. Brucellosis program activities during FY 2007 demonstrate continued commitment by all states to achieve and maintain final eradication of brucellosis from the United States domestic cattle, bison, and swine herds. Diligent effective surveillance and judicious affected herd management continue to be critical program activities. As final eradication nears, focused, efficient, and effective surveillance is paramount to the integrity of a national brucellosis-free classification for the United States.

PROPOSED NATIONAL BRUCELLOSIS SURVEILLANCE PLAN

David Cummings,
USDA-APHIS-VS

When households, businesses or governments consider whether to buy more insurance, more security precautions or increased surveillance, more is— by definition — better. Every dollar spent yields a small, maybe even tiny increment of greater safety. But even though more is always better to some degree, we certainly wouldn't spend all of our budgets on the preventative items. We have a variety of pressing needs. So, we look for the sweet spot that strikes the best balance for our short-, medium- and long-run situation. Over the past year, I have had the opportunity and privilege to chair a Federal-State Working Group on National Brucellosis Surveillance Planning. For me this was truly a learning experience; I was able to work closely with some real experts on brucellosis control, eradication and surveillance, and I and the Working Group encountered multiple parties expressing a wide range of perspectives on the various and inter-related brucellosis surveillance issues. To begin, let me reiterate why this working group came to be. Clifford, in his opening remarks, touched on each of these points. First, for decades, "brucellosis surveillance" has been synonymous with "animal health infrastructure" but this is almost certainly not sustainable. It's not feasible to fund tuberculosis (TB), animal identification and other pressing needs with brucellosis surveillance money. The brucellosis surveillance program has made enormous progress and all parties want to preserve those gains and not regress in any way. Although most States are brucellosis-free, surveillance in low-risk areas has changed little over the years. Finally, appropriations are declining for both brucellosis eradication and surveillance. We need to approach this with an eye toward fiscal responsibility and putting our appropriated Federal dollars toward our highest brucellosis priorities.

Federal spending on brucellosis surveillance is roughly \$30 million. This money supports sample collection, transportation, testing and investigation costs, as well as personnel, equipment, materials and overhead. In the end, we see that we spend a lot on slaughter and first point testing. Proposing changes to national brucellosis surveillance has been discussed since at least 2005. It's a process, maybe even a journey, to alter this historic and institutionalized program. These steps are involved, and these are the steps I will walk you through during my talk:

- National Surveillance Unit evaluation, 2006
- Federal-State Working Group for Brucellosis Surveillance, 2007
- Vetting of Working Group proposals, ongoing
- Implementation, 2008-2011

The Veterinary Services National Surveillance Unit (NSU) evaluation completed during 2006 was a foundation step for brucellosis surveillance planning. I'm sure many of you recall that Ebel presented the NSU 2006 evaluation findings to this Committee last year. Those findings highlighted that unneeded redundancies exist in current surveillance, that is, collection of multiple samples from the same animals within a short period of time. NSU analysis suggested that the combination of slaughter surveillance and brucellosis ring test (BRT) testing for dairy herds was redundant. Similarly, for beef herds, first point sampling is often redundant with slaughter sampling. Current surveillance intensity is also imbalanced. The program is currently biased toward finding affected dairy herds, but these herds face a much lower risk of brucellosis infection compared to beef herds. Current Federal spending for detecting dairy herds is nearly equivalent to its spending for detecting beef herds, but on a per herd basis, the spending on dairy is nine times more than beef. Finally, NSU reported that non-standardized testing and data entry do not support regional or national collaboration, but I believe Drs. Brady and Ebel will elaborate on those points when they speak next.

The NSU evaluation of 2006 recommended that: (1) in the beef sector, slaughter surveillance continue at current levels; (2) in the dairy sector, discontinue slaughter surveillance and use only BRT by conducting one round per year in states that have been Class-free for five or more years; (3) in Class-free states, conduct strategic first point testing of out of state cattle and cattle from smaller herds; (4) perform slaughter sampling at the 40 to 50 largest slaughter establishments that process over 95 percent of U.S. cattle; (5) identify and use one standard laboratory protocol to be conducted on all blood samples, and conduct testing at a limited number of laboratories; (6) standardize data entry across all laboratories to

ensure consistent practices and entry of all animal identification information; and (7) promote and fund abortion screening as a long-term surveillance activity for brucellosis. Following the NSU evaluation, a Federal-State Working Group was formed in December 2006. Reviewing the NSU findings, and also the NSU recommendations, was a starting point for this brucellosis surveillance planning working group. Those recommendations from the earlier NSU evaluation, the Working Group considered them all and arrived at similar proposals regarding laboratory testing and abortion screening. The Working Group, however, offered a set of proposals that differed from the above evaluation recommendations in how slaughter surveillance, BRT and first point testing could be combined and feasibly implemented to result in the most effective and fiscally responsible approach.

The Working Group's charge was to propose an effective and efficient surveillance plan for bovine brucellosis, and to consider implementation issues and draft a skeletal implementation plan. The idea was that implementing changes would necessarily take several years to do it smoothly, and ideally at least some small-scale changes could begin in 2008. This Working Group included four State Veterinarians and Veterinary Service representatives from Headquarters, Eastern and Western Regional Offices, NSU, four Area Veterinarian in Charge (AVIC), and National Veterinary Services Laboratory (NVSL). We also had an APHIS public affairs person to assist in communication planning. Between December 2006 and June 2007, this working group met through a series of teleconferences and in-person meetings.

I would characterize the discussions as candid. In some cases, working group members advocated a change as something that absolutely needed to be done. In other cases, some group members expressed that if change is inevitable, then this is the best way to go. The group had no guarantees that it would reach consensus, but following are proposed changes that the group agreed to unanimously support to reduce redundancies and imbalances in low-risk States (no changes were proposed for higher-risk areas). Low risk States were defined as Class Free for at least five years and not bordering the Greater Yellowstone Area.

Proposal number one was to remove federal funding for all first point testing activities (blood sample collection, shipping, testing, reporting) at markets and other first points of concentration in low-risk States. It appears that 11 low-risk states currently conduct first point testing. Even if federal funding were removed, some or all of those low-risk states may choose to continue first point testing. The extent of federal support for first point testing varies among the 11 States. Generally, the federal contribution is for shipping and laboratory testing, although in some States the Federal Government pays significantly more, or less, than shipping and laboratory testing. It was noted that the Federal Government does not require first point testing in low-risk states. No change would be needed to the Code of Federal Regulations (CFR), but smooth implementation would obviously require communication and budget planning, to name just two logistics. Implementing this change would require updating the guidelines and dollar amounts in the Federal-State cooperative agreements that support surveillance.

Proposal number two was to remove federal funding for all brucellosis ring testing (BRT) activity—milk sample collection, shipping, testing and reporting—in low risk States. As you might guess, this proposal generated significant discussion and exploration. One reason it emerged and survived was that the BRT—an excellent and cost-effective test—could target only dairy cattle, whereas slaughter surveillance targeted both beef and dairy cattle and was perceived to form the backbone of brucellosis surveillance. It was also expected that some States and industry may opt to continue use of the BRT even without federal funding. A Federal rule change to remove the BRT requirement would be needed to enact this change, and a change to the Brucellosis Uniform Methods and Rules (UMR). When that is nearing completion, cooperative Federal-State cooperative agreements would be updated.

Proposal number three was to no longer require slaughter surveillance at plants that process less than 500 cattle per year, in low-risk States that have been Class Free at least 10 years, but to continue testing all domestic bison and elk. Implementing this change in a State would be subject to approval by both the State Veterinarian and the AVIC. As you know, APHIS-VS contracts with the Food Safety and Inspection Service to collect and package blood samples at small- and medium-size slaughter facilities. This was the only slaughter-based proposal made by the working group, although there were many discussions of the pros, cons and implementation logistics of several other potential alterations to slaughter surveillance. A Federal rule change in the CFR would also be required to enact this change, and a change in the UMR. Revising the APHIS-Food Safety and Inspection Service contract for blood sample collection would be the final step.

Proposal number four was to identify, screen and investigate abnormal abortion events as if the event were a foreign animal disease. This would involve developing guidelines for transitioning brucellosis in the United States from a program disease to a foreign animal disease. The working group spent less time on this particular recommendation, but the key idea was that abortion screening remains highly important in brucellosis surveillance and may evolve as the country progresses further toward eradication.

Proposal number five was to research and pursue validation in the United States of a new herd-level testing protocol using bulk milk and/or serum for both brucellosis and tuberculosis surveillance. One example of such technology would be the fluorescent polarization assay (FPA). If a herd-level testing protocol for both brucellosis and TB were validated in the future, the working group discussed that such a breakthrough would open the door to serious consideration of further and substantial changes to slaughter blood surveillance. It is difficult to accurately project a timeline for this recommendation; approving the technology is a first step, and then completing a Federal rule change would be next followed by the logistics of implementing such testing in the field and at laboratories.

Vetting these ideas in State, industry and Federal circles has been ongoing and today's session in this Committee is a watershed date in that vetting process. Clifford emphasized that your input will be critical to the decisions concerning brucellosis surveillance and any regulatory changes that may be considered. Since the working group drafted its proposals in June, State Veterinarians have presented those in draft form to various industry groups and other State Veterinarians. In May and June 2007, the working group contacted a small cross-section of the cattle industries informally to gauge initial reactions to these proposals. The VS Management Team heard the proposals formally in June and discussions have proceeded also within APHIS-VS as to whether and how changes should be made. Communication throughout the State-Federal-industry animal health infrastructure will of course be the key to successful implementation. States and industries and federal offices need adequate time and information to make smooth transitions. As Clifford noted, VS and the working group will need your help in developing a communication plan for any changes so that industries receive a consistent, timely, factual message.

Timelines for implementation were estimated by the working group. As I mentioned earlier, whether a CFR change is required often determines the timeline for when changes to these surveillance methods could begin:

- o First point testing: 2008 or 2009
- o Brucellosis ring testing: 2010
- o Slaughter surveillance: 2010
- o Abortion screening: TBD
- o Herd-level testing for brucellosis and tuberculosis: 2011

Again, what I have presented are proposals for discussion. All of us truly look forward to your discussions today. I'm afraid that any huge-scale program such as brucellosis eradication and surveillance is going to have aspects that are clunky and in need of tuning. Please help to identify the sweet spot that uses preventative spending well and addresses today's highest priorities. Although the working group inevitably considered laboratory issues as those overlapped with overall surveillance planning, I have not even touched on laboratories. That was intentional because Brady and then Ebel are about to speak on those. I'll close by relating what one working group member said to me. He said, "You know, early in my career I was there when the brucellosis program was ramping up and that was the right thing. Now, as I near the end of my career, I know that the brucellosis program needs to be in a different place. It would be very rewarding professionally to help it arrive to where it should be today."

PROPOSED BRUCELLOSIS LABORATORY CONSOLIDATION PLAN

Robert C. Brady
Area Epidemiologist, New England

A Committee was formed in January, 2006, to come up with recommendations for restructuring the brucellosis laboratory system. The Committee was Chaired by Michael Gilsdorf, and included Bob Hillman, David Warner, Dix Harrell, Deb Donch, Eric Ebel, Steve Hennager, John Belfrage, Chuck Massengill, Rick Nabors, George Teagarden, Francisco Collazo-Mattei, Mark Camacho, Eric Cline, and Teresa Sigafoose. I served as the Coordinator. The Committee's objectives were to increase the cost efficiency of brucellosis testing, identify funds saved for use elsewhere in the brucellosis program, and maintain the accuracy of testing and speed of reporting results. The Committee decided on the information it needed, and concluded the best way to obtain most of this information was to get it directly from the brucellosis laboratories. Other information was obtained from the two regional offices, Ruminant Diseases Staff, and National Veterinary Services Laboratories (NVSL). A questionnaire was sent to all brucellosis laboratories in August, 2006. A second questionnaire was sent to 15 laboratories in May, 2007.

There are 82 laboratories approved to conduct serological testing for brucellosis. All receive reagents free from NVSL. There are 362 technicians approved to conduct brucellosis serological tests. Each receives an annual proficiency test provided free by NVSL. Forty-two laboratories receive USDA money, mostly through cooperative agreements. This laboratory funding totals \$3.1 million. Thirty-five laboratories received no USDA funds, and five laboratories did not answer this question. The Committee tried to determine how many brucellosis laboratories are needed to meet the serological testing needs of the United States. We assumed that the number of samples tested would remain at the 2006 level, since changes in surveillance would require two years to implement. We believe it is necessary to continue supporting abortion screening with free reagents and proficiency tests. We also believe it is necessary to continue support for the three laboratories in the Greater Yellowstone Area (Wyoming, Montana, and Idaho), since wildlife in this area is the last known reservoir of brucellosis (*B. abortus*) in the United States.

Criteria for selecting laboratories to continue receiving USDA funding included the cost of testing samples at the laboratory, the capacity and willingness of the laboratory to test additional out-of-state samples, the geographic proximity of the laboratory to cattle populations and adult cow slaughter plants, and the ability of the laboratory to produce reliable test results and report them quickly. Cow/bull slaughter operations are concentrated in California, Texas, the Upper Midwest, Pennsylvania, and the Southeast. Fifteen laboratories that were proposed to serve as Regional laboratories were sent a second questionnaire in May, 2007. They were asked how many additional out-of-state samples they could test, and how much additional money they would require from USDA to test this number of samples (Table 1).

Table 1. Additional sample capacity and cost per additional sample of 15 proposed regional brucellosis laboratories

City	State	How many more samples?	Cost per additional sample
Davis	CA	400,000	\$0.46
Jefferson City	MO	2,000,000	\$0.19
Topeka	KS	364,000	\$0.35
Fort Worth	TX	125,000	\$0.00
Austin	TX	125,000	\$0.00
Lubbock	TX	118,000	\$0.00
Palestine	TX	120,000	\$0.00
Ithaca	NY	125,000	\$1.82
Atlanta	GA	300,000	\$0.59
Live Oak	FL	465,000	\$0.25
Frankfurt	KY	2,000,000	\$0.40

Madison	WI	175,000	\$0.59
Laramie	WY	50,000	no answer
Boise	ID	279,500	\$0.55
Bozeman	MT	no answer	no answer

The cost per additional sample in Table 1 was derived by dividing the amount of USDA money the laboratory said it would require by the number of additional out-of-state samples they said they could test. At this point, our Committee was divided on the best course of action. Some felt we had enough information, and should go ahead and recommend a system of Regional laboratories. Others felt it would be better to develop national laboratory standards and a uniform price per sample that USDA would pay approved laboratories to test blood for brucellosis. Under the first option, the 12 regional laboratories would be those shown in Table 2. Georgia was not included because its cost-per-sample was \$0.59, which was more than twice that of Live Oak, Florida (\$0.25). The Florida laboratory indicated it could meet the testing needs of the Southeastern United States. New York was not included because its cost of \$1.82 was too high, considering that Kentucky could meet the testing needs of the Northeast at lower cost-per-sample (\$0.40). Wisconsin was not included because \$0.59 for testing out-of-state samples was considered too high (although Wisconsin tests in-state samples at very low cost to USDA).

Table 2. Proposed list of Regional Brucellosis Laboratories under First Option

Davis, CA	Palestine, TX
Jefferson City, MO	Live Oak, FL
Topeka, KS	Frankfurt, KY
Fort Worth, TX	Laramie, WY
Austin, TX	Boise, ID
Lubbock, TX	Bozeman, MT

This first option proposes that 17 laboratories that currently receive \$901,496 in USDA funds would no longer receive this money. The approximately 1 million samples tested by these laboratories would be redistributed to five of the Regional laboratories, as follows:

- California would receive samples from Washington and Oregon
- Missouri would receive samples from Tennessee and Arkansas.
- Kansas would receive samples from Arizona and North Dakota
- Florida would receive samples from Alabama, Georgia, and South Carolina
- Kentucky would receive samples from Indiana, West Virginia, Delaware, Maine, New Jersey, Ohio, and New York

It would cost USDA \$310,038 to test these 1 million samples at the five Regional laboratories (Table 3). Thus, a net savings to USDA of \$591,458 is expected. Seven states that currently receive USDA funds to do brucellosis serological testing would continue to receive those funds. These states likely receive sufficient state funding that USDA's cost per sample at these laboratories is competitive with the Regional laboratories (Table 4.) The first option includes the following recommendations:

- In 2008, or perhaps 2009, stop USDA funding for 17 laboratories, and redistribute their samples to 12 regional brucellosis laboratories, as described above.
- Maintain funding for seven other state laboratories, as listed above.
- Allow the 17 de-funded laboratories to continue brucellosis testing, if they wish, by using state funds, or by charging user fees.
- If this option is adopted, it will require very careful planning and coordinated implementation.
- Ample notice must be given to each affected laboratory. This would be an amount of time sufficient for hiring and training additional technicians, acquiring needed reagents, and obtaining and installing needed laboratory equipment.

This option has a number of limitations. The method of calculating USDA cost per sample is crude, merely dividing the amount of USDA money the laboratory receives by the number of samples they test. This option is based mostly on responses received to a questionnaire sent out by the

Brucellosis Laboratory Restructuring Committee. Some people said questions were ambiguous, and some of the people answering the questions may not have had the most accurate information. Most of the data used is now more than a year old. Our analysis does not take other cost factors into account, such as shipping costs. Finally, some states would rather choose which laboratory they send their samples to, as opposed to be told by USDA which laboratory to use.

This resulted in Committee members proposing an alternative option. Key points of this option include:

- Approving brucellosis laboratories based on national standards which would be developed. Laboratories would have to follow these standards in order to be eligible for USDA funds.
- Establish a nationwide price per sample that USDA would pay for brucellosis testing.
- Clearly specify what is expected in exchange for that price per sample, including which tests would be used, the time frame for reporting results, maintenance of test equipment, and, possibly, data entry.

This second option also has some limitations:

- Determining a national price for brucellosis testing would require detailed analysis by an economist. No economist from the Centers for Epidemiology and Animal Health was available to serve on the Brucellosis Laboratory Restructuring Committee when it was formed in early 2006.
- Determining a national price per sample would likely require site visits, and be time consuming.
- Setting a federal price for brucellosis testing that is uniform throughout the country would disadvantage states where labor and facility costs are higher.
- A system of monitoring laboratories for compliance with standards, and dealing with laboratories which do not comply, would need to be established.

The Brucellosis Laboratory Restructuring Committee seeks input from the USAHA Committee on Brucellosis as to which alternative is better, or if some third alternative would be best.

Table 3. Comparison of USDA cost for brucellosis testing at 17 laboratories vs. Regional laboratories

State	No of samples	USDA funds	USDA cost/sample	Proposed destination laboratory	USDA cost/sample at destination	USDA cost at destination
WA (2)	79,100	\$52,000	\$0.66	CA	\$0.46	\$36,386
OR	17,143	\$11,500	\$0.67	CA	\$0.46	\$7,886
AZ	153,579	\$126,982	\$0.83	KS	\$0.35	\$53,753
ND	7,600	\$20,000	\$2.63	KS	\$0.35	\$2,660
TN	45,000	\$24,410	\$0.54	MO	\$0.19	\$8,550
AR	207,000	\$200,000	\$0.97	MO	\$0.19	\$39,330
AL	36,000	\$75,833	\$2.11	FL	\$0.25	\$9,000
GA	236,457	\$134,452	\$0.57	FL	\$0.25	\$59,114
SC	16,484	\$20,000	\$1.21	FL	\$0.25	\$4,121
WV	10,266	\$49,538	\$4.83	KY	\$0.40	\$4,106
OH	111,664	\$74,970	\$0.64	KY	\$0.40	\$44,666
DE	1,406	\$3,186	\$2.27	KY	\$0.40	\$562
ME	5,646	\$3,093	\$0.55	KY	\$0.40	\$2,258
IN	33,121	\$39,032	\$1.18	KY	\$0.40	\$13,248
NJ	14,452	\$9,000	\$0.62	KY	\$0.40	\$5,781
NY	46,543	\$57,500	\$1.24	KY	\$0.40	\$18,617
Total	1,021,461	\$901,496				\$310,038

Table 4. Seven states that would continue receiving USDA funding, and their cost per sample.

State	No. of samples	USDA funds	USDA cost/sample
Colorado	95,000	\$3,729	\$0.46
South Dakota	138,500	\$2,098	\$0.02
Michigan	171,009	\$20,000	\$0.12
North Carolina	192,959	\$69,123	\$0.36
Vermont	8,647	\$2,592	\$0.30
Virginia	24,139	\$10,000	\$0.41
Wisconsin	979,868	\$1000	<\$0.01

PROPOSED BRUCELLOSIS LABORATORY TESTING STANDARDIZATION PLAN

Eric Ebel
Food Safety Inspection Service

Motivation for standardization of serologic protocol

The data generated from slaughter surveillance should support estimation of national herd prevalence; this should be done at least annually. A crucial part of estimating prevalence is the sensitivity and specificity of the diagnostic protocol used in the program. Eventually, these estimates will support the U.S. case for brucellosis freedom. Test results should not depend on which laboratory a sample is tested, but our current serologic protocol is inconsistent across laboratories. There are different numbers of different tests run in different laboratories. This might not be a problem if all tests, protocols and laboratories had the same performance characteristics. But, published evidence suggests they don't. In the past, we had more complete reporting of laboratory data and greater oversight across laboratories. For example, all laboratories reported all test results and regional epidemiologists visited all laboratories at least annually. This oversight probably imposed some uniformity in serologic protocols because epidemiologists responsible for several States had their own preferences. One benefit of a future standardized laboratory protocol is the valid aggregation of testing data across all laboratories to support national herd prevalence estimates. When the international community (or a domestic auditing group) scrutinizes our program, they can readily appreciate the uniformity in our program and agree with our arguments in favor of brucellosis freedom. Another benefit is improved monitoring of test results across laboratories across time. Improved monitoring supports identifying problems in disease occurrence or laboratory performance earlier, so these problems can be addressed sooner. Other benefits may include reduced costs of conducting tests, as well as supplying reagents and other equipment and materials needed for testing. The costs of standardization are substantial but justified. Some additional equipment may be needed in some laboratories. Additional training to get everyone up to speed will be needed. But, the biggest cost is the lost independence of laboratory personnel and epidemiologists to make the decisions they believe are best for their individual situations. Changing human behavior is difficult.

Strategy for change

The process by which affected herds are detected via slaughter surveillance begins with serologic testing. But, it does not end there. Trace-back investigation, herd serologic testing, and isolation via culture of suspect cattle are needed before a herd is determined to be affected. All of these steps are imperfect; so we can never be 100 percent confident in detecting affected herds. Ironically, culture probably has a higher chance of missing infected cattle than the other steps of the diagnostic algorithm. A double irony is that the culturing protocol is probably much more standardized across laboratories than the serologic protocol. We want to minimize the cost of misclassification

$$\left(\text{i.e., } \left(\frac{\$}{\text{false} - \text{pos}} \times \# \text{ false} - \text{pos} \right) + \left(\frac{\$}{\text{false} - \text{neg}} \times \# \text{ false} - \text{neg} \right) \right)$$

during the serologic testing component of our slaughter surveillance. In the current low prevalence environment, this objective amounts to maximizing the serologic protocol's specificity subject to maintaining sensitivity at credible (i.e., 80-90 percent) levels. For the purposes of illustration, we contacted four large State-Federal cooperative laboratories (in different States) and received their serologic protocols for slaughter samples. All four protocols were different; but all used the rapid automated presumptive (RAP) as an initial screening and all used two confirmatory steps. Three of these laboratories used multiple tests for one of their confirmatory steps. Based on published sensitivity and specificity estimates for the various tests, we assessed the overall sensitivity and specificity of these protocols. Given the low expected number of infected cattle in the United States, the overall sensitivity of these protocols (e.g., range 76 percent to 87 percent) was roughly similar; that is we expect to miss 1 or 2 of every 10 infected animals tested. Given the large expected number of uninfected cattle in the United States, the overall specificity of these protocols (e.g., range 99.1 percent to 99.9 percent) was problematic. Such a difference in overall specificity amounts to 900 false-positive cattle vs. 140 false-positive cattle among every 100,000 uninfected cattle tested. The laboratories whose protocols included

the most tests had the lowest specificities; and the laboratory using the fewest tests had the highest specificity. So, running more tests (often in the name of trying to rule out false-positive cattle) actually increased the number of false-positive test results.

We demonstrate that a protocol that screens all samples using the RAP, then retests the RAP-positive samples with the fluorescence polarization assay (FPA), then retests FPA-positive cattle using the complement fixation (CF) test will generate an overall sensitivity of approximately 83 percent and a specificity of 99.99 percent! Such a specificity amounts to roughly four false-positive results from every 100,000 cattle tested. In comparison to the example protocols above, this protocol achieves essentially equivalent sensitivity with much improved specificity (thereby minimizing the cost of misclassification). Some will complain about the absence of the rivanol or card or particle concentration fluorescence immunoassay (PCFIA) test in this protocol. This complaint can be addressed, however, if we use those tests in a supplemental role. If an investigation of a positive sample is conducted and a rivanol or PCFIA test-result might help decide whether to test its herd of origin, then these supplemental tests can be used. This use of the other tests does not involve the routine and arbitrary testing of all positive samples; it only applies supplemental tests on an as-needed basis. Furthermore, those supplemental tests were not used to determine if a sample warranted investigation. Instead, those supplemental tests only influenced the final disposition of the investigation. Multiple tests during the confirmatory stage of serologic testing will increase the overall sensitivity of the protocol but will decrease its specificity. It is strange, then, that most objections to the standardized protocol we've suggested are based on concerns that the number of false-positive cattle will increase as a result. In fact, the opposite should occur.

It must be acknowledged that people are using protocols they are comfortable with and believe are doing a good job. But, in all our discussions on this topic, no one has quantified the overall sensitivity and specificity they think their protocol achieves. It is the predictability of a diagnostic protocol that allows decision-makers to choose appropriate actions in response to test results. If we don't know the quantitative performance characteristics of our protocol, then how can we make decisions that are consistent, transparent and effective? There is a natural human propensity to be creative and different. Standardizing the brucellosis serologic protocol across all laboratories threatens this propensity. One approach for smoothing the transition is to allow laboratories to conduct other tests on samples as needed as long as the standard protocol is always completed. These ancillary data can be compared with the standard protocol to determine their relative performance. If a better protocol is available, we want to incorporate it and make it our standard. But, we can't improve if we're not willing to change. Humans also prefer to be in control and standard protocols threaten loss of control in the brucellosis program. This sentiment is best expressed by one of VS top epidemiologists, "I don't mind if everybody uses the same protocol; as long as the protocol they use is mine." But, serologic results are only the beginning of the diagnostic protocol for brucellosis and we need to know that investigations begin in a consistent manner. We all know serologic testing is imperfect; individual tests are designed to be positive or negative with fixed predictable errors! Inserting judgment at this stage is counter-productive. In contrast, the brucellosis program is strongly reliant on the expert judgment of epidemiologists to manage investigations, classify the status of herds and manage affected herds once they are detected. This reliance will not change and, ultimately, the classification of affected herds will not change as a result of a standard serologic protocol.

Follow-through

We need to plan for adequate training and equipment to make these changes. We need better data about the correlation between serologic tests. We need to commit to continual assessment of the validity of serologic tests. FPA was the most scrutinized diagnostic test in recent memory. Yet, the brucellosis program generates huge amounts of data that could be used to better assess the performance characteristics of all serologic tests. In the end, a standard serologic protocol will support credible analysis of our brucellosis status. Overall, the standard protocol will perform better than most alternatives.