UNITED STATES ANIMAL HEALTH ASSOCIATION - 2005

RESOLUTION: **20 APPROVED**

SOURCE: COMMITTEE ON JOHNE'S DISEASE

SUBJECT MATTER: PRODUCTION OF JOHNIN PURIFIED PROTEIN DERIVATIVES AT THE NATIONAL VETERINARY SERVICES LABORATORIES

DATES: Hershey, Pennsylvania – November 3-9, 2005

BACKGROUND INFORMATION:

Tests that measure cell-mediated immunity, such as the intradermal skin test and the interferon-gamma assay, are beneficial for the detection of early stage paratuberculosis infection. Antigen preparations utilized in these assays have traditionally been Johnin purified protein derivatives (PPD). However, production of Johnin PPDs in the United States has resulted in inconsistent products. Diagnostic labs and researchers are hampered by the lack of well-characterized Johnin PPDs for use in these assays.

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), National Veterinary Services Laboratories (NVSL) 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:

ANIMAL AND PLANT HEALTH INSPECTION SERVICE, VETERINARY SERVICES (APHIS-VS)

The United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS), Veterinary Services (VS), National Veterinary Services Laboratories (NVSL), Brucella and Mycobacterium Reagents Team (BMRT) is currently working with the Agriculture Research Service (ARS), National Animal Disease Center (NADC) and APHIS field veterinarians on monitoring the Johne's Demonstration Herds to evaluate Johnin PPD production methods. There are several variables involved in the production process that may affect the diagnostic sensitivity and specificity of the product in sheep and cattle, and the NVSL is working towards defining an optimal and repeatable Johnin PPD production method. The BMRT is currently raising cultures of Mycobacterium avium paratuberculosis that will be used to create 3 to 4 experimental batches of Johnin PPD. The method of culture growth and the method of Johnin PPD production will be closely monitored and recorded. Each of the PPD products will be evaluated in the laboratory setting as well as within sheep and cattle – with the help of NADC, other Johne's research laboratories, and the Johne's Demonstration Herds. Once an optimal experimental Johnin PPD product is identified, the BMRT will use the same production method in multiple batches of Johnin PPD. The entire process for evaluating and optimizing the Johnin PPD production method is hindered by the slow growth rate of the Mycobacterium spp. of bacteria and the time needed to compare skin test results in animals to culture results from those animals as a measure of true infection status. The BMRT is estimating that this validation process may take at least 18-24 months before a final production method is identified and proven to be reproducible.

At the current time, NVSL has not received funding to support this Johnin PPD production project, and as a result, we rely on the collaboration with other research groups to provide data on the performance of the PPD products in animals. The data that is generated must be reviewed by the APHIS Johne's Disease Control Program Staff to determine if a Johnin PPD product would be a valuable diagnostic tool within the Johne's Disease Control Program. If the APHIS Johne's Disease Control Program Staff decides to incorporate the use of a Johnin PPD into the program standards, the NVSL will at that time seek funding to produce the Johnin PPD product.