UNITED STATES ANIMAL HEALTH ASSOCIATION
Resolution
114th Annual Meeting ~ November 11-17, 2010
Minneapolis, MN

RESOLUTION NUMBER: 33 APPROVED AS AMENDED

SOURCE: COMMITTEE ON BIOLOGICS AND BIOTECHNOLOGY

SUBJECT MATTER: UPDATING ANTIQUATED TESTING REQUIREMENTS FOR ANIMALS USED IN THE PRODUCTION OF LICENSED SERUM ANTIBODY PRODUCTS

BACKGROUND INFORMATION:

Code of Federal Regulations (CFR) Chapter 9, 113.450 details the general requirements for antibody products. In part (c) Animals, it states that "all animals used in the manufacturing of antibody products shall be individually subjected to applicable tests for infectious diseases". Specifically, donor horses will be tested for equine infectious anemia (EIA), piroplasmosis, dourine, glanders and brucellosis upon arrival and again annually for EIA and brucellosis (if "housed" with other species). Donor cattle will be tested for brucellosis and tuberculosis upon arrival and annually. These test requirements have been in place for decades without any amendment. For many years, dourine and glanders have been eradicated from the United States (US) and are therefore classified as foreign animal diseases. *Brucella abortus* has been eradicated in the US except for the Greater Yellowstone Area. For this reason, some laboratories are now charging for brucellosis testing. There have been recent outbreaks of piroplasmosis and tuberculosis in different parts of the United States. There have been efforts by the United States Department of Agriculture (USDA) and private industry to improve tuberculosis (TB) testing in recent years to eliminate false positives. Gamma interferon testing has proven to be a very reliable confirmatory test for TB suspect animals in recent outbreaks (presentation/report - TB committee, 2010 United States Animal Health Association). The percentage of test-positive EIA samples in the United States has decreased dramatically from nearly 4 percent in 1972 to less than 0.01 percent in 1998. EIA prevalence in the United States is estimated to be less than 8:100,000 (USDA, Animal and Plant Health Inspection Service (APHIS), Veterinary Services (VS) info sheet, Sept. 2006). Required pasteurization of equine serum products at 58-59º C for 60 minutes (9-CFR.450 (e) 1) will also inactivate any blood born EIA virus. Brucellosis in horses causes fistulous withers and with the effective eradication program in domestic bovines it is now virtually eradicated in equine (last confirmed US case in equine was many years ago).

Problems encountered by firms with animals tested include: 1.) Cost ($72/head for dourine, glanders, piroplasmosis at the National Veterinary Services Laboratory. $6/head for EIA and $4/head for *Brucella* (RMRAHL). 2.) False positives (infrequent with EIA, common with TB, *Brucella,* and occasionally with glanders and dourine). Ramifications from false positives can result in a log jam in quarantine pens for new arrivals. TB false positive incidence seems to increase with time in hyperimmunized production animals that have never left a plant site. This results in multiple visits and re-tests by USDA-APHIS veterinarians and, in some cases, removal of valuable production animals that have to be slaughtered only for the Veterinary Medical Officer to confirm at NVSL that there are no TB lesions. During these times animal movement on or off the plant can also be affected. TB testing should only be necessary for incoming donor animals and not repeated every year thereafter if they never leave the premises (unless sold or

dead). 3.) Brucella testing steers and horses. This should not be necessary for castrated cattle or horses and at a minimum should possibly only be required upon arrival, especially if these animals originate from a *Brucella* class free state. Re-testing steer and horses every year that never leave the premises unless sold or dead makes no sense. 4.) Why is there a continued need to test horses for dourine and glanders considering that these diseases have not been reported in the United States for many years?

RESOLUTION:

The United States Animal Health Association (USAHA) requests that United States Department of Agriculture, Animal and Plant Health Inspection Service, Veterinary Services update regulations regarding testing for infectious diseases in serum antibody production animals in 9-CFR 113.450 in order to eliminate unnecessary and costly testing. USAHA requests: 1) That testing for dourine and glanders for incoming horses no longer be required for United States origin horses, 2) That annual tuberculosis (TB) testing for donor cattle no longer be required after an initial negative test upon arrival, if the animal originates from a TB-free area and never leaves the premises, and 3) That initial and annual *Brucella* testing in steers and horses be discontinued as a requirement, especially if these animals originate from a *Brucella*-free classified state.

INTERIM RESPONSE:
The U.S. Department of Agriculture, Animal and Plant Health Inspection Service (APHIS), Veterinary Services (VS) appreciates the concerns of the United States Animal Health Association regarding eliminating unnecessary testing in serum antibody production animals. APHIS has reviewed the concerns expressed in the resolution and largely agrees with those concerns. VS' Center for Veterinary Biologics plans to publish a notice that provides new guidance to the industry regarding testing requirements for animals used in the production of serum and antibody products. In the interim, we will work with manufacturers on an individual basis to address their specific concerns.

FINAL RESPONSE:
The U.S. Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS), Veterinary Services (VS) recognizes the concerns of the United States Animal Health Association (USAHA) and appreciates the opportunity to respond.

USDA APHIS VS Center for Veterinary Biologics is currently drafting a document to provide new guidance to industry regarding testing requirements for animals used in the production of serum and antibody products. In the interim, VS will work with manufacturers on an individual basis to address their specific concerns.