

# UNITED STATES ANIMAL HEALTH ASSOCIATION – 2004

**RESOLUTION NUMBER:** 15            **APPROVED**

**SOURCE:** COMMITTEE ON SHEEP AND GOATS

**SUBJECT MATTER:** *BRUCELLA OVIS* TESTING STANDARDIZATION

**DATES:** OCTOBER 27, 2004

## **BACKGROUND INFORMATION:**

Laboratories that are conducting *Brucella ovis* ELISA testing report that there are problems with both control sera and antigens produced and provided by National Veterinary Services Laboratory (NVSL). There have been many false-positive test results due to inconsistent quality of the control sera and antigens. While NVSL has been made aware of the problem regarding the quality of the reagents, staff has not communicated consistently with all of the laboratories that are affected. The false-positive test results have resulted in a lack of consumer confidence in testing which is a critical part of control programs. These testing problems pose risks to many major sheep-producing states that rely on valid test results for interstate movement.

## **RESOLUTION:**

The United States Animal Health Association (USAHA) recommends that the National Veterinary Services Laboratory (NVSL) provide a standardized *Brucella ovis* ELISA test. NVSL should also provide laboratory testing for this process.

## **RESPONSE:**

The Department of Agriculture, Animal and Plant Health Inspection Service, Veterinary Services, National Veterinary Services Laboratories (NVSL) has confirmed, through immunoblotting techniques, that there is a potency problem with the antigen used in the *B. ovis* ELISA, which is resulting in poor discrimination between positive and negative animals. A search of the literature indicates that newer methods of antigen production have led to acceptable antigens for other species of rough brucella. Preliminary ELISA work has verified that antigens produced by these newer methods perform better in tests with known positive and negative *B. ovis* antisera.

The OIE Manual of Standards for Diagnostic Tests and Vaccines also contains a well-tested, recommended *B. ovis* reference isolate for antigen production and one method for its use. NVSL is in the process of importing the reference strain from the National Institute for Agricultural Research (INRA) reference laboratory in Nouzilly, France. In the meantime, NVSL has begun the production of small lots of antigen from other antigenically similar rough brucella using several different extraction methods. We will evaluate the performance of the resulting antigens to determine which method is the most satisfactory. In addition to a change in antigen, there will probably be several other ELISA-specific technical changes to the *B. ovis* ELISA procedure.

Although the standardization and validation of the new system will not be completed for several months, a new and more functional antigen will be produced and function-tested, hopefully, within 90 days. Once a working antigen is produced, NVSL control sera can be better scrutinized to determine whether they are satisfactory or whether new ones will need to be produced to augment the anticipated increased sensitivity and specificity of the assay.