UNITED STATES ANIMAL HEALTH ASSOCIATION - 2005

RESOLUTION: **41 APPROVED**

SOURCE: COMMITTEE ON FOREIGN AND EMERGING ANIMAL DISEASES

SUBJECT MATTER: DEVELOPMENT AND IMPLEMENTATION OF RAPID MILK POLYMERASE CHAIN REACTION TESTING FOR FOOT AND MOUTH DISEASE

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

BACKGROUND INFORMATION:

A rapid milk polymerase chain reaction (PCR)-based test has been developed at the Plum Island Animal Disease Center (PIADC) to detect foot-and-mouth disease virus (FMDV) in raw milk. Progress has been made to develop nucleic acid extraction procedures that will permit the test to be utilized with a 96-well plate configuration to obtain positive or negative results in approximately 4 hours. Additional research is needed to develop extraction procedures to optimize throughput utilizing a real-time Smart machine. The basic test has been performed in 27 of the 41 animal health diagnostic laboratories that now constitute the National Animal Health Laboratory Network (NAHLN). However, lack of funding within the United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS), Veterinary Services (VS) prevents this test from being field validated in FMD-affected countries to determine actual performance against various dilutions of the virus in bulk milk samples. In addition, without funding to further develop the extraction protocol to optimize throughput with the real-time Smart machines, the NAHLN laboratories cannot proceed to develop the necessary surge capacity near milk producing areas.

In the event of a major FMD outbreak, it is essential that milk movement not be disrupted so milk from non-infected herds can continue to move to processing plants where milk can be pasteurized prior to further processing, thus greatly reducing any potential risk of FMDV reaching the animal population. In the event of such an outbreak, deployment of rapid PCR-based technology would greatly facilitate FMD surveillance by animal health authorities and greatly facilitate testing of dairy herds to establish and maintain negative herd status within FMD control zones.

RESOLUTION:

The United States Animal Health Association (USAHA) encourages the United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS), Veterinary Services (VS) to place the highest priority in developing and validating the performance (including sensitivity, specificity, reproducibility and other statistical parameters) of various polymerase chain reaction (PCR)-based platforms that might be further developed and validated to determine the presence of foot-and-mouth disease virus (FMDV) in various concentrations in bulk milk under field conditions in FMD-affected countries. USAHA also urges USDA-APHIS-VS to proceed as rapidly as possible to develop the necessary extraction procedures to optimize laboratory throughput, thus permitting these technologies to be deployed by the National Animal Health Laboratory Network (NAHLN) laboratories at the earliest possible time. USAHA further urges USDA-APHIS-VS to conduct the necessary training to utilize this technology to provide reliable laboratory surge capacity so as to permit rapid evaluation of bulk milk samples from dairies located in FMD control zones.

RESPONSE:

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

Veterinary Services (VS) and the National Milk Producers Federation personnel met in October 2005 to discuss this project. It was agreed that having a validated, sensitive, specific, easy-to-run assay for detecting foot-and-mouth disease virus (FMDV) in milk was important. It was also decided that because of the problems involved in working with lactating dairy cows in a bio-containment environment, the possibility of doing some of this work in a country where foot-and-mouth disease (FMD) is endemic should be investigated.

The Animal and Plant Health Inspection Service (APHIS) and the Agricultural Research Service (ARS) have been collaborating on the development and validation of a real-time PCR assay to detect FMDV nucleic acid. The assay VS is using was designed by a team of scientists from ARS and Tetracore. Twenty-nine National Animal Health Laboratory Network (NAHLN) laboratories have been trained and proficiency tested to conduct this real-time PCR for FMD. The assay has been optimized for tissues and swabs and is currently being optimized for milk. ARS and APHIS have done proof-of-concept work using the ARS/Tetracore developed real-time PCR assay for FMDV nucleic acids in milk, which will make having this assay in our diagnostic assay toolbox valuable. VS recognizes the value of milk as a sample for FMD surveillance, as well as the value of this test in moving milk safely inside of quarantine zones. Due to the loss of some crucial staff at Foreign Animal Disease Diagnostic Laboratory (FADDL), they have not been able to move ahead with the optimization of this assay for milk and the validation of the assay for tissues and swab concurrently. Initial field validation efforts have been focused on tissues and swabs because this will allow the test to be used to detect FMD in many species, whereas the use of milk samples limits us to dairy cows only. By March 2006, FADDL should have in a place a Head for the newly formed Proficiency and Validation Services Section, which will enable them to move forward with the optimization and validation of this assay in milk. Once FADDL has completed the optimization and validation of this test for milk samples, participants from NAHLN laboratories will be trained to conduct the assay using milk samples.