

## **REPORT OF THE COMMITTEE ON JOHNE'S DISEASE**

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Vice Chair: Pending

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The Committee met on October 20, 2013 at the Town and Country Hotel, San Diego, California, from 12:30-5:30 p.m. There were nine members and 14 guests present. Welcome and review of last year's resolution and action items was provided.

### **Presentations & Reports**

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

Michael Carter

USDA-APHIS-VS

In the Animal and Plant Health Inspection Service (APHIS) FY 2012 budget, livestock commodities regulated by USDA were organized into 'Commodity Health Line' structures or groupings. APHIS' Cattle Health line supports efforts to protect the health and thereby improve the quality and productivity of the cattle industries. For fiscal year 2013, the President's proposal recommended numerous cuts to APHIS' budget line items and the Johne's line item (as part of the Cattle Health line item) was no exception. Under the Cattle Health line item, Johne's disease 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 polymerase chain reaction (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 Code of Federal Regulations (CFR) part 80 banning the interstate movement of Johne's disease positive animals unless requirements are met for moving directly to slaughter. And lastly, 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.

#### **NJWG Treasurer's Report**

Ken Olson, PhD, PAS

Johne's Disease Integrated Program (JDIP)

Review of NJWG income and expenses from the previous year. Presently, the NJWG had approximately \$14,000 in available funds.

### **National Dairy FARM Program – Updates and Johne's Disease**

Jamie Jonker, PhD

Vice President Scientific & Regulatory Affairs, National Milk Producers Federation

The National Dairy FARM (Farmers Assuring Responsible Management) Program was created four years ago to establish a national, voluntary dairy animal care program to bring consistency and uniformity to the practices used on America's dairy farms. The original reference manual was used to guide animal care practices on farms that have enrolled in the program since 2009. After a 15-month comprehensive review, an updated and revised *FARM Animal Care Reference Manual* was released in July 2013.

The National Dairy FARM program now has participant farms producing more than 70% of the nation's milk supply, through 53 cooperatives and proprietary processors enrolled in the program. Over 8,300 on-farm second-party evaluations have been conducted with about 270 Third-Party Verifications conducted by the end of 2013.

The FARM Program's wide-ranging guidelines and best practices help a dairy producer address Johne's disease control. The best practice of a written Herd Health Plan developed in conjunction with a licensed veterinarian is a comprehensive program for disease prevention, identification, and treatment for all ages of dairy animals. The written Herd Health Plan will include Johnes' Disease control if deemed necessary by veterinarian and farm manager. The FARM Program also uses the Johne's Disease Risk Assessment Program (sponsored in part by the National Milk Producers Federation) as an additional tool for dairy producers to understand Johne's disease risk on their farms.

### **NCBA Johne's Disease Presentation Overview**

Kathy Simmons, DVM

NCBA

It has been estimated that eight percent of all beef cattle herds may be infected with Johne's disease. The presence of Johne's disease in a cattle herd can result in economic losses through decreased milk production and lighter weaning weights, decreased reproductive efficiency, increased culling rates and death. Beef cattle producers understand the need to take proactive steps to prevent and control Johne's disease in their cattle herds. Johne's disease should be managed as a herd problem and not treated as an individual cow disease.

In the last year, the National Cattlemen's Beef Association (NCBA) policy concerning Johne's disease has shifted from the support of governmental disease programs to the promotion of individual herd security against this disease. The NCBA Cattle Health and Well-Being Committee facilitates a Herd Security working group which brings together producers, state affiliates, veterinarians, government employees, educators and researchers to have an open exchange of ideas, information and differing perspectives concerning herd biosecurity measures. Herd security is not about one disease, but rather about keeping the herd safe and secure from all diseases, including Johne's disease. NCBA continues to support research and improved diagnostic procedures for Johne's disease. Additionally, NCBA encourages the use of the Beef Quality Assurance (BQA) best management procedures checklist for herd security in controlling Johne's disease. Producers are encouraged to work with their veterinarians to develop a risk assessment and to establish appropriate risk management practices to prevent and control Johne's disease in their cattle herds. Both NCBA and the beef industry are 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 commitment to total quality management.

### **An Update on the New York Cattle Health Assurance Program and its Johne's Module:**

David Smith, DVM

New York State Department of Agriculture and Markets

The New York State Cattle Health Assurance Program (NYSCHAP) is a pioneering effort to improve the health, productivity and profitability of dairy and beef herds. The program focuses on bringing herd owners and managers together with advisors to craft herd health programs that are tailored to each herds own goals and resources. There were 890 active participants at the end of 2012, 84 of which were beef

herds and 806 which were dairy. The advisory team consists of veterinarians from Cornell University, and the New York State Department of Agriculture, as well as cooperating private veterinarians.

The Johne's component of NYSCHAP remains strong, despite the elimination of federal support. The State of New York recognizes the value of Johne's control and supports its producers primarily through subsidization of diagnostics costs. Testing has moved away from individual culture and now rRT PCR is the mainstay of the New York Johne's program. Many farms have had very good results with significant reduction in Johne's prevalence, but serious attention to management details is critical to achieving this benefit. Interest in Johne's vaccine has been light in New York. NYSCHAP does offer the option, but with significant restrictions. Overall NYSCHAP strives to anticipate producer's evolving needs and roll out new module to meet them. Recent examples include Foot Health and Calf Health. We anticipate adding a Drug Residue Awareness/Avoidance module soon.

### **JDIP Vaccine Development Project Phase III Study Update**

Murray Hines, DVM

University of Georgia

Johne's disease vaccine efficacy study and validation of a caprine vaccination and challenge model.

Murray E. Hines II, Sue E. Turnquist, Marcia R S Ilha, Sreekumari Rajeev, Arthur L. Jones Lisa Whittington, John P. Bannantine, Yrjö T. Gröhn, Robab Katani and Vivek Kapur. Submitted to *Frontiers in Microbiology*.

A *Mycobacterium avium* subspecies *paratuberculosis* (MAP) vaccine that reduced the incidence of clinical disease and/or reduced fecal shedding of MAP would aid control of Johne's disease (JD). The objectives of this study were 1) to evaluate the efficacy of five attenuated strains of MAP as vaccine candidates alongside one commercially available MAP vaccine (Silirum®, Pfizer) using the protocols and endpoints proposed by the Johne's Disease Integrated Program (JDIP), Animal Model Standardization Committee (AMSC), and 2) to validate the AMSC Johne's disease goat challenge model (see Hines et al., 2007b). Eighty goat kids were vaccinated orally twice at eight and ten weeks of age with one of the experimental vaccines or once subcutaneously at eight weeks with Silirum®, or an oral sham control vaccine consisting of goat milk. Kids were challenged orally with a total of approximately  $1.44 \times 10^9$  CFU divided in two consecutive daily doses using a bovine MAP K10-like isolate (ATCC-700535). Immunological tests performed included Agar Gel Immunodiffusion (AGID), enzyme-linked immunosorbent assay (ELISA), and cell mediated response by comparative purified protein derivative (PPD) skin testing (*M. avium*, Johnin and *M. bovis* PPD's). Kids within each group were euthanized and necropsied at 13 months post challenge. Results indicated all challenged kids had gross and/or microscopic lesions compatible with JD suggesting none of the vaccines prevented infection. However, there was a marked reduction in fecal CFU/g and necropsy lesion score in the group given the Silirum® vaccine and a lesser reduction in the 329 vaccine group. A marked reduction in MAP CFU/g and PCR percent positivity was also detected in necropsy tissues from kids given the Silirum® vaccine, and increased CFU/g were detected in tissues from kids given the 315 and 319 vaccines vs. the positive control group. Vaccination also resulted in false-positive PPD skin test reactions for *M. avium* PPD and Johnin. These data show Silirum® was the best performing vaccine followed by attenuated vaccine strain 329. Furthermore, the goat challenge model for Johne's disease has been validated.

### **Johne's Disease Integrated Project (JDIP) / Mycobacterial Diseases of Animals (MDA) Diagnostics Update**

Vivek Kapur, BVSc, PhD

Pennsylvania State University

While considerable advances have been made in Johne's disease (JD) diagnostics over the past decade, progress seems to be plateauing. The primary factors that continue to impede progress in JD diagnostics include: (i) Pathogen or pathogenesis related factors. These include a protracted incubation period with latent infection, and a growing recognition that adult infection may be important; Unpredictable disease progression and considerably lower frequency of shedding as compared with infection, and this is also manifested by low pathogen loads in tissues and feces of many animals and intermittent shedding of the organism. (ii) Technological factors, including the need for continued improvement in sensitivity and the fact that multiple types of assays are required to meet the needs for optimal sensitivity and specificity of existing pathogen detection or serological assays; and, (iii) Implementation or Operational factors, including those with quality control, standards, and cost-benefit considerations. The JDIP program had

initiated and the MDA is continuing to work on the improvements in JD diagnostics through the development of a sample repository of materials (serum, milk, feces) from well characterized animals to be used as a means for new diagnostics assay development and standardization. In addition, JDIP/MDA has embarked on a diagnostic assays benchmarking study that used a blinded study design with head-to-head comparisons of serological (ELISA), as well as pathogen detection (PCR and culture) assays in a community wide study. It appears that the community is at a key inflection point as relates to JD diagnostics, and that to move beyond incremental progress, there is a need to help redefine the strategic objectives, and perhaps explore opportunities to leverage between JD and bovine TB diagnostics and to help clarify the role of MAP in human Crohn's disease. A progress report was provided on diagnostic efforts made in JDIP and future goals for the newly formed multi-state initiative for Mycobacterial Diseases of Animals (MDA).

#### **DHI efforts in Johne's disease control**

Jay Mattison, CEO

National Dairy Herd Information Association

Mr. Mattison provided an update on the Dairy Herd Information Association's Johne's activities. No details of the summary were provided.

#### **NVSL Serum/Milk Check Test Results**

Charles Lewis

National Veterinary Services Laboratories (NVSL), USDA, Animal and Plant Health Inspection Service (APHIS)

In 2013, 82 laboratories participated in the Johne's Serologic Proficiency Testing process. Of these, 71 were domestic laboratories within the United States and 11 were international laboratories (representing Canada, Chile, The Netherlands, New Zealand, and Northern Ireland). Forty-four (44) laboratories participated in the Johne's Milk ELISA Proficiency Testing process, including 38 domestic and six international laboratories (Canada and The Netherlands). For the 2013 proficiency panel, the National Veterinary Services Laboratories (NVSL) approved 30 laboratories to perform the Prionics ELISA and 48 laboratories to perform the IDEXX ELISA for serum testing. NVSL approved 46 laboratories to perform the milk ELISA, 14 for the Prionics and 32 for the IDEXX ELISA assays.

The total number of laboratories approved to perform the serologic assay decreased from 81 total laboratories in 2012 to 78 laboratories in 2013. There was an increase in the number of laboratories approved to perform the milk ELISA test, from 44 total laboratories in 2012 to 46 laboratories in 2013.

#### **NVSL Fecal Check Test Results**

Suelee Robbe-Austerman

National Veterinary Services Laboratories (NVSL), USDA-APHIS

A total of 63 laboratories participated in the 2013 Johne's Disease Fecal Proficiency Panel (seven Canadian, three European Union, one New Zealand, one Australian and 51 USA laboratories). Overall, the number of laboratories that requested individual proficiency panels for direct polymerase chain reaction (PCR) and liquid culture methods increased from 2012 and decreased for solid culture methods. Overall, 93% passed using direct PCR on their initial attempt if a commercial kit was used and 65% passed if an in house procedure was used. For liquid culture, 95% passed using the TREK system, and 56% passed using the MGIT system. For solid media, 95% passed. False positive results with either direct fecal PCR or confirmatory culture PCR continue to be the most common cause of failure.

#### **Multi-State Initiative-Mycobacterial Diseases of Animals update**

Ken Olson, PhD, PAS

The multi-state initiative, approved by USDA, National Institute of Food and Agriculture (NIFA) in September, 2012, is focused on two mycobacterial disease complexes - paratuberculosis (Johne's disease; JD) and the tuberculosis complex of diseases (TbC; i.e bovine tuberculosis). It provides a vehicle to maintain and expand the networking, collaboration and basic infrastructure developed through JDIP, allowing participants to identify, obtain and share resources needed to address issues related to Johne's and other mycobacterial diseases. Projects within each of its five objectives will be designed to address the major animal, human, and societal issues surrounding detection and control of mycobacterial

infection, including how these organisms move and spread within cattle, small ruminant and wildlife populations.

**The American Association of Mycobacterial Diseases, Inc. (AAMD)**

Ken Olson, PhD, PAS

The American Association of Mycobacterial Diseases (AAMD) is a new, not-for-profit organization, incorporated in Pennsylvania. Its' objective is "To assist producer groups, researchers, regulators, and funding agencies by promoting scientific research, education and extension activities in developing and implementing science based solutions for the prevention and control of mycobacterial diseases".

**Group Discussion**

Discussion of current programs, usage and needs for further advancing the program. Summary of suggestions will be forwarded to the Multi-State Initiative-Mycobacterial Diseases of Animals and age-related macular degeneration (AMD) for consideration in their program.

**Committee Business:**

No resolutions or recommendations were made. Further, there was not a quorum present at the time of the committee business meeting.