UNITED STATES ANIMAL HEALTH ASSOCIATION—2007

RESOLUTION NUMBER: 65 APPROVED

SOURCE: COMMITTEE ON IMPORT EXPORT

SUBJECT MATTER: IMPORTATION OF FETAL BOVINE SERUM

DATE: RENO, NEVADA, OCTOBER 18 – 24, 2007

BACKGROUND INFORMATION:

The United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS), Veterinary Services (VS) has the responsibility of ensuring that fetal bovine serum (FBS) imported into the United States (US) is free of pathogens which do not exist in the US and pose a risk to the US livestock population.

Since Bovine Spongiform Encephalopathy (BSE) has become the primary disease limiting the trade of live cattle, meats and bovine products throughout the world, the limited supply of USDA approved FBS has not been able to keep up with the demand resulting in price differences that make USDA approved FBS as much as 10 times higher than non USDA approved FBS. This price difference encourages smuggling and misrepresentation of FBS between origins, thus putting at risk the traceability and safety of "USDA approved FBS", throughout the world.

Gamma irradiation has been used by USDA-APHIS-VS for several decades, as a method to inactivate potential pathogens in ruminant serum imported from countries known to have livestock diseases that do not exist in the United States. Importations of ruminant serum have been authorized by USDA-APHIS-VS in limited quantities for development research and diagnostic purposes by both governmental and private institutions.

Gamma radiation is currently being used as approved treatments to eliminate potential pathogens in medical products used for both human and animal medical applications. Gamma irradiation is also authorized by USDA for the treatment of many food products of animal and plant origin.

Many research laboratories and biologics manufacturers can use gamma irradiated serum from BSE free countries, especially in those applications where the absence of BSE is most critical.

Resolution number 13 approved at the 2004 United States Animal Health Association (USAHA) annual meeting recommended that USDA-APHIS allow the importation of gamma irradiated commercial shipments of FBS.

At the 2005 USAHA annual meeting, USDA-APHIS responded that a proposed rule for the importation of irradiated FBS was still being prepared for publication. A resolution from both the Committees on Import/Export and Biologics and Biotechnology asking USDA-APHIS to continue the follow up was approved at the 2005 USAHA annual meeting.

At the 2006 USAHA annual meeting, USDA-APHIS responded that the risk assessment had been completed and that a proposed rule was being prepared.

RESOLUTION:

The United States Animal Health Association (USAHA) requests that the United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS), Veterinary Services (VS), publish a proposed rule to allow the importation of fetal bovine serum (FBS) from countries free of foot and mouth disease (FMD) and bovine spongiform encephalopathy (BSE) following gamma irradiation as provided in Veterinary Services (VS) notice 98-05 in approved private irradiation facilities to inactivate other diseases of concern to the livestock industry.

RESPONSE:

USDA, APHIS, Veterinary Services
The U.S. 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. As a result of the 2006 risk assessment, it was determined that the risk of foot-and-mouth disease (FMD) infectivity in gamma-irradiated fetal bovine serum (FBS) was low but not zero. Because the risk was not zero, the VS National Center for Import and Export (NCIE) had to establish a procedure for FBS importation that would result in an acceptable level of risk. NCIE consulted with the Foreign Animal Disease Diagnostic Laboratory and the National Veterinary Services Laboratories to develop several options for allowing the importation of irradiated FBS, thereby increasing the available supply of fetal bovine serum while safeguarding the health of U.S. animals. VS management is discussing these options and we expect a decision in the second quarter of 2008. Once the decision is finalized, NCIE will begin the process for a proposed rule.