

UNITED STATES ANIMAL HEALTH ASSOCIATION – Johne's Disease Committee

In 2006 the Johne's Disease Committee passed two resolutions and eleven recommendations. The resolutions were approved by USAHA and sent to USDA. The following are the responses to the requested actions.

RESOLUTION NUMBER: 11 APPROVED

SOURCE: COMMITTEE ON JOHNE'S DISEASE

SUBJECT MATTER: INDEMNIFICATION TO ELIMINATE CATTLE CONFIRMED POSITIVE FOR *MYCOBACTERIUM AVIUM PARATUBERCULOSIS* (MAP)

DATES: MINNEAPOLIS, MINNESOTA – OCTOBER 12-18, 2006

BACKGROUND INFORMATION:

Providing indemnification to producers for culling cattle confirmed positive for *Mycobacterium avium paratuberculosis* (MAP) by an officially recognized test for slaughter when such cattle are clinically normal and a high or moderate MAP shedder, will serve to prevent further transmission of the disease. Indemnification tied to program participation will also enhance identification, testing and confirmation of MAP positive animals, thereby promoting Johne's disease free status herds.

RESOLUTION:

The United States Animal Health Association (USAHA) recommends that the United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS), Veterinary Services (VS) request necessary funding to provide limited indemnification of cattle for producers who participate in the National Johne's Control Program, meet all Program Standards and cull to slaughter any animal confirmed positive for *Mycobacterium avium paratuberculosis* (MAP) by an officially recognized test provided further that the indemnification will apply only to animals determined to be clinically normal and a high or moderate MAP shedder.

The USAHA further requests that Congress recognize the importance of funding a Johne's disease indemnification program to augment, and not subtract from, current minimal funding for the National Johne's Control Program. USAHA recommends that this program remain voluntary.

RESPONSE:

United States Department of Agriculture (USDA), Animal Plant Health Inspection Service (APHIS), Veterinary Services (VS)

The United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS), Veterinary Services (VS) appreciates this recommendation and remains committed to improving our Johne's control program. However, we have several concerns regarding the request to provide indemnity for cattle confirmed positive for *Mycobacterium avium paratuberculosis* (MAP).

These include:

- No authorization for indemnity in the statute which establishes the Johne's program (7 USC Sec. 7626). This statute limits USDA to funding requests for conducting research, testing, and evaluation of programs for the control and management of Johne's disease in livestock. In

addition, authorizations of appropriations for the Johne's program only extend through 2007. USDA can not consider acting on this request until the new farm bill updates this restriction.

- Indemnity can only be applied to eradication programs (regardless of whether they are voluntary or mandatory). The Johne's program is a **control** program. Removal of some infected animals, while leaving others within the herd, will not produce a reduction in the national herd prevalence and can not be considered eradication. Currently, the economic models published show that test and cull programs can not remove the infection from the herds and would not be cost-effective methods to eradicating Johne's disease.
- Any herd owner that would participate in the indemnity program would have to make eradication of the disease the goal of their herd plan which requires the removal of all infected animals. Removal of some infected animals, while leaving others, will not produce a rapid reduction within a producer's herd prevalence levels, thereby prolonging the cleanup efforts.
- Enzyme-linked immunosorbent assay (ELISA) testing is the most cost-effective method of managing the infection on the farm after the presence of MAP has been confirmed in moderate to heavily infected herds. Confirming ELISA positive animals to establish their eligibility for indemnity delays removal of the animal from the herd, in addition to accumulating further costs to the program.
- Producers that are only willing to remove heavily shedding animals after applying for indemnity would not be considered committed to Johne's eradication in their herd. Industry has not provided any information supporting how the inclusion of indemnity would increase participation in the voluntary program, or increase the commitment of producers already enrolled.

As a result of these concerns, VS will not pursue indemnity funds for the Voluntary Bovine Johne's Disease Control Program at this time.

RESOLUTION NUMBER: 12 APPROVED

SOURCE: COMMITTEE ON JOHNE'S DISEASE

SUBJECT MATTER: QUANTITATIVE BULK TANK MILK TESTS FOR DETECTING JOHNE'S DISEASE

DATES: MINNEAPOLIS, MINNESOTA – OCTOBER 12-18, 2006

BACKGROUND INFORMATION:

The routine availability of quantitative bulk tank test levels of *Mycobacterium avium paratuberculosis* (MAP) would enable producers to know and understand how their level of MAP compared on a national basis and would encourage individual progress to reduce levels of MAP in their herd. Such quantitative results would also reduce the cost of routine testing, help in identifying Johne's positive herds and encourage greater producer participation in the National Johne's Control Program, particularly if buyers or marketers of milk could provide free or subsidized testing in return for producer participation in the national program.

RESOLUTION:

The United States Animal Health Association (USAHA) recommends that the United States Department of Agriculture (USDA), Agricultural Research Services (ARS) and the research community have a greater focus on development of quantitative based tests for detecting *Mycobacterium avium paratuberculosis* (MAP) in bulk tank milk.

RESPONSE:

United States Department of Agriculture (USDA), Agricultural Research Services (ARS)

ARS proactively initiated the development of a quantitative-based test for detecting MAP in bulk tank milk in 2006; this is a quantitative real-time PCR test for Johne's disease in milk and other tissues that uses the unique target sequences, ISMapO2, identified by ARS through the Johne's genome sequence project. ARS has developed a test format that includes a probe enabling the quantification of the amount of MAP DNA present in a test sample. ARS is collaborating with Dr. Sandra Godden at University of Minnesota in using this test on colostrums samples obtained from noninfected and infected dairy herds, and to date has evaluated this experimental test on over 350 samples. When completed, the results will be submitted to the University of Minnesota, which will then conduct validation studies by comparing the results to fecal shedding of the bacterium. ARS plans further research on this approach to enabling the quantification of MAP in bulk tank milk.

The Committee passed the following recommendations. Actions reported to the committee in response to the recommendations are listed.

1. That USDA continue support of the **National Demonstration Herd Project (NDHP)** by facilitating meetings with VS providing travel expenses for the NJWG Demonstration Herd Subcommittee to work with Charles Fossler and Jason Lombard and staff at CEAH to analyze the resultant data and prepare manuscripts in a timely manner. Additionally, for CEAH to allocate more funds to assist the Johne's Disease epidemiologists to enhance the efforts of CEAH staff working with the National Johne's Program. Furthermore, that Jason Lombard continues as an active participant in this process and continues to participate as coordinator of the NDHP with the newly hired John's Epidemiologist Dr. Charles Fossler.

Response – Results from analysis of data from the National Demonstration Herd Project was the focus of a half-day session of the National Johne's Working Group on October 18, 2007. Preliminary analysis shows results are consistent with effectiveness of the control program in reducing incidence of Johne's disease on cattle operations. An outline of analyses and potential publications was presented.

2. **Laboratories that passed the Johne's organism detection check test outside the normal time sequence** (typically February through May each year) should be given "preliminary approval" as an approved laboratory for that specific methodology i.e. solid media, liquid media or PCR testing. Preliminary approval would be given when laboratory results are submitted after NVSL report at the annual USAHA meeting. Additionally, requests for check test kits would be honored from laboratories that are implementing a new test method outside the time when test kits are routinely shipped to participating laboratories. Preliminary approval would be provided following submission of check test results that meet or exceed the test criteria established that year. However, that preliminary approval would not include listing of that laboratory in the approved laboratory list as published in the USAHA proceedings nor would that laboratory be listed on the USDA-APHIS web site of approved laboratories that year. Laboratories that pass the annual organism based proficiency test are officially approved January 1 following the annual USAHA meeting.

Response – Procedure has been put in place.

3. **Laboratories that fail organism detection test and desire a retest** should complete the following protocol through NVSL.
 - a. Each laboratory would be required to provide a written self-assessment report outlining possible deficiencies or situations as to what factors lead to an inadequate check test. Included would be a plan to enhance the laboratories proficiency to detect MAP in fecal samples. A template for this report is being developed. If a commercial test kit or test system is being used for organism detection, the company should be contacted to help determine the source of the problem and their findings should be included in the self assessment.
 - b. Each laboratory would be encouraged to seek additional training either from another local laboratory considered proficient in organism detection or at NVSL.
 - c. Letters from NVSL notifying each laboratory about test results will also be sent to the Designated Johne's Coordinator (DJC) for that state and to the National Johne's Coordinator (NJC) for their information. Labs that do not pass the check test must contact the NJC and their DJC regarding continuation of their opportunity to perform organism detection tests for the Voluntary Bovine Johne's Disease Control Program.
 - d. Labs that fail the organism based check test are encouraged to re-take the check test following submission of their written self-assessment and approval of the National Johne's Coordinator, if adequate check test kits are available at NVSL.

Response – Procedure has been put in place.

4. **Laboratories that fail two sequential organism detection test and desire a retest** should complete the following protocol through NVSL.
 - a. Each laboratory would be required to provide a written self-assessment report outlining possible deficiencies or situations as to what factors lead to an inadequate check test. Included would be a plan to enhance the laboratories proficiency to detect MAP in fecal samples. If a commercial test kit or test system is being used for organism detection, the company must be contacted to help determine the source of the problem and their findings should be included in the self assessment.
 - b. Laboratories in this category will be required to send the person responsible for the organism detection testing to NVSL or to another laboratory with the necessary experience and expertise approved by NJC for further training in mycobacterial detection methods.
 - c. Laboratory would be required to purchase and submit results from a second check test following mandatory training at NVSL or another laboratory as approved by the NJC.
 - d. Letters from NVSL notifying each laboratory about test results will also be sent to the DJC for that state and to the NJC for their information.

Response – Procedure has been put in place.

5. USDA-APHIS-VS signed a cooperative agreement (#05-9100-0996-GR) with a team of scientists to develop a **consensus recommendation on diagnostic testing for bovine paratuberculosis** in the U.S. These recommendations have been developed and were reviewed and approved by the NJWG. The Committee accepts and recommends that USDA adopt the Diagnostic Testing for Bovine Paratuberculosis in the U.S. as developed under cooperative agreement #05-99100-0996-GR. This recommended test regimen for the detection of paratuberculosis in cattle is included in these proceedings following the Committee Report.

Response – Completed – accepted by USDA

6. The Committee recommends that USDA-APHIS-VS provide funding to identify target herd sensitivities and the **most cost-efficient testing alternatives for detection of *M. paratuberculosis*** in dairy and beef cattle herds at different levels of the Johne's Disease Test Negative Program.

Response – Funding was provided to the University of Minnesota for this project and a preliminary concept paper report was presented to the National Johnes Working Group on Friday, October 19.

7. The Committee recommends that USDA-APHIS-VS-NVSL continue to **develop a systematic protocol for the production and characterization of a uniform, quality Johnin purified protein derivative (PPD) and manufacture Johnin PPD**. The Johnin PPDs must be of equivalent sensitivity and specificity from batch to batch. These products must be available for distribution to researchers upon request.

Response – In process, efforts are underway at NVSL

8. The Committee recommends that NVSL provide a **pilot test panel of ten test samples**, consisting of three or more different mycobacterial species, to interested diagnostic laboratories **performing confirmatory PCR tests** on all acid-fast suspect positive cultures for *M. paratuberculosis*. The laboratories will provide PCR methodologies and results, reported as positive or negative, back to NVSL.

Response – Accomplished

9. The Committee acknowledges and appreciates the improvement and speed in which the Center for Veterinary Biologics (CVB) has licensed products important to the NJCP. We recommend that CVB **review milk Enzyme-linked immunosorbent assay (ELISA)** in an expedient manner. In order for laboratories to qualify to perform the milk ELISA as a 'program' test, a **proficiency test panel** must be developed for laboratory approval. The Committee recommends that NVSL acquire milk samples from an outside source and not purchase lactating cows for the sole purpose of providing milk for the proficiency panel.

Response – One ELISA test kit has been approved by CVB for marketing as a milk ELISA test kit and efforts are underway by NVSL to develop an ELISA test kit.

10. The Committee approved a recommendation that NVSL provide and distribute a fecal sample from a low / moderate shedding cow to be used in a pilot study involving approximately 5 – 10 labs for each of the three culture methods (HEY, Trek and MGIT) and quantitative direct PCR to **evaluate sources of variation in fecal culture shedding levels**. Data will be reported to CEAH.

Response – This effort was not completed last year, but plans are underway for implementation in 2008.

11. The Committee recommends that USDA and livestock producers **expedite the implementation of a national animal identification system (NAIS)**. NAIS would greatly enhance the ability to identify and control movement of infected animals. We also recommend development of an indemnification program, supported in part by producers, to increase the confidence that these animals will not spread disease to other herds. Furthermore we recommend producers consider the high risk of introducing Johnes's disease when purchasing cattle.

Response – Efforts continue towards implementation of a national animal identification system.