UNITED STATES ANIMAL HEALTH ASSOCIATION
2016 Resolution
120th Annual Meeting
October 13-19, 2016 ~ Greensboro, NC

RESOLUTION NUMBER: 38 **APPROVED**

SOURCE: **COMMITTEE ON TUBERCULOSIS**

SUBJECT MATTER: **Optimization and Standardization of Purified Protein Derivative Tuberculin Application for Interferon-gamma Release Assays**

BACKGROUND INFORMATION:

Infection with *Mycobacterium bovis* (*M. bovis*) continues to impact the United States cattle industry with a significant number of tuberculosis (TB) infected herds detected in different states in 2016. The caudal fold tuberculin (CFT) test is the primary screening test used in the bovine TB program. A major disadvantage of this test is that it requires cattle to be handled twice, once for the injection and a second time to interpret the test. Further, the person performing the test must also be adequately trained and sufficiently experienced to interpret the test results accurately. Experience is critical; determining a "response" may be subjective, especially if the response to the injection is weak. Test result accuracy may also depend on the purified protein derivative (PPD) tuberculin which is applied. Current regulation allows a range of potency as prescribed in the respective regulation of Title 9 Code of Federal Regulations (CFR) 113.409(c).

Currently used antibody tests demonstrate poor specificity resulting in too many false negative test results leading to undetected reactors remaining in the herd. In addition, antibody test can interfere with the caudal fold test.

BOVIGAM™ is one official auxiliary test used in cattle herds with the approval of the State Animal Health Official and United States Department of Agriculture, Animal and Plant Health Inspection Service, Veterinary Services, National Import Export Services Service Centers. This test may be used under direction of the Designated TB Epidemiologist and with concurrence of the Regional TB Epidemiologist. BOVIGAM™ is an IFN-y release assay which is widely used in different national tuberculosis eradication programs world-wide. In 2015 OIE approved BOVIGAM™ for use as a primary test. Resolution 29/2014 recommends the use of BOVIGAM™ utilizing Lelystad PPD due to the improved sensitivity whereby specificity remains equivalent in comparison to PPD from CSL origin. However, test accuracy is dependent upon standardized and harmonized batch production of the applied PPD tuberculin for the stimulation of the whole blood samples.

An optimized and more standardized PPD tuberculin for IFN-y release assay applications should be developed to improve the national tuberculosis program which is urgently needed by the cattle industry.

RESOLUTION:

The United States Animal Health Association urges the United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS), Center for Veterinary Biologics (CVB) to work with USDA-APHIS Veterinary Services (VS) Cattle Health staff to optimize purified protein derivative tuberculin for interferon-gamma release assays and that the resulting product(s) be submitted to APHIS-VS-CVB for licensing purposes.