

UNITED STATES ANIMAL HEALTH ASSOCIATION-2004

RESOLUTION NUMBER: 13 **APPROVED**

SOURCE: COMMITTEE ON IMPORT EXPORT
COMMITTEE ON BIOLOGICS AND BIOTECHNOLOGY

SUBJECT MATTER: IMPORTATION OF FETAL BOVINE SERUM

DATES: OCTOBER 27, 2004

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 from other countries is free of pathogens which do not exist in the United States and pose a risk to the U.S. livestock population.

Since Bovine Spongiform Encephalopathy (BSE) has become the main 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 rewards 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 occur in the United States. Importations of ruminant serum have been authorized by USDA-APHIS-VS in limited quantities for developmental research and diagnostic purposes by both governmental and private institutions.

Gamma irradiation 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:

The United States Animal Health Association (USAHA) urges the United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS), Veterinary Services (VS) to re-propose the concept and feasibility of authorizing the use of gamma irradiation for the importation of commercial shipments of Fetal Bovine Serum (FBS) from countries and/or regions that are free of Bovine Spongiform Encephalopathy (BSE), but have restrictions because of other pathogens that can be eliminated by gamma irradiation, thus helping assure a reliable, affordable, safe and continuous supply of pathogen-free FBS to research laboratories and biologics manufacturers.

RESPONSE:

The Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS), Veterinary Services (VS), has in place a mechanism by which commercial quantities of fetal bovine serum (FBS) may be imported into the United States from countries considered by the USDA to be free of foot-and-mouth disease (FMD) and free of bovine spongiform encephalopathy (BSE). The provisions for this type of importation are provided in VS Notice 98-05 and include gamma irradiation at USDA inspected and approved private irradiation facilities to inactivate other diseases of concern that include exotic Bluetongue and Akabane.

USDA has received a proposal from private industry to irradiate FBS sourced from FMD countries. Currently, APHIS is evaluating the proposal for efficacy and feasibility. If APHIS finds the proposal addresses all of USDA's concerns, USDA would consider proposing a rule to incorporate the proposal into the import regulations.

On February 25, 1994, USDA, APHIS, published a proposed rule "Importation of Fetal Bovine Serum" [Docket No. 89-174-1]. That proposed rule removed the prohibitions on the importation into the United States of FBS from countries in which FMD and Rinderpest exist. It required, among other things, that the FBS:

- originate from a BSE-free country;
- be collected from dams that have passed ante- and -postmortem inspection;
- be collected from slaughterhouses inspected and approved by FSIS;
- be filtered through 0.45 micron or smaller filter;
- not be commingled with any other ruminant serum;
- be imported to the US via import permit;
- be quarantined at a USDA, APHIS inspected and approved irradiation facility, and
- undergo 2.2 megarads of gamma irradiation at dry ice temperature.

This proposed rule was withdrawn, after an extension of the comment period, due to extensive industry opposition. However, due to the interest expressed in recent years, USDA-APHIS is considering re-proposing (with amendments) this previously proposed rule.