REPORT OF THE COMMITTEE ON JOHNE'S DISEASE

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The Committee met on October 26, 2008 at the Sheraton Greensboro Hotel, Greensboro, North Carolina, from 12:30 to 5:30 p.m. There were 33 members and 16 guests present. Introductions were made by all in attendance.

Status of 2007 Resolutions and Recommendations

RESOLUTION 35: NATIONAL JOHNE'S DISEASE DEMONSTRATION HERD PROJECT

RESOLUTION: The United States Animal Health Association (USAHA) recommends that the United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS) continue to prioritize funding for the National Johne's Disease Demonstration Herd Project.

RESPONSE: The U.S. Department of Agriculture, Animal and Plant Health Inspection Service, Veterinary Services (VS), recognizes the United States Animal Health Association's concerns and appreciates the opportunity to respond. VS sees the value in collecting additional years of data now that calves born under the project management plans are entering the productive phase of their lives. VS continued to support the project in fiscal year 2008. VS is also evaluating alternatives to reducing the scope of the project for fiscal year 2009 if funds are not available to support the project in full.

RESOLUTION 36: MILK ELISA TESTING FOR JOHNE'S DISEASE

RESOLUTION: The U.S. Animal Health Association (USAHA) requests the USDA, Animal and Plant Health Inspection Service (APHIS), Veterinary Services (VS) incorporate the milk ELISA testing method into the VBJDCP by recognizing it as an approved screening test for Johne's disease and require that laboratories performing the milk ELISA test must pass an annual proficiency test under the direction of the National Veterinary Services Laboratories (NVSL).

RESPONSE: The U.S. Department of Agriculture, Animal and Plant Health Inspection Service, Veterinary Services (VS), recognizes the United States Animal Health Association's concerns and appreciates the opportunity to respond. VS will incorporate the milk enzyme linked immunosorbent assay (ELISA) testing method into the Voluntary Bovine Johne's Disease Control Program (VBJDCP). The National Veterinary Services Laboratories (NVSL) has developed and implemented a milk ELISA proficiency test for the 2008 testing period. Kits were distributed in early 2008, and results are being analyzed from the first round of testing. From initial evaluation of the process, NVSL has plans to continue the milk ELISA proficiency test during the 2009 testing period. The addition of milk ELISA as a screening test will be included in the Uniform Program Standards for the VBJDCP during the next revision.

RESOLUTION 37: STRATEGIC PLAN FOR JOHNE'S DISEASE

RESOLUTION: The United States Animal Health Association (USAHA) requests that United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS), Veterinary Services (VS) provide financial and personnel support for the development of the new national Strategic Plan for Johne's Disease.
RESPONSE: The U.S. Department of Agriculture, Animal and Plant Health Inspection Service, Veterinary Services (VS), recognizes the United States Animal Health Association's concerns and appreciates the opportunity to respond. VS agrees that the current Johne's strategic plan needs revision and is providing support for this effort. Activities have been initiated to develop this revised strategic plan including a meeting on March 12-14, 2008, in Chicago, Illinois, and several conference calls.

RESOLUTION 38: MILK ELISA TESTING FOR JOHNE'S DISEASE IN THE NATIONAL PROGRAM
RESOLUTION: The United States Animal Health Association, recognizing the Voluntary Bovine Johne's Disease Control Program (VBJDCP) is a voluntary program, requests that the United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS) to allow the Quality Certification Services (QCS)-certified and Designated Johne's Coordinator (DJC)-approved Dairy Herd Improvement Association (DHIA) field personnel to collect and submit milk samples to approved laboratories for milk enzyme linked immunosorbent assay (ELISA) testing for Johne's disease under the direction of the herd's Johne's certified veterinarian.
RESPONSE: The U.S. Department of Agriculture, Animal and Plant Health Inspection Service (APHIS), Veterinary Services (VS), recognizes the United States Animal Health Association's concerns and appreciates the opportunity to respond. Allowing official sample collection by nonaccredited veterinarians and personnel who are not veterinarians would be a significant change to VS policy. However, VS will change its policy to allow Dairy Herd Improvement Association (DHIA) field personnel, who are certified by the Quality Certification Services and approved by State Animal Health Officials, to collect and submit milk samples to approved laboratories for milk ELISA testing as part of the official Voluntary Bovine Johne's Disease Control Program (VBJDCP) for herd classification. Additionally, APHIS will put a program requirement into the Uniform Program Standards for the VBJDCP for DHIA field technicians to complete the same training required of accredited veterinarians to gain Johne's disease certification. This training would give them the basic information regarding the organism, clinical signs, disease epidemiology, and national and State program information they would need to accurately collect the samples.

National Johne's Education Initiative was presented by Teres Lambert, National Institute for Animal Agriculture (NIAA).

The NIAA and USDA-APHIS-VS have a cooperative agreement to help educate the industry about Johne's disease. The ultimate goal of all communication pieces is to educate so the incidence of Johne's disease is reduced on U.S. farms.

Before developing industry education tactics for the 2008 National Johne's Education Initiative marketing plan, NIAA surveyed the designated Johne's disease coordinators (DJCs). DJCs' comments include:

- make the www.johnesdisease.org more user friendly, include more information and keep the web site current;
- when appropriate, target dairy-only audiences and beef-only audiences;
- with budgets dwindling, they would like more assistance with educational material.

What has NIAA accomplished to date? The Johne's education initiative website redesigned and significantly more information added. Results showed 204 hits per day. Eight news releases were written and disseminated to print media and radio stations. Scattering news release throughout the year for a constant presence in the media:

- alerted dairy producers to the National Dairy Producer survey and encouraged their participation. Released March 28;
- shared information about the updated johnesdisease.org website. Released in May;
- announced the availability of the dairy prevention/control/risk assessment collateral piece and the beef prevention/control/risk assessment collateral piece. Three separate news releases: 1.) dairy publications only; 2.) beef publications only; and 3.) general livestock/agricultural publications. Released July;
- announced the availability of the dual dairy/beef testing brochure. Three separate news releases: 1) dairy publications only; 2) beef publications only; and 3) general livestock/agricultural publications. Released September; and
- news release sent to publications also resulted in two editors writing their own Johne's article: National Cattlemen and Bovine Veterinarian.

In addition to news articles and announcement on radio stations, we're seeing articles online such as at AgOnline.

Two feature articles were written and disseminated to the print media under the pen name of T.S. Gatz. The information from these articles was gleaned from the Johne's Workshop in East Lansing in April 2008.

- The first feature article had a known reach of at least 250,000 producers.
- The second feature article had a known reach of more than 350,000 readers.
- The reach of both articles was most likely significantly larger as most publications do not indicate whether they use an article or not.

Two four-color collateral pieces—one for dairy and one for beef—were written and disseminated. Both pieces address prevention and control and have lists so producers can conduct their own risk assessment.

- 27,000 dairy risk assessment brochures have been printed, with 20,274 disseminated to date.
- 16,000 beef risk assessment brochures have been printed, with 15,011 disseminated to date.

A four-color collateral piece that addresses testing and best test, and serves both the beef and dairy industries were developed, with 25,000 copies printed: 14,793 have been disseminated to date.

One-hundred of the dairy prevention/control/risk assessment brochures, 100 of the beef prevention/control brochures and 100 of the testing brochures were furnished at no cost to DJCs. DJCs could purchase additional quantities at NIAA's print cost of only $0.16 each plus postage, and this resulted in about 9,500 additional copies supplied to DJCs.

- Sent 100 of the dairy risk assessment collateral piece to dairy cooperatives, with additional quantities offered at the cost of printing only: $0.16 each.
- Sent an email to beef and dairy extension specialists about the Johne's disease prevention/control/risk assessment beef-specific and dairy-specific collateral pieces and offered 100 complimentary copies of all brochures. This resulted in further outreach to producers.
- Contacted national and state beef and dairy websites that producers use and asked that the www.johnesdisease.org website link be added to their website. At this point in time, six more websites now include this Johne's disease information website.
- Conducted three Johne's disease radio interviews: a 4- to 5-minute interview with an Iowa radio station, a 4- to 5-minute interview with the Northern Ag Network and the third with Truffle News Media.
- Attended the American Dairy Science and Animal Science conference and disseminated the Johne's prevention/control/risk assessment collateral pieces.
- Attended the World Dairy Expo and disseminated 250 of the dairy risk assessment and 250 of the testing brochures.
- A mass mailing to bovine practitioners was made via an insert in AABP convention's registration packet. This insert alerted veterinarians to the availability of the three collateral pieces.
- Answered inquiries for additional information about Johne's disease. Two inquiries stick out: 1.) Johne's and sheep; and 2.) Johne's and bison. These were turned over to Dr. Carter.
- Responded to requests from producers and veterinarians for one of the three brochures.

What is on tap for NIAA's Johne's producer education work? Two more months of work remain. What will be produced will hinge on need.

United States Johne's Disease Program Updates FY 2008 was presented by Dr. Michael Carter, National Johne's Program Coordinator, VS-APHIS -USDA.

In 1997, USAHA National Johne's Working Group (NJWG) appointed a committee to design an affordable and flexible program based on sound scientific knowledge. The result was the U.S. Voluntary Johne's Disease Herd Status Program (VJDHSP). Instead of trying to certify herds free of Johne's disease, the VJDHSP provides minimum requirements for a program to identify herds of low risk with *M. paratuberculosis* infection. These guidelines are used as a model for the Uniform Program Standards for the Voluntary Bovine Johne's Disease Control Program (VBJDCP) approved by USDA-APHIS-VS in April of 2002. The latest revision to the program standards occurred in June of 2006 with the including of pooled fecal samples for level 3 test negative testing and updating the laboratory approval section of the standards.

For FY 2008 from States that have reported by October 10, 2007, 49 States had adopted the VBJDCP or had programs that were considered in compliance with these standards. In FY 2008, reported activities include 450,805 cattle tested by ELISA and 55,859 cattle tested by fecal culture or PCR, 7,265 enrolled herds (5,511 dairy and 1,762 beef) of which 1,397 are test negative herds (772 dairy and 625 beef). Herds enrolled as test negative herds are progressing through to level 4. There are 529 Johne's program level 1 (284 dairy and 245 beef), 473 Johne's program level 2 (284 dairy and 209 beef), 104 Johne's program level 3 (50 dairy and 54 beef), and 291 Johne's program level 4 herds (174 dairy and 117 beef). This represents a decrease in all categories except for Johne's program level 4 beef herds which is up from 92 herds.

In FY 2008 USDA-APHIS-VS receive $10.53 million. Of this $4.0 million was distributed through cooperative agreements with the States for use with the National Johne's Demonstration Project ($1.5 million – 17 States), and State Cooperative Agreements ($2.5 million including an earmark for Wisconsin). This is also the fourth year for

funding the Johne's Education Initiative (JEI) coordinator through a cooperative agreement with NIAA. Accomplishments include three brochures published and distributed along with the maintenance of the JEI website with the inclusion of a section linking producers to State websites identifying VBJDCP herds.

USDA-APHIS-VS also continued support of the Vaccine Validation Project with the Johne's Disease Integrated Program. This is a 3 year funded effort initiated at the end of FY 2007 to validate some of the numerous vaccine candidates developed by universities, preparing the way hopefully for commercial uptake. In addition, USDA-APHIS-VS-NVSL will be starting a PCR validation project for goats in preparation of the 2009 National Animal Health Monitoring Service Goat Study.

USDA-APHIS-VS has approved the use of milk ELISA for the herd classification component of the program and will be updating the program standards to reflex this and the allowance of using DHIA field technicians to collect samples which will be used to classify herds.

National Johne's Working Group (NJWG) Report was given by Dr. Ken Olson, NJWG Treasurer, and was accepted by the Committee. A complete report of the NJWG is included at the end of this report.

Johne's Disease Integrated Program (JDIP) Education/Outreach Project was presented by Ken Olson and Ernest Hovingh, JDIP Education
A summary of the JDIP information is included in the NJWG report at the end of this report.

Mycobacterium avium paratuberculosis (MAP): Infrequent Human Pathogen or Public Health Threat was presented by Mike Collins, University of Wisconsin-Madison. The full report can be viewed at: http://academy.asm.org/index.php?option=com_content&task=view&id=100&Itemid=55.

The Executive Summary is provided as follows:

Crohn's Disease (CD) is a devastating illness in search of a cause and a cure. More than 800,000 people in North America suffer from CD, a gastrointestinal disorder characterized by severe abdominal pain, diarrhea, bleeding, bowel obstruction, and a variety of systemic symptoms that can impede the ability to lead a normal life during chronic episodes that span months to years. Researchers and clinicians agree that onset of CD requires a series of events. Implicated are certain inherited genetic traits, an environmental stimulus, and an overzealous immune and inflammatory response. The combination of these factors contributes to a disease whose course is variable among patients and whose symptoms range from mild to devastating on any given day. The economic and social impact of this disease is substantial for the patient, the family, the community, and the healthcare system.

Long considered an autoimmune and chronic inflammatory disorder, current CD therapies are designed to treat symptoms of overactive inflammation in the gut. Chronic inflammation, however, does not generally induce itself. Inflammation is normally caused by a foreign body, an inanimate object (i.e., splinter) or animate objects like rogue cells (i.e., cancer) or microorganisms (i.e., bacterium, virus, or fungus). Until the cause of inflammation is eliminated, the body continues to send in its clean-up crew, the white blood cells of inflammation whose job it is to expel the tissue invader. Inflammation only subsides when the causative agent is finally banished.

There is suspicion, supported by reports of genetic inability to interact appropriately with certain bacteria or bacterial products in some patients, that CD may have a currently unrecognized infectious origin, perhaps environmentally derived. That CD is a set of wide-ranging symptoms, more like a syndrome than a specific disease, suggests that if its origin is microbial, more than one etiologic agent may ultimately be identified. Bacterial suspects at the moment include a *Mycobacterium* and a variant of the normal bacterial flora of the gut, *Escherichia coli*. The possibility of more than one infectious cause that leads to a similar set of symptoms confounds the research agenda to find both a cause and a cure for CD.

One acknowledged potential microbial agent of CD is MAP, a microorganism that causes a gastrointestinal disease similar to CD in ruminants, including dairy cattle, called Johne's disease (or paratuberculosis). People with CD have 7:1 odds of having a documented presence of MAP in blood or gut tissues than those who do not have CD, thus the association of MAP and CD is no longer in question. The critical issue today is not whether MAP is associated with CD, but whether MAP causes CD or is only incidentally present, not an inciter or participant in the disease process.

If MAP is involved in the disease process of CD or other gastrointestinal disorders, then we need to determine how people are exposed to this microorganism, how to prevent that exposure, and how to treat the infection. Despite its prevalence in the U.S. population in numbers that exceed most cancers, CD is not a focus of research attention in the same way as these other feared diseases. The American Academy of Microbiology convened a colloquium with experts in medicine, microbiology, veterinary pathology, epidemiology, infectious diseases, and food safety to describe the state of knowledge about the relationship between MAP and CD and to make recommendations for effective research that will move the field forward.

The general consensus of the assembled experts was that there are certainly reasons to suspect a role for MAP in CD:

- MAP persists in contaminated soil and water, which links the environmental factor of CD to the disease.
- MAP has a cell wall that contains muramyl dipeptide (MDP). One genetic trait that is affiliated in certain patients with CD is the NOD2 gene, which regulates ability to respond appropriately to MDP, thus the link between the genetic trait and MAP, or other bacteria.
- MAP causes Johne's disease, an illness of cattle and other ruminants that has many similarities with CD. The similarities of MAP disease in animals, for which the etiologic agent is known, and CD, for which the etiologic agent is unknown, provide a symptomatic link between agent and disease.
- MAP can survive standard milk pasteurization processes and has been identified in off-the-shelf milk in retail grocery stores in the U.S. and the European Union (EU). There is increasing concern that MAP can also be found in cheese made from the milk of MAP-infected cattle and meat from Johne's diseased animals. These observations could provide the exposure route of CD patients to MAP.
- Treatment of some CD patients with antibiotics that have activity on certain other Mycobacteria, although not specifically selected for their activity against MAP, provides short-term or long-term relief or remission of symptoms.

Circumstantially, these observations appear to make a compelling case for MAP as involved in CD. On the other hand, the ability to definitively identify MAP as the cause of CD, or the cause of a significant number of CD cases, has been stymied by the elusive characteristics the organism itself, the lack of broadly available and validated clinical tools to easily and definitively identify MAP in accessible tissues, and the late symptomatic stage at which CD is finally diagnosed, where the origin of the destructive inflammation could have been years before the patient sought medical care. Most important, however, is the lack of resources, financial and scientific, to generate the tools that clinicians and patients need to determine whether MAP is involved in the disease process or not.

Several important clinical trials of antibiotics have been attempted in CD patients, with variable results. Treating CD patients with existing antibiotics with activity against other *Mycobacteria* (*M. tuberculosis*, which causes tuberculosis [TB], and *M. avium* complex, [MAC], which is pathogenic in immune compromised persons) have either failed to provide relief (TB drugs) or produced promising outcomes for some patients, but not all (MAC drugs). Confounding these clinical results is the lack of information about which patients in the clinical trial population were actually infected with MAP, and whether any MAP organisms in infected patients were susceptible to the antibiotics used in the trials. Without sensitive and specific diagnostics that can detect early MAP infection, knowledge of how and where to isolate MAP for antibiotic susceptibility studies, and drugs that are known to be active against MAP itself, alone or in combination, the role of MAP in CD will remain circumstantial and the controversy over CD etiology will continue.

There is little known about where exactly viable MAP can be found in human tissues or, since most pathogenic *Mycobacteria* are intracellular, in which cells MAP can live and grow in humans. While the site of infection and tissue pathologies of MAP in animals can be assessed at necropsy, there is enough dissimilarity between digestive processes of ruminants and humans that this information may not necessarily inform studies in humans.

Of concern from a public health perspective is the ongoing presence of MAP disease in commercial livestock that supply the U.S. with dairy and meat products. If, in fact, CD is a zoonotic infection (one that is passed from animals to humans) and MAP is the (or one) cause of CD, then early identification of MAP disease in veterinary practice and appropriate management of these animals to safeguard the food supply will be critical to guard the public health.

Even in animals, it is nearly impossible to diagnose Johne's disease in the early stages of disease. Diagnosis is by a combination of clinical observation (wasting and reductions in milk production in dairy cattle, for instance) and microbiological, histopathological, and immunological testing of Johne's disease suspects. Although efforts to eliminate Johne's disease and MAP from livestock herds are ongoing, the lack of an accurate and easily-administered diagnostic for early disease onset is hampering these efforts. The results are mixed, and food products containing MAP or MAP DNA can be found on supermarket shelves. Veterinary diagnostics that are sensitive (detect MAP at early stages of infection) and specific (identify MAP and not other microorganisms) will be necessary to eliminate Johne's disease from the commercial food supply. Research to discover and validate these techniques may also shed light on diagnosis of human disease.

Colloquium participants agreed that research to elucidate the role of MAP in CD must address two major unknowns: 1.) whether MAP from livestock and other animals is transmissible to humans and how it is transmitted and 2.) whether humans are susceptible to infection and disease after exposure to MAP. No single study will fill all the gaps in our understanding of the possible relationship between MAP and CD. Furthermore, participants agreed that validated, reproducible biological markers confirming human MAP infection are desperately needed.

If MAP can be causally associated with CD using reproducible analytical techniques, appropriate patient populations can be treated with antibiotics that are selected for their MAP activity. Then, at least MAP-infected CD patients will have both a cause and a cure.

National Veterinary Services Laboratory (NVSL) Report of Approved Laboratories was given by Beth Harris, NVSL. Proficiency panels for Johne's disease organism detection (culture and direct PCR) were mailed to participants in January, 2008. Due to contamination problems and inconsistent results with the negative and low positive samples, this kit was recalled by NVSL and a replacement kit made available at no cost to participants in June, 2008. Combined summary results from both panels are as follows:

A total of 71 laboratories, (64 USA laboratories, 7 international; Canada -3, United Kingdom -2, Ireland -1, Sweden -1) participated in the 2008 Johne's disease proficiency panel.

A total of 45 laboratories participated using Direct PCR; 35 laboratories passed, 3 did not submit results, and 7 laboratories did not meet the criteria for passing.

A total of 39 laboratories participated using HEY media; 20 laboratories passed 14 laboratories did not pass and 5 laboratories did not submit results

Thirty-five laboratories participated using liquid media systems. Two laboratories used Bactec 460 with both laboratories passing. Twenty-four laboratories used ESP with 23 passing, and nine used MGIT 960 with 6 passing.

Forty-four laboratories participated in the pooling proficiency panel. Nineteen laboratories used direct PCR with 18 passing and one laboratory not submitting results. Seven of 7 laboratories passed using HEY solid media. Twenty laboratories used a liquid media system with 18 passing and two not meeting the criteria for passing. Of the laboratories using liquid culture for the pooling proficiency panel, 4 used the MGIT 960 with all passing, one laboratory used the BACTEC 460 and passed, and 15 laboratories used the ESP system with two not passing.

Test panels for the Johne's ELISA serology proficiency test were distributed in June, 2008, with 86 U.S. laboratories and 9 international laboratories participating (Canada, Chile, Netherlands, and Northern Ireland). With approximately 37 percent of all results being scored by October 15, 2008 using the z-score grading scheme, 95 percent of laboratories taking the Prionics ELISA panel received passing scores and 87 percent of laboratories taking the IDEXX ELISA panel passed. Final results and re-tests are scheduled to be released by October 31, 2008.

A milk ELISA proficiency panel was offered and distributed for the first time in June 2008. A total of 36 laboratories participated in this panel, with all laboratories receiving a passing score.

Committee Business:

During Committee business session, two resolutions were taken under consideration, amended, approved and sent to the Committee on Nominations and Resolutions.

Report of the Committee on Johne's Disease

NATIONAL JOHNE'S DISEASE CONTROL PROGRAM STRATEGIC PLAN

Dr. Andy Schwartz
Committee on Johne's Disease, Chair

Johne's Disease Strategic Plan Subcommittee
October 23, 2008

Introduction

The Johne 's Disease Strategic Planning Subcommittee met on March 13 and 14, 2008 in Chicago to update the previous strategic plan dated July 2004. The group considered how the program is doing and what should change over the next five years to most effectively address Johne 's disease. For a glimpse into the group's thinking that led to this plan see Appendix A: *Results of the Strategic Planning Subcommittee Questionnaire.* A draft from that meeting was previewed at the National Johne's Working Group meeting at the National Institute of Animal Health (NIAA) Annual Meeting, April 2008. That draft was widely distributed to industry, academia, and government for comment. The result is this Strategic Plan designed to prevent and control Johne's disease in a world where Federal and State government agriculture budgets are shrinking and primary attention is on program animal diseases which does not include Johne's disease.

With this plan, the program would evolve in several important ways:

1. Moving from a primarily Federal/State program to one that becomes more of a public/private partnership. As the possible connection of Johne's disease to human health remains unresolved and federal and state funding shrinks it is important that industry becomes a stronger partner.
2. Updating the herd classification system while continuing to recognize lowest risk/prevalence herds.
3. Making formerly required program components voluntary and making them more useful and more readily available.
4. Focusing educational efforts on producers and professionals (e.g. veterinarians and herd management consultants) that can help prevent and control Johne's disease.
5. Focusing research on control and prevention of Johne's disease with the highest priorities given to improving diagnostic tests, control strategies and vaccines
6. Marketing this new approach for controlling and preventing Johne's disease
7. Changing roles because of this new approach. See Appendix B: Redefined roles and responsibilities.

Note that Johne's disease is a contagious, chronic, essentially untreatable bacterial infection that primarily affects the small intestine of ruminants that can cause death due to dehydration and emaciation. Cattle affected by Johne's disease are often culled given their poor condition. For a brief history of the national program see Appendix C.

Overall Goal and Measures

Goal:

Through a public/private partnership, increase the availability of effective tools to reduce:

- the prevalence of MAP/Johne's in the national herd
- the impact of Johne's disease on individual farms
- the risk of introducing Johne's disease to uninfected herds

Valuable tools include:

- more useful risk assessments and herd management plans
- faster, more accurate diagnostic tests and procedures including those that can detect the causal agent at a younger age in cattle and expanded for use with other species.
- validated prevention and disease management/control practices
- safe and effective vaccines, including those currently available and newly developed safer vaccine delivery systems and procedures

Suggested Measures:

- survey of producers to determine adoption of recommended tools
- monitor the disease prevalence
- develop other measures based on need and practicality

Strategies

There are four strategies needed to accomplish the overall goal:

1. Focus educational efforts on demonstrating potential economic and biosecurity benefits of prevention and control of Johne's disease.

2. Focus research efforts on control and prevention of Johne's disease.
3. Update the classification system while continuing to recognize lowest risk/prevalence herds.
4. Make herd assessment and management tools readily available and encourage their use.
5. Develop a coordinated public-private communication plan to market and deliver the updated strategies

Strategy Details

1. **Focus educational efforts on demonstrating potential economic and biosecurity benefits of prevention and control of Johne's disease.**
    a. Evaluate potential improvements in content and delivery methods for veterinarians and producers. Expand efforts to make materials available for:
        i. producers
        ii. veterinarians
        iii. industry consultants (e.g. nutrition and management specialists)
        iv. service providers (e.g. Dairy Herd Improvement Association (DHIA) Technicians and milk procurement field staff)
        v. extension agents
    b. Expand awareness and use of existing online resources such as the veterinarian certification and producer education modules such as those available at the University of Wisconsin-Madison: http://www.vetmedce.org/index.pl?op-show:id=133363
    c. Coordinate educational efforts through the National Johne's Working Group:
        i. utilize surveys of producers, veterinarians and other influencers to identify additional information needs and preferred delivery methods
        ii. develop tools to educate producers on the economic costs of low and high prevalence Johne's disease.
        iii. work with the Johne's Disease Integrated Program to transfer research findings into producer friendly publications
        iv. create educational articles through the Johne's Education Initiative. Articles may be written to allow for the addition of local success stories and where to get assistance with testing and education.
    d. Prioritize federal, state, and private funding for development and production of educational materials.
2. **Focus research efforts on control and prevention of Johne's disease.** It is important for the research community and program efforts to be more coordinated**.** Priority research needs to be on rapid, more accurate, easier to use diagnostics; more effective and safer vaccines; documentation of the economic costs of the disease; and identification of more effective management tools.
    a. Diagnostics
        i. development of Johne's disease diagnostic tests that:
            - are appropriate for small ruminants, cervids and camelids in addition to cattle
            - in the longer term, are able to detect the disease in younger animals
            - provide rapid, more accurate tests that focus on:
                a. better cell-mediated immunity (CMI) tests and improved antigens
                b. fewer *M. bovis* cross reactions
                c. bulk tank testing – quantitative ELISA milk test
                d. environmental sampling protocols for dairy and beef
        ii. development of tuberculosis (TB) diagnostic or testing procedures that do not cross-react with the Johne's vaccine(s)
    b. Vaccines
        i. evaluation of the current vaccine
        ii. development and validation of improved vaccines that provide:
            - less shedding
            - fewer side effects (abscesses, etc.)
            - reduced cross-reactivity with the TB test
            - improved ease of use
            - improved safety when administering the vaccine
    c. Economic impact
        i. quantify the costs/benefits of recommended management practices
        ii. make data and cost analysis and management practice recommendation tools available to consultants who work with producers

iii. work with DHIA to include these analysis and recommendation tools into their system and utilize data from the records system to further enhance the tools

d. Management practices that help control the disease and provide economic benefit for the livestock owner
   i. focus on specific critical goals of demonstration herds and complete that effort
   ii. emphasize analysis of data from existing studies (demonstration herds and other field studies)

e. Other concerns:
   i. ARS basic research needs to continue.
   ii. JDIP is an important conduit for research work being funded through Cooperative State Research, Education, and Extension Services (CSREES). JDIP seems to work and needs to continue with its research and outreach efforts. Efforts also need to be made to assure that results form other publicly funded research are available to the program.
   iii. funding:
      - federal funding would be available for field studies to support and evaluate prevention and control programs
      - funding can be leveraged from JDIP/CSREES, ARS, diagnostic companies and other industry partners

3. **Update the classification system while continuing to recognize lowest risk/prevalence herds.** The classification system will be scientifically sound, address differences in herd size and will encourage all susceptible animal species to participate.
   a. Recognize lowest risk/prevalence herds using a classification that is similar in rigor to the current Level 4 of the current test negative program.
   b. Maintain performance standards for lowest risk/prevalence herds.
   c. Recognize progress for other herds:
      i. states can use a modification of the current herd classification system, an approach similar to the Concept Paper dated March 7, 2008 titled Herd Testing Strategies to Achieve Classification Levels or another approach
      ii. producers currently enrolled in the program would be eligible to continue in a revised system

4. **Make herd assessment and management tools readily available and encourage rather than require their use.**
   a. Develop additional new tools as needed and make all tools available to help producers assess herd status and progress
   b. Risk assessments (RA) and Herd Management Plans (HMP)
      i. RA and HMPs conducted by a third party would be required only for newly enrolled herds.
      ii. for renewals:
         - templates would be available to producers for free as self assessment tool
         - livestock owners may be assessed a fee if the RA or HMP are completed with the help of a third party such as veterinarians, industry groups, extension personnel or government officials
         - the renewal process, including renewal form, would be simplified
   c. Eventually phase out current Johne's Program HMPs in favor of implementing good management practices that are part of overall herd health, quality assurance or bio-security programs:
      i. Information about the specific good management practices that affect the prevalence of Johne's disease would be readily available to:
         - producers
         - veterinarians
         - extension specialists and agents
         - industry-based advisors, consultants and service providers
         - quality assurance programs would be encouraged to incorporate good management practices for Johne's disease prevention and control
   d. Make diagnostic tests readily available
      i. the tests would be available through approved State and private labs
      ii. USDA APHIS-VS-NVS maintains responsibility for certifying labs and validating tests
   e. Make vaccine and safe vaccine delivery systems readily available
      i. widespread use of vaccines requires research, development and availability of vaccines that are more acceptable nationally and without the cross-reactivity with *M. bovis*

ii. as improved vaccine and vaccine delivery systems become available, there will be a need for APHIS to validate them and to work with states to make vaccination legal

f. Funding availability – funds for RA, HMP, and testing may be available depending on federal and state funding and priorities

5. Develop a coordinated public-private communication plan to market and deliver the updated program and strategies.

a. Look for ways to build market incentives for achieving the lowest levels of risk/prevalence
b. Develop public-private communication and marketing plan
    i. include clear consistent messages
    ii. emphasize a unified message about the newly simplified program and its benefits
    iii. clarify any changes that may occur in the herd classification system
c. Present to industry groups at the NIAA, USAHA, American Dairy Science Association (ADSA), American Society of Animal Science (ASAS), American Association of Bovine Practitioners (AABP) and industry meetings.
d. Use industry publications and newsletters to get the word out about the program and why it is important to change the approach to a simplified, public/private cooperative program.
e. Have the standards committee revise the standards to align with the concepts in this plan
f. Make sure the existing participants in the program are grandfathered into the new program
    i. develop a funding mechanism for both the public and private components of the public-private partnership including possibilities of matching funds and leveraging existing funding

NATIONAL JOHNE'S DISEASE CONTROL PROGRAM STRATEGIC PLAN
Appendix A: Results of the Strategic Planning Subcommittee Questionnaire

Introduction
At the 2007 USAHA Annual Meeting, a resolution was passed to establish a SubCommittee of the Committee on Johne's Disease to revise and update the National Johne's Disease Control Program strategic plan for the next five years. As a way to begin working on the revised strategic plan, each member of the subcommittee was sent a questionnaire that contained the questions listed below. The Subcommittee members' answers were compiled as shown below. This document was used as a way to focus the discussion as the subcommittee began its work.

What have been the 3 most successful aspects of the National Johne's Disease Control Program since 2004?
- increased education and resulting awareness and knowledge about the disease and steps to take to control it (14/14)
- improving infrastructure (14/14)
- improved results (4/14)
- improved diagnostics (3/14)

What have been the 3 least successful aspects of the National Johne's Disease Control Program since 2004?
- funding: decreases, non-sustainable, inequity (9/14)
- education and marketing (6/14)
- cumbersome program (6/14)
- diagnostics: Still need fast accurate test (4/14)
- poor participation (4/14)
- industry support (4/14)
- lack of consistency (2/14)
- miscellaneous (6/14): cattle only, not responsive, demo herds, government run, little effect

Should the next 5 year goal of the National Johne's Disease Control Program to decrease prevalence or elimination?
- reduction in prevalence (11/14)
- elimination (0/14)
- both reduction of prevalence generally and elimination of infection when achievable (3/14)

How can the National Johne's Disease Control Program operate successfully with declining funding from USDA?
- use funds more efficiently by making changes to the program:
  - cull heavy shedders ASAP
  - pool fecal cultures
  - encourage more use of the Johne's Vaccine
  - list status herds on web site so they become known as low risk heifers
  - use our current funding more efficiently
  - provide standardized fee
  - shorten/simplify the RA-HMP for renewals
  - provide a lower fee
  - only those who implement management changes allowed subsidized testing
  - require Monensin feeding
  - develop a support organization to help inform congress about the importance of Johne's disease to the cattle industry today
  - test only those herds that are closed
  - change roles of APHIS and States and producer organizations
  - develop improved information
  - use of milk ELISA for testing through DHIA milk testing laboratories
  - use of environmental fecal testing for herd detection of infected dairy herds
  - research funding should focus on research to develop an accurate young animal test
- raise awareness/Educate producers (6/14)

- industry helps with funding (5/14)
- combine with other biosecurity/quality assurance programs (3/14)
- create program that is more market driven (2/14)
- show link to Crohns disease (2/14)
- miscellaneous comments (3/14): Lobby states and federal legislatures for funding, matching state funds to gain federal funds, federal funding going down

What should be the role of each group in the National Johne's Disease Control Program?

Industry
- promotion (7/14)
- design and set direction (5/14)
- help create market incentives/disincentives (5/14)
- funding (4/14)
- partnering (3/14)
- education (2/14)
- lobbying (1/14)

States
- implementation, administration and oversight (11/14)
- support (4/14)
- education (3/14)
- questions about whether States can or should be involved (3/14)
- cost sharing (1/14)

Federal
- funding (9/14)
- national coordination for program consistency (7/14)
- general administration, structure and guidance (5/14)
- support lab work (2/14)
- support training programs for vets and producers (1/14)
- facilitate a market driven program that offers incentives for Johne's free milk and beef (1/14)

Research
- generally work to improve program (8/14)
- improve diagnostic tests (6/14)
- focus on management, control and elimination protocols (5/14)
- improve vaccines (3/14)
- economics (2/14)

Extension
- education (14/14)
- intertwine Johne's with other management programs (1/14)

DHIA technicians (added group)
- encourage participation/inform about detriments of Johne's disease (1/14)

What should be the research priorities?
- more accurate, more sensitive and less costly diagnostics, especially for young animals (12/14)
- improved vaccine, especially one that does not interfere with TB tests (9/14)
- show and document the economic impact of Johne's on producers (including beef); give them tools to define costs for their operations (7/14)
- learn more about the disease, transmission and control (including management practices) (4/14)
- set up demo herds, analyze data from them and wrap them up with usable data on effectiveness of current strategies (3/14)

- miscellaneous comments (6/14): risk/reward analysis, food safety and public health implications; cattle and wildlife vectors and transmission; genetic susceptibility and resistance; Identification of super-shedders; identify genetically low risk cattle for Johne's disease (1 each)

What should be the Johne's disease producer education and outreach priorities?

- get the word out about the disease and control strategies (8/14)
- provide more data about the economics of the disease (7/14)
- promote the program with a steady, consistent flow of information especially success stories (5/14)
- encourage use of/explain best ways to use diagnostics (2/14)
- get information about the demo herds out (2/14)
- make program part of other risk assessment/quality assurance or biosecurity programs (2/14)
- miscellaneous comments (3/14): Opportunities for producer to question "experts;" producer input into research priorities; Bring tools to determine cost of disease and benefit of management to the industry

How can current program participants be encouraged to remain active in the program?

- create incentives (9/14)
- modify the program to simplify and add flexibility (8/14)
- educate producers about the impacts of the disease (7/14)
- continue funding/increase subsidies (2/14)
- add a select number of actual working participants (producers) to the Johne's Working Group – there the people on the front lines feeling the actual economic impacts of the disease

How can producer participation be enhanced?

- education and promotion (6/14)
- simplify program and add flexibility (5/14)
- create incentives (5/14)
- move Johne's to broader herd plans and quality assurance (3/14)
- involve industry organizations more (2/14)
- maybe use program funds to pay for testing breeding animals, if the sale managers agree to advertise all animals are tested (1/14)
- add other species to program (1/14)

How should program activities and results be monitored to assess program success including accounting for producers participating in other Johne's disease control efforts?

- some form of testing (5/14)
- use surveys (5/14)
- don't use national databases (2/14)
- monitoring will be difficult because of funding and the fact that this is a voluntary program (2/14)
- miscellaneous ideas—number of samples, counting presentations and articles, auditing herds, use conference calls (4/14)

NATIONAL JOHNE'S DISEASE CONTROL PROGRAM STRATEGIC PLAN
Appendix B: Redefined roles and responsibilities

1. Industry
    a. Develop and implement a plan for future administration and funding of the program. The herd classification program would have different aspects based on different interests.
        i. DHIA: Johne's laboratory services with appropriate disease data collected, stored, analyzed and managed as part of their herd management services. Work with researchers to include Johne's evaluation and management tools in their program offerings.
        ii. breed associations: program adoption of recommended management practices, program participation and assist by encouraging marketing breed stock.
        iii. dairy coops: educate producers, market and encourage members to participate in the program.
        iv. producers: change management approaches using tools to prevent and control Johne's disease and provide feedback on the practices and the program.
    b. For the leadership to be effective there needs to be an identified champion from each industry (animal species) who ideally has access to marketing and publication tools.
    c. Specific groups within the industries are in the position to make research findings and other educational information available to producers. These include dairy cooperatives and allied industries such as veterinarians, producer consultants and service providers such as DHIA.
    d. Work with Federal/State government to develop a coordinated communication and marketing plan to explain the value of the program and the plans for transition from a Federal/State program to a public/private program.
    e. Allied industries such as veterinarians, cooperative field staff, and other respected producer consultants would be in a key position to help distribute information about the disease, diagnostics, prevention and management/control (including vaccination) to the producer in the form of help with assessing herd risks and planning for maximum herd health and performance (includes current or improved risk assessments (RA) and herd management plans (HMP)). Veterinarians will help with vaccination where it is determined to be an appropriate tool.
    f. Milk cooperatives will help with education and marketing of the program.
    g. Producers will use the tools available to reduce the effects of Johne's disease, providing feedback on the use and implementation of these tools. They may pay herd classification participation, testing, vaccines and other services and products as needed. Program funds may be available based on Federal and State funding and priorities.
    h. Industry consultants and service providers (e.g. DHIA) would incorporate Johne's test data into herd management analysis and recommendations. This is a particularly powerful lever for change when the producer trusts and uses the data, analysis and recommendations provided. Develop measures to assess program value and effectiveness.
2. State
    a. Assist with transition of the program to industry with their continued participation based on the level of their individual State funding and priorities.
    b. Assist in rewriting the Uniform Program Standards for the Voluntary Bovine Johne's Disease Control Program (VBJDCP) and any needed modifications to state regulations.
    c. Field personnel, including current Designated Johne's Coordinators (DJC) and others, would be available to help with risk assessments and herd management plans as well as low risk herd classification for a fee if requested.
    d. Diagnostic laboratories will maintain their Johne's test certification from NVSL and be available for the testing needed for low risk herd certification. Producers may pay market costs, though subsidies may be available at some level as long as the APHIS-VS appropriation stays above the base.
3. Universities
    a. Assist with research that may be funded through USDA and coordinated by the Johne's Disease Integrated Program.
    b. Assist in outreach education particularly through Cooperative Extension.
    c. Serve as NVSL-accredited laboratories for diagnostic testing.
4. Federal
    a. Basic APHIS-VS role:
        i. NVSL: laboratory certification, proficiency testing etc.

ii. Centers for Veterinary Biologics (CVB): licensure of biologic including diagnostics and vaccines.
iii. National Animal Health Monitoring System (NAHMS) would continue to include assessment of Johne's in future national studies.
iv. fund the national demonstration herd project to completion focusing on analysis of data and application of the findings.
v. collect and analyze data about the national program to assess progress.
vi. make continuing education available to veterinarians.
vii. help rewrite the program standards especially for the classification program.
viii. prioritize funding for:
    - creation and production of educational materials.
    - field studies. field veterinarians may be available to help with low risk herd classification for a fee if requested.
    - subsidize testing as long as the funding continues above the base amount
    - APHIS field personnel to deliver the Johne's program.

b. CSREES would fund research and extension functions. They would make educational materials available to extension agents.
c. A portion of the Johne's funding base could be used to help fund the measurement of the program as described above:
    i. survey producers to determine extent of use of tools and identify additional information needs.
    ii. sample those using tools to monitor changes in herd prevalence.
    iii. NAHMS studies can be one way to achieve the surveys described above.

NATIONAL JOHNE'S DISEASE CONTROL PROGRAM STRATEGIC PLAN
Appendix C: Recent history of the national program

In the fall of 1995, the United States Animal Health Association (USAHA) appointed the National Johne's Working Group (NJWG) to assist the Committee on Johne's Disease in developing a national, coordinated Johne's disease effort in conjunction with the States and cattle industries. The NJWG developed a strategic plan designed to reduce the prevalence of Johne's disease in U.S. cattle. That earlier version included a national educational campaign, the Voluntary Johne's Disease Herd Status Program for Cattle, and guidelines for States to assist infected herds. This national program was designed from the start to be producer driven and voluntary.

In 1996**,** a national study of U.S. dairies, Dairy NAHMS 96, found that approximately 22 percent of U.S. dairy farms sampled had at least 10 percent of the herd infected with Johne's disease. The study determined that infected herds experienced an annual financial loss. Small herds (<50 cows) lost an average of $178 per cow, while large herds (>500 cows) lost $181 per cow. This loss was due to reduced milk production, early culling, and poor conditioning at culling. The costs of Johne's disease in beef herds still need to be determined.

In 1998, the USAHA approved the Voluntary Johne's Disease Herd Status Program for Cattle (VJDHSP). The VJDHSP provides testing guidelines for States to use to identify cattle herds as low risk for Johne's disease infection. With numerous tests over several years, herds progress to higher status levels. The higher the status level, the more likely a herd is not infected with Johne's disease.

In April of 2002**,** USDA-Animal and Plant Health Inspection Services-APHIS Veterinary Service (VS) incorporated portions of this program into its national program standards: Uniform Program Standards for the Voluntary Bovine Johne's Disease Control Program (VBJDCP). VBJDCP test negative herds (often referred to as status herds) serve as a source of low Johne's disease risk replacement animals.

In June of 2004, the Committee on Johne's Disease formed an Strategic Planning Subcommittee. The group met June 15 through June 17, 2004 in Riverdale Maryland. The five objectives that were developed included as part of that revision were the following:

1. increase producer participation;
2. improve educational efforts;
3. close gaps in knowledge about Johne's disease;
4. improve reporting;
5. develop an eradication plan.

In March 2008, the Committee formed an ad-hoc Strategic Planning subcommittee. The group met to discuss changes that are needed to the program over the next five years.

REPORT OF THE NATIONAL JOHNE'S WORKING GROUP (NJWG)

Ken Olson

The NJWG met on Thursday afternoon October 23 and all day Friday October 24, 2008 during the USAHA Annual Meeting, Greensboro, North Carolina. The meeting was called to order at 1:00 pm. The meeting was Chaired by Scott Wells and Jamie Jonker. Approximately 75 members and guests attended the sessions.

Andy Schwartz provided an update on the APHIS-VS responses to the 2007 Resolutions.

- **Resolution 35** recommended that funding for the National Johne's Demonstration Herd Project be a priority. USDA APHIS VS responded that support was continued in FY 08 and that alternatives were being considered for FY 09 if full funding is not available.
- **Resolution 36** requested recognition of the milk ELISA test as an approved screening test for the program and that laboratories performing it pass an annual proficiency test. USDA-APHIS-VS responded that they would incorporate the milk ELISA into the Voluntary Bovine Johne's Disease Control Program (VBJDCP), that the National Veterinary Services Laboratory (NVSL) had developed and implemented a milk ELISA proficiency test that would be continued. The milk ELISA is to be added to the Uniform Program Standards in the next revision.
- **Resolution 37** requested that USDA APHIS VS provide financial and personnel support for development of a new Johne's Strategic Plan. USDA APHIS VS responded positively and provided support for conference calls, a planning meeting and personnel to assist in the process.
- **Resolution 38** requested that Quality Certification Services (QCS) and Designated Johne's Coordinator (DJC) approve Dairy Herd Improvement Association (DHIA) field personnel to collect and submit milk samples to approved laboratories for milk ELISA testing under the direction of the herd's Johne's certified veterinarian. USDA-APHIS-VS indicated that they will change current policy to allow QCS certified DHIA field personnel, who are approved by State Animal Health Officials to submit milk samples to approved laboratories for milk ELISA testing as part of the VBJDCP for herd classification.

NJWG treasurer, Ken Olson reported that the NJWG had an initial balance of 30,663.55, with no added income and expenses of $693.00 for past meetings leaving a balance of $29,970.55 as of August 29, 2008. The Johne's CD project included income of $93,078.28 and expenses of $71,140.28. The income from three major sources: $30,318.28 was the initial balance, Sponsors of the CD project, $27,000 and sales of Johne's CD ROMs for $37,909.00.

National Johne's Coordinator's Annual Report, Mike Carter reported a total of 8,818 herds in the VBJDCP at the end of 2007. It appears that the number of herds will decline in 2008, as will the number of tests run of all types but the milk ELISA where an increase is occurring. Program funding is under pressure. The Department is currently operating under a continuing resolution that maintains funding a last year's level; however, the proposed budget from the Administration is $3.3 million and the Senate version is $6.8 million that includes a $1 million earmark for Wisconsin, so it is uncertain where it will end up. APHIS-VS has funded several research projects including:

- National Johne's Demonstration Herd Project
- Small ruminant PCR validation project with NVSL
  - primarily preparing for National Animal Health Monitoring System (NAHMS) 2009 Goat study and to lay ground work for a national small ruminant classification program
- vaccine validation project
  - $500,000 3 year grant to JDIP
  - established to develop a coordinated validation protocol for the large number of mutant and attenuated vaccine candidates developed by U.S. researchers.

Anticipated future directions for the program included:

- change herd classification to eliminate references to disease freedom
  - will focus on probability that disease is less than a certain prevalence
  - more scientifically valid
- inclusion of milk ELISA as a screening test for the Test Negative Herd Classification component.
  - decision memo has been signed to allow DHIA field technicians to collect milk ELISA samples for herd classification
  - requires approval of State Animal Health Official

Johne's Disease (JD) Strategic Plan update and review, Jamie Jonker presented the proposed strategic plan that had been developed in response to action take at the last meeting. He thanked the group that worked on the plan, reviewed the process used in development of the proposed plan and key points included in the draft. He indicated that the primary focus for the meeting would be to finalize the proposal for presentation to the Committee.

Proposed JD Herd Classification, Scott Wells presented an overview of the Concept paper: Herd Testing Strategies to Achieve Classification Levels for the U.S. Voluntary Bovine Johne's Disease Control Program. The Voluntary Bovine Johne's Disease Control Program (VBJDCP) is central to USDA-APHIS-VS Johne's disease control efforts and has three main components: education, management, and herd classification. The goal of herd classification is to classify cattle herd risk for JD according to the risk of potential JD transmission. In 2006, the Committee recommended that USDA-APHIS-VS identify the most cost-efficient testing alternatives for detection of *Mycobacterium avium paratuberculosis* (*MAP*) in dairy and beef cattle herds at different levels of the program.

It had became apparent that in order to suggest cost-effective testing alternatives for the different levels of the program, defined targets for each level were needed. In reality the current program levels are defined by testing strategies, not by a risk characterization for the herds at each level.

In response to this identified need, this concept paper is an outline of recommendations for test strategies for classifying U.S. cattle herds by risk level for the national VBJDCP. The recommendations are based on review of scientific literature, data analysis, and discussions by a team of experts in the fields of epidemiology, diagnostics, and cattle management systems (SJ Wells, University of Minnesota; IA Gardner, University of California-Davis; CP Fossler, USDA-APHIS-VS CEAH; AJ Roussel, Texas A&M University; S Tavornpanich, Thailand International Animal Health Affairs).

The concept applied in development of JD Herd Test Strategies is to classify herds by maximum true within-herd prevalence of JD. The proposed categories are based on statistical probabilities, to assure that the upper 95 percent confidence limit for true within-herd prevalence is below the specified values for the respective level. The NJWG recommended that the Program Standards Committee develop a plan for implementation incorporating the principles of this concept paper for consideration by the group at their fall 2009 meeting.

Open discussion. Ideas/thoughts on JD Strategic Plan, Ken Waters facilitated discussion related to the proposed Johne's Strategic Plan and the Herd Classification concept paper. After initial instructions those present divided into groups of approximately 4 to 6 for in depth discussion. Each group provided brief oral report and a written summary of their responses to questions on each item. These were collected, summarized by Ken Waters and returned to the group for their use in the Friday discussion.

The meeting was adjourned for the evening, and continued on Friday, October 24, 2008.

JDIP Update - Vaccine, Diagnostics, Ken Olson opened by sharing brief comments on the report from the American Academy of Microbiologist (AAM) as an indication of the reason that we need to continue to push forward to address JD at the farm even if there are funding and other challenges. He reported that the JDIP/APHIS Vaccine Project is underway with vaccine candidates being solicited. Two laboratories will screen candidates through an in vitro process. The best candidates from this evaluation will move forward for testing through a mouse model. The best candidates identified here will be evaluated through a goat model. It is expected that one or more candidates will be identified for commercial development. The total time line is three years. A project to develop guidelines for evaluation of diagnostic testes is in its preliminary stages. National Research Initiative (NRI) funding will be sought. It is anticipated that the process will provide a way to compare tests across populations. JDIP is also working with USDA APHIS VS in an effort to document impacts of the Johne's program that are not captured in current reporting. DJC's, extension and industry are being surveyed to obtain information that will be summarized for program use. It was also noted that the International Colloquium that will be held August 9-14, 2009 at the University of Minnesota will include a one-day workshop targeted at veterinarians and producers that highlights field application of Johne's research. The JDIP Year 5 Request for Applicants (RFA) is available on www.jdip.org

JD Vaccination Clinical Trial Update, Beth Patton reported on the Wisconsin project that involves three of their demonstration herds. It includes a total 148 vaccinated animals and 120 controls. Comparisons are being done on a within herd basis. Preliminary results show:

- overall decrease in whole herd prevalence
- 46 percent lower infection prevalence in vaccinates; (p= 0.03 pooled data)
- lower levels of shedding in vaccinates (p=0.02)
- significantly fewer clinical cases in vaccinates (p=0.01)

Observations included:

- strong evidence current vaccines will aid in control
- new vaccine candidates include DNA, subunit and mutant vaccines
- goals for new vaccine candidates include that they will:
  - maintain efficacy
  - reduce side effects

NVSL Update - Need for ELISA moderate positive control, Beth Harris reported on work at NVSL to provide low to moderate shedder positive control samples. This is in response to recommendations of the Scientific Advisory Subcommittee and the Committee. Moderate shedding cows have been identified and the processes to be used defined. Laboratories may sign up to participate through March 2009. Results will be provided to laboratories and the SAC by October 2009 for further consideration.

Nevena Djuranovic reported on a new IDEXX Pourquier *M.pt.* Ab ELISA kit that will replace the IDEXX HerdChek* *M.pt.* Ab ELISA test kit. It is currently in the USDA licensing process for use on bovine serum, milk and plasma samples. It is approved for use in several other countries.

Ernest Hovingh reported preliminary results from the VS Dairy Producer Survey. Surveys were sent to approximately 15 percent of the dairy producers in each state. Response to the survey was good with over a 25 percent response rate. Demographics of the respondents are very similar to the national population. Interestingly the open on-line survey received minimal responses and most of those who received the survey chose to respond with the paper rather than the electronic version. Results showed generally good knowledge of the disease, but surprisingly 30 percent of the respondents did not know if their state had a program. Financial incentives were a positive, but concern over disease in their herd now and in the future was also a driving force for participation. Respondents indicated a willingness to pay more for low risk animals and to keep their herd free of Johne's. They did feel that the value of both replacements and culls were reduced in Johne's positive herds. Additional results will be available in the near future.

Chuck Fossler reported on the National JD Demonstration Herd Project. A total of 61 dairy and 21 beef herds are in the project. At the end of 2008, there will be five years of prevalence data on most herds. This will begin to allow evaluation of the incidence in cattle born in the 1st and 2nd years of participation. It was noted that for incidence analysis, many of the principal investigators recommend following herds for at least 7-8 years. There is still a need to examine the association between management practices and MAP. Preliminary results suggest that prevalence has decreased in participating herds since start of project and that producer efforts have been effective in reducing incidence of Johne's disease in younger cattle. Further work is needed to identify factors that have the greatest effect on incidence and prevalence. It is still early in analysis. Incidence results so far represent only half of participating dairy herds because 4 years of data were necessary. This means that current results are limited to cattle born during first year of participation—cattle born in subsequent years could not yet be included.

Jason Lombard presented results from the NAHMS Dairy 2007. States included in the study include approximately 80 percent of the dairy cows and herds in the country. The study did find that 68.1 percent of the herds sampled were positive. Other conclusion reported included:

- JD educational programs are working. This is demonstrated by
  - producer familiarity with the disease
  - implementation of control practices
- Herd-level prevalence is higher than commonly reported
  - this impacts the testing strategy and method that may be suggested
  - high Cow-level specificity (Sp) and moderate Cow-level sensitivity (Se) impact results
  - it is difficult to make comparisons because different analysis have been used, so can't ascertain national trends
- Bulk milk testing looks promising as herd screening tool

Additional results are available at http://nahms.aphis.usda.gov/dairy/index.htm

Roxanne Pillars reported on results obtained from the Michigan Johne's Demonstration herds on Economics of JD Control. Their objective was to determine if implementing a JD control program is economically feasible. Costs were obtained from an economic questionnaire administered annually starting in 2004. They sought to assess costs directly attributable to Johne's Control Program. They fell into four categories: supplies; management; labor and capital investment. Benefits came from milk production, future production (or retention pay off (RPO)) and cull income. Four different NPV Scenarios were calculated that represent

1. losses decline linearly with JD eradication after 20 years
2. losses and prevalence remain constant after last year of study while still investing in control program
3. no control – losses increase at rate equal to that in 1
4. no control – losses remain constant at baseline level

They found annual economic losses due to JD had a mean: of $79/cow; median of $66/cow and ranged from $16 to $243/cow. Annual cost of JD control program (without actual laboratory costs) had a mean of $30/cow, a median of $24/cow and ranged from $6 to $81/cow. They reported that all producers were satisfied with JD control program and plan to continue to invest in it after end of study. On average, the cost of JD control program was less than economic losses caused by the disease and JD control programs can be cost effective. Doing something to control JD was always a better economic decision than doing nothing

Ken Waters led the remainder of the session in a review of the comments generated the previous day and in further discussion of the strategic plan.

Actions taken by the NJWG include:

- accept the Strategic Plan and submit it to the Committee, which passed unanimously
- The Committee should submit a Resolution encouraging USDA to continue funding support for the Johne's Disease Demonstration Herds through year 8 (up to three additional years) – passed unanimously
- Submit the concept paper, Herd Testing Strategies to Achieve Classification Levels for the U.S. Voluntary Bovine Johne's Disease Control Program, to the Program Standards Subcommittee to develop a plan for implementation - passed 14 to 8
- Recommended a task force to review programs that may work for producers who do not want to participate in state/federal program – 7 to 7 with 4 abstentions – result was no action.