UNITED STATES ANIMAL HEALTH ASSOCIATION
2014 RESOLUTION
118TH ANNUAL MEETING
OCTOBER 16-22, 2014 ~ KANSAS CITY, MO

RESOLUTION NUMBER: **29** **APPROVED**

SOURCE: **COMMITTEE ON TUBERCULOSIS**

SUBJECT MATTER: **Approval of Lelystad Tuberculins for Use in the Bovigam® Assay**

BACKGROUND INFORMATION:

The Bovigam® assay is currently approved by the United States Department of Agriculture, Animal and Plant Health Inspection Service for the diagnosis of *Mycobacterium bovis* in cattle. The Bovigam assay is used as a confirmatory test for caudal fold test tuberculin responders. The assay currently uses CSL tuberculin.

The Tuberculosis Scientific Advisory Sub-Committee (TB SAS) recently reviewed documentation on field trial comparisons of CSL tuberculin and Lelystad tuberculin in the Bovigam® assay. The comparisons showed that the assay sensitivity in confirmed *M. bovis* infected cattle was 73.8% and 45.2% for Lelystad and CSL tuberculins, respectively. This difference was statistically significant. Assay specificity in presumed *M. bovis* negative cattle was 96.9% and 95.1%, respectively for Lelystad and CSL tuberculins. This difference was not statistically significant.

In 2012, the TB SAS also reviewed similar data that demonstrated increased sensitivity of the Bovigam® when Lelystad tuberculin was used compared to CSL tuberculin.

Conclusions of the 2014 report from the TB SAS indicated that it would be appropriate to use Lelystad tuberculins in the stimulation phase of the Bovigam® assay.

RESOLUTION:

The United States Animal Health Association requests the United States Department of Agriculture, Animal and Plant Health Inspection Service to license the Bovigam® assay so that Lelystad tuberculins may be used in the stimulation phase of the assay as part of official tuberculosis program procedures.

INTERIM RESPONSE:

The United States Department of Agriculture, Animal and Plant Health Inspection Service, Veterinary Services (VS) recognizes the concerns of the United States Animal Health Association and appreciates the opportunity to respond.

In order to proceed, the manufacturer must submit an application to the Center for Veterinary Biologics (CVB) for licensure. Once the application has been received, CVB will work with the manufacturer to expedite evaluation of the Lelystad tuberculins for use in the Bovigam assay. Concurrently, VS will review information about the performance of the Lelystad tuberculins in the Bovigam assay according to VS Memorandum 552.40, Evaluation of Tests Proposed for Official Use In the Bovine Tuberculosis Eradication Program. We can then issue a decision regarding official program use after the CVB evaluation for licensure is completed.