

REPORT OF THE COMMITTEE ON JOHNE'S DISEASE

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The Committee met on October 21, 2012 at the Greensboro Sheraton Hotel, Greensboro, North Carolina, from 12:30-6:00 p.m. There were 24 members and 22 guests present. Self- introductions were made by all in attendance.

Status of 2011 Resolutions and Recommendations

RESOLUTION NUMBER: 12 APPROVED

SOURCE: COMMITTEE ON JOHNE'S DISEASE

SUBJECT MATTER: NATIONAL VETERINARY SERVICES LABORATORY CERTIFICATION FOR DAIRYHERD IMPROVEMENT LABORATORIES

BACKGROUND INFORMATION:

Evaluation of United States Department of Agriculture (USDA)-approved milk enzyme linked immunosorbent assay (ELISA) has shown that milk ELISA is comparable in accuracy to currently available serum ELISA kits. Previous resolutions from the Committee on Johne's Disease to include milk ELISA testing of Dairy Herd Improvement (DHI) samples as official screening tests for the Voluntary Bovine Johne's Disease Control Program (VBJDCP) have been approved by the United States Animal Health Association (USAHA). The national Dairy Herd Improvement Association (DHIA), through efforts of Quality Certification Services (QCS), has developed and implemented a laboratory milk ELISA proficiency program that meets the standards of proficiency for DHI laboratories and exceeds the standards of proficiency required by the milk ELISA proficiency program administered by the USDA, Animal and Plant Health Inspection Service (APHIS), Veterinary Services (VS), National Veterinary Services Laboratory (NVSL). The availability of two milk ELISA proficiency programs increases the costs of participation and testing for DHI laboratories. In an effort to reduce costs to DHI testing laboratories and to increase testing infrastructure for milk ELISA testing, a consolidation of the two proficiency systems is recommended that would meet the requirements of each of the individual proficiency programs.

RESOLUTION:

The United States Animal Health Association, recognizing the Voluntary Bovine Johne's Disease Control Program is a voluntary program, requests that the United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS), Veterinary Services (VS), National Veterinary Services Laboratory (NVSL) implement the protocol for Dairy Herd Improvement laboratory certification through the USDA-APHIS-VS-NVSL Johne's milk enzyme linked immunosorbent assay (ELISA) proficiency test program using the Quality Certification Services ELISA Proficiency Program test data.

FINAL RESPONSE:

The U.S. Department of Agriculture, Animal and Plant Health Inspection Service, Veterinary Services (VS) supports this resolution. The National Veterinary Services Laboratories (NVSL) is collaborating with Quality Certification Services (QCS) for certification of Dairy Herd Improvement (DHI) and non-DHI laboratories.

As part of this collaboration, NVSL receives annually a panel of well-characterized milk samples from sources routinely used in the QCS monthly test panel. NVSL evaluates these milk samples for suitability; then, if needed, requests additional amounts of the specific milk samples to be used in the proficiency test panel. Sufficient volume of the specific milk samples is supplied for kit assembly to ensure the kit composition meets the description within the Uniform Program Standards for the Voluntary Bovine Johne's Disease Control Program – 2010.

NVSL distributes the proficiency test kits to all participating laboratories. In 2012, NVSL distributed the milk ELISA proficiency kits in early February. The DHI laboratories receiving these kits conduct all required milk testing (enzyme-linked immunosorbent assay (ELISA) and milk quality testing) using these kits, but no fee is administered to the DHI laboratories for the NVSL supplying the proficiency test kits.

All laboratories (DHI and non-DHI) report their proficiency test results through the QCS online reporting program. At the end of the reporting deadline (February 29 for 2012), NVSL downloads all results from the QCS online reporting program, evaluates the submitted results, and administers certification notices to laboratories that successfully complete the Johne's Milk ELISA Proficiency Test. NVSL distributed certificates and results in March 2012 for laboratories successfully completing the proficiency test.

Presentations and Reports

The Role of Animal and Plant Health Inspection Service in the Future of Johne's Disease Control

Michael Carter

USDA-APHIS Veterinary Service (VS)

The President's fiscal year 2013 budget proposal recommended numerous cuts to Animal and Plant Health Inspection Service (APHIS) budget line items and the Johne's line item (as part of the Cattle Health line item) was no exception. One recommendation was for the elimination of Johne's program activities. Under the Cattle Health line item Johne's is no longer a specified activity, and so APHIS would like to identify what will continue as part of Veterinary Services' function.

The National Veterinary Services Laboratories (NVSL) will continue to manage the proficiency tests for milk and serum ELISA, fecal culture and fecal PCR. The cost of proficiency testing will be covered by User Fees. NVSL will also continue to maintain the lists of approved laboratories for various Johne's disease tests. The Center for Veterinary Biologics will continue its evaluation, approval, licensure and monitoring of diagnostic test kits for Johne's disease since APHIS will need to continue this activity regardless of where the funding comes from.

To a lesser extent, APHIS will provide minimal coordination activities limiting itself to hosting but not organizing the periodic conference calls for the USAHA Committee on Johne's Disease and the designated Johne's coordinators. APHIS will also continue to participate in the USAHA Committee on Johne's Disease and the National Johne's Working Group. APHIS will act as a reference point for international import and export negotiations and provide Veterinary Accreditation with guidance as necessary.

Since Johne's is a cattle health disease, minimal field activities can continue such as being involved with State education activities but APHIS will not be the driver of State Johne's programs and will not act in the designated coordinator roles. APHIS will continue to enforce 9 CFR part 80, banning the interstate movement of Johne's disease positive animals unless requirements are met for moving directly to slaughter. APHIS will also stay involved with the Mycobacterial Disease of Animals Multistate Initiative both as a Johne's disease and a tuberculosis disease stakeholder to the project.

National Johne's Working Group (NJWG) Treasurer's Report

Ken Olson

Johne's Disease Integrated Program (JDIP)

Review of NJWG income and expenses from the previous year. Presently, the NJWG had approximately \$13,000 in available funds.

National Milk Producers Federation (NMPF) Report

Jamie Jonkers

NMPF

The National Milk Producers Federation (NMPF), based in Arlington, VA, develops and carries out policies that advance the well-being of dairy producers and the cooperatives they own. The members of NMPF's 30 cooperatives produce the majority of the US milk supply, making NMPF the voice of more than 32,000 dairy producers on Capitol Hill and with government agencies.

NMPF has standing policy about animal diseases that continue to reduce profitability for dairy producers and which may impede exports and international market development. Diseases such as tuberculosis, brucellosis, and Johne's Disease and others can significantly increase costs to dairy producers in terms of decreased milk production, loss of animals, and replacement of animals. NMPF supports adopting Federal programs and securing adequate funding to prevent and/or eradicate animal diseases.

NMPF administers the National Dairy FARM Program: Farmers Assuring Responsible Management™ which is a nationwide verifiable program addressing dairy animal care and well-being. The FARM Animal Care Program provides consistency and uniformity to best practices in animal care and quality assurance in the dairy industry. An important part of the FARM Animal Care Program is developing and implementing a Herd Health Plan which includes requirements for disease prevention and treatment. A Johne's Disease control program could be an integral part of a Herd Health Plan.

NCBA Report

Mallory Gaines

National Cattlemen's Beef Association (NCBA)

Johne's Disease is a chronic infectious disease of cattle and other ruminants caused by the organism *Mycobacterium avium* subsp. *paratuberculosis*. The National Cattlemen's Beef Association (NCBA) currently holds a policy position on Johne's Disease program quality that urges USDA-APHIS Veterinary Services (VS) to continue efforts to certify laboratories to conduct serology and fecal culture analysis tests for Johne's Disease in cattle and further resolves to urge the Secretary of Agriculture to continue to place Johne's Disease as a priority for intramural and extramural research funding. Additionally, the policy resolves to continue to maintain Congressional awareness and support to adequately fund Johne's Disease control and research programs.

NCBA views Johne's Disease in beef cattle as a herd biosecurity issue. Biosecurity includes the sum of all actions to keep disease out of the cattle herd. The Beef Quality Assurance Program (BQA) provides best management practices for Johne's Disease control in beef cattle herds. The federal Johne's Disease program ended on September 30, 2012. Johne's Disease program regulations became guidance documents. NCBA's efforts to ensure the future sustainability of Johne's Disease control involve:

- Promoting producer education and herd biosecurity plans that include Johne's Disease
- Supporting the basic infrastructure for state Johne's Disease control efforts
- Supporting continued funding for Johne's Disease research

The beef industry is committed to taking steps to prevent Johne's Disease from entering low risk herds and controlling the disease in already infected herds as part of our pledge to total quality management to ensure that consumers receive wholesome and safe beef products.

Update on Research/Resources/Producer Tools

Ken Olson

Johne's Disease Integrated Program (JDIP)

The presentations that follow provide an overview of several ongoing efforts and new tools that have been developed, so were not discussed here. One good source of new information is from the presentations at this year's International Colloquium on Paratuberculosis (ICP). The meeting brought together over 300 participants from around the world to share results from their work and discuss program activities in their countries. The proceedings are available on the International Association for Paratuberculosis (IAP) site (<http://www.paratuberculosis.info/web/index.php>) that also includes information on the next ICP that will be held June 22 – 26, 2014 in Parma, Italy. Recent ICP proceedings are also available on the Searchable Proceedings of Animal Conferences (S-PAC) (<http://spac.adsa.org/>).

JDIP JD-RAP

Ernest Hovingh

University of Pennsylvania

Dr. Hoving provided an update on the JDIP Johne's Disease Risk Assessment Practicum (JD-RAP).

JDIP Diagnostics Update

Scott Wells

University of Minnesota

Comparing diagnostic tests for Johne's disease has always been challenging. JDIP is working to address the challenges that exist on two fronts. The initial effort focused on developing a modified version of the Standards for Reporting of Diagnostic Accuracy (STARD) that is relevant to paratuberculosis (Johne's disease) in ruminants. The new guidelines, called STRADAS-para TB, (Standards for Reporting of Animal Diagnostic Accuracy Studies for paratuberculosis) were published in the August issue of the journal Preventive Veterinary Medicine (volume 101:18-34).

The second portion of the project is now underway under the direction of Ray Sweeney (U of Penn) and Murray Hines (U of GA, Tifton Diagnostic Lab) and will include a "head-to-head" comparison of diagnostic tests. Goals of the project are to: 1) create a repository of well-characterized samples for use in the studies of Johne's disease diagnostic test accuracy; and 2) use samples collected to create the repository to compare performance of multiple diagnostic tests for paratuberculosis in dairy herds. Holstein herds participating in Dairy Herd Improvement Association (DHIA) system and not using paratuberculosis vaccine are eligible for inclusion in the study. Eligible animals in these herds will be those in lactation 2 and greater, and lactating at the time of sample (milk, feces and serum) collection. Infected and non-infected herds will be included in the study.

Once all the samples have been banked in the repository, test sets will be sent to the four laboratories that are participating in the head-to-head comparison of tests:

- Antel BioSystems – Serum ELISA and milk ELISA
- Cornell Animal Health Diagnostic Center – TREK and qualitative PCR
- Johne's Research Laboratory (U of Penn) - HEYM and Tetracore PCR
- Johne's Testing Center (UW-Madison) – MGIT

Results will be available in 2012. Samples in the repository will be available for future use by other researchers.

JDIP Vaccination Update

Vivek Kapur

There is a strong interest among many producers and veterinarians in having a more effective vaccine available to help combat Johne's disease. The JDIP Vaccine Project, sponsored in part by USDA-APHIS-VS, was established to help in this effort. The objective of the project is to gather candidates showing vaccine potential and submit each to a consistent, rigorous, three phase screening process designed to identify those with the greatest potential for commercial development. The first two phases are now complete. Of the eighteen knockout mutants submitted, eight were identified as having the best attenuation in the macrophage portion of study and were moved into Phase II, the mouse trial. The five mutants showing the best protection from challenge have now been moved forward into the final phase of the vaccine project, Phase III, the goat model. Phase III is being conducted in the lab of Dr. Murray Hines II at the University of Georgia. A total of 80 goat kids are being used on the five test and three control groups. Results of this work will be available next fall. Additional information about the project is available on the JDIP web-site (www.jdip.org).

Introducing the Mycobacterial Diseases of Animals (MDA) Multistate Initiative

Ken Olson

The Mycobacterial Diseases of Animals (MDA) Multistate Initiative is official and operational. This new multistate initiative is focused on two mycobacterial disease complexes - paratuberculosis (Johne's disease; JD) and the tuberculosis complex of diseases (Tbc: i.e. bovine tuberculosis). Primary objectives are to maintain the networking, collaboration, and basic infrastructure developed through Johne's Disease Integrated Program (JDIP), allowing participants to identify, obtain and share resources needed to address issues related to Johne's and other mycobacterial diseases. Since there is minimal funding associated with the multistate initiative, it is anticipated that this collaboration will also increase the potential for success in obtaining future competitive grants.

The MDA has five primary areas of effort:

- Increase understanding of the epidemiology and transmission of Mycobacterial diseases in animals, including predictive modeling;
- Develop and implement new generations of diagnostic tests for JD and Tbc;
- Improving our understanding of the biology and pathogenesis of Mycobacterial diseases, as well as the host response to infection;
- Develop programs to evaluate and develop new generations of vaccines for JD and Tbc; and,
- Develop and deliver education and outreach material related to JD and Tbc in electronic and print form for use by extension specialists, veterinarians, government agencies, producers and other stakeholders. Utilize trade media, producer organizations and other outlets to aid in dissemination of information generated through the initiative.

Interested individuals are invited to join the effort. The initial MDA Annual Meeting will be held on Sunday, December 2, 2012 in Chicago in conjunction with the Conference of Research Workers in Animal Diseases (CRWAD).

NJDEI Update

Teres Lambert

National Johne's Disease Education Initiative (NJDEI) Coordinator

The National Institute for Animal Agriculture (NIAA) has overseen the National Johne's Disease Education Initiative (NJDEI) for the USDA-APHIS Veterinary Services (VS) for the past several years. This agreement is coming to a close March 31, 2013. While a majority of educational and outreach efforts will be ending—including the quarterly dairy and beef e-newsletters, the website www.johnesdisease.org will remain active. Prior to the end of the contract with USDA-APHIS-VS, all state Designated Johne's Coordinators (DJCs) or a state's animal health department will be emailed a zipped file containing pdfs of educational documents printable in four color and in black and white on standard-size paper. It has been a privilege to work with the USDA-APHIS-VS and state DJCs in helping educate producers and others about Johne's disease prevention and control.

Group Discussion on Future Industry Needs from Johne's Committee

Scott Wells

University of Minnesota

Group discussion included possibility of disease tracking at slaughter, but the point was brought up that since Johne's disease is not a regulatory disease program, this would likely need to be an industry led initiative. Several examples of other countries with examples of industry driven Johne's disease control programs include Australia and New Zealand. Johne's Disease Risk Assessment Practicum (JD-RAP) is thought to be a good resource for dairy producers. NCBA is prioritizing Johne's disease control by including it in their farm biosecurity efforts, but they need data on the economic impact of Johne's disease in beef herds. Recommendations were made to keep Johne's disease in industry publications at least 1-2 times per year. There was discussion that the new MDA could facilitate networking between interested parties.

NVSL Serum/Milk Check Test Results

Jeff Nelson

National Veterinary Services Laboratory, USDA-APHIS

In 2012, 79 laboratories (10 international and 69 USA laboratories) took the Johne's disease serologic proficiency test and 44 laboratories took the Johne's disease milk ELISA proficiency test. This year the National Veterinary Services Laboratories (NVSL) approved 30 laboratories to perform the Prionics ELISA and 51 laboratories to perform the IDEXX ELISA for serum testing. Some laboratories are approved to perform both the Prionics and IDEXX ELISAs. NVSL approved 44 labs to perform the milk ELISA. It was noted that there was a decrease in the number of individuals approved to perform the Prionics serologic ELISA, 38 in 2012 vs. 47 in 2011 and an increase in the number of individuals that are approved to perform the IDEXX serologic ELISA, 64 in 2012 vs. 58 in 2011. A slight decrease in the number of labs approved to perform a milk ELISA, 44 in 2012 vs. 48 in 2011, was also noted.

NVSL Fecal Check Test Results

Suelee Robbe-Austerman

NVSL

Dr. Robbe-Austerman provided the report on the fecal check test results. No summary was provided.

Effect of Positive Test Results for *Mycobacterium avium* Subspecies *paratuberculosis* on Weaning Weights in Beef Cow-Calf Herds

Allen Roussel, Bikash Bhattarai, Geoff Fosgate, Jason Osterstock, Chuck Fossler, Seong Park
Texas A&M University

The objective of this study was to estimate the economic loss due to decreased adjusted weaning weight (AWW) of beef calves nursing cows with positive serum ELISA or bacterial culture of the feces (BCF) for *Mycobacterium avium* subspecies *paratuberculosis* (MAP). Records of cattle from beef herds participating in the National Johne's Disease Demonstration Herd Project from 1999 to 2009 were analyzed. Cows having a positive ELISA weaned calves that weighed 12.2 pounds less than those from cows with a negative ELISA for MAP. Cows having a strong positive ELISA weaned calves that weighed 47.4 pounds less than those with a negative ELISA for MAP. Cows having positive results on BCF for MAP weaned calves that weighed 73.3 pounds less than cows that were negative on BCF for MAP. Cows classified as heavy shedders for MAP in the feces weaned calves that weighed 129 pounds less than cows that were classified as negative on BCF for MAP. Based on the average calf price in the US during the study years, the loss per calf weaned by cows with a strong positive ELISA was \$57.59 while the loss per calf weaned by cows that were heavy shedders on BCF was \$157.60. A substantial loss in the income due to decreased AWW is associated with serologic status and fecal shedding of beef cows, presumably due to the decrease in milk production by the cow.

Update on Minnesota Demonstration Herd Project and Other Johne's Disease Research

Scott Wells, University of Minnesota

Dr. Wells provided this report to the Committee.

Update on Demonstration Herd Project, 2007 Johne's Disease Prevalence Study and Needs for NAHMS 2014 Study

Jason Lombard

In 2005, the USAHA Committee on Johne's Disease requested that NAHMS conduct a study to determine the national prevalence of herd-level infection with *Mycobacterium avium* subspecies *paratuberculosis* (MAP). The study was conducted during 2007 and cultures of composite fecal samples were used to determine herd level infection prevalence. The apparent herd level prevalence was approximately 70% across all herd sizes with more than 95% of herds with 500 or more cows having at least one composite fecal sample culture positive for MAP. Using sensitivity estimates from the NAHMS Dairy 2002 study and specificity estimates from expert opinion, a Bayesian approach was used to estimate the true prevalence of MAP on US dairy operations. The true prevalence of MAP was estimated to be 91.1% (95% probability interval, 81.6 to 99.3%). The methods used and results are published in Preventive Veterinary Medicine (Lombard et al., 2012). A list of publications completed as a result of the demonstration herd project was distributed. A copy of this list is provided at the end of this report.

DHI efforts in Johne's disease control

Jay Mattison, NDHIA

Mr. Mattison provided the report to the Committee, no summary available.

Johne's Testing for DHIA Herds Processed at DRMS

Ken Olson

Johne's Disease Integrated Program (JDIP)

(Presented on behalf of John Clay, Dairy Records Management System)

Over 16,200 herds with 2.2 million cows have their records processed each month at the Dairy Records Management System (DRMS). During the past two years:

- 1,559 herds have sampled 173,939 cows using Johne's milk ELISA
- 378 herds had samples in each of the four 6-month periods*
- 380 herds had samples in the last 6-month period but not in prior 18 months

The following procedure is used for providing information to producers. DHIA reports are mailed without the Johne's report. Data are forwarded to DRMS from six laboratories providing ELISA testing. When Johne's data arrives, it is merged with management information and the Johne's report, that merges animal identification (ID), Johne's, production and reproduction information, is either mailed or producers can retrieve it from website. The following observations can be made:

- Consistent numbers of herds and cows are being tested for Johne's
- Many herds tried service but did not continue
- Majority of testing by herds processed through DRMS occurred in four states (Minnesota, Michigan, Wisconsin and Pennsylvania)
- Marked changes in use of service is not expected

Committee Business:

Two action items and one resolution were taken under consideration, amended and passed as detailed below.

Action item 1: The USAHA Johne's Disease Committee and National Johne's Working Group (NJWG) will work with USDA-APHIS-VS and the newly established Mycobacterial Diseases of Animals (MDA) to continue teleconferences on Johne's disease and tuberculosis complex. We will work with the participants to determine frequency and content on these calls.

Action item 2: The USAHA Johne's Disease Committee approved utilizing NJWG (not to exceed \$5,000) for evaluation and/or establishment of non-profit status for the MDA.