
RESOLUTION NUMBER: 12 APPROVED

SOURCE: COMMITTEE ON BIOLOGICS AND BIOTECHNOLOGY

SUBJECT MATTER: Standards for Labeling Requirements for Fetal Bovine Serum

BACKGROUND INFORMATION:

The animal serum industry and its products, especially Fetal Bovine Serum (FBS), have suffered reputational damage over the years due to issues with product integrity and traceability.

In 2006, serum producers organized the International Serum Industry Association (ISIA), which established ethics and industry standards and set the stage for improving the industry's reputation through audit and certification processes.

Notwithstanding this effort, in 2013 an incident occurred via discovery that over a five-year period (2008-2013) an estimated 280,000 liters of FBS had been adulterated and mislabeled. United States (US) and European authorities were alerted and measures were taken to recall the unused products. The company involved has since gone out of business, but the consequences of this incident on research projects, diagnostic lab results, and vaccine producing companies is still unknown. It is possible that years of research may have been adversely affected, as well as the accuracy of diagnostic test results, safety of vaccines, and the reproducibility of protocols. The recall alert stated that FBS may have been adulterated with "adult bovine serum albumin (BSA) of US origin, water and/or cell growth promoting additives...in varying portions...ranging from 23-50% of the products composition..." Furthermore, it appeared that some lots were inaccurately represented as to their origin. Estimates were that the company involved in this incident controlled up to 25% of the worldwide market for FBS.

Because the United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service does not have authority to directly regulate the serum industry and animal serum products, their involvement in this incident and other reported cases is limited to preventing the adverse effects questionable products may have on individual licensees of Veterinary Biologic products. FBS used by researchers, constituting approximately one third of all serum produced and used in the US, is not regulated. Therefore, in most cases, the serum producer is not held accountable by USDA in the event of issues with its products and their potential adverse effects.

RESOLUTION:

The United States Animal Health Association urges the United States Department of Agriculture, Animal and Plant Health Inspection Service, Veterinary Services to study the possibility of requesting authority and/or amending existing regulations, which would support standards for labeling requirements for all Fetal Bovine Serum products, as well as penalties and recall responsibilities.