
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.

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. The United States 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 of U.S. origin, water and/or cell growth promoting additives...in varying portions...ranging from 23 to 50 percent 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 percent 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 United States, 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.

INTERIM RESPONSE:

The United States Department of Agriculture, Animal and Plant Health Inspection Service (APHIS), Veterinary Services (VS) recognizes the concerns of the United States Animal Health Association and appreciates the opportunity to respond. Since fetal bovine serum (FBS) does not fit the definition of a veterinary biologic under the Virus-Serum-Toxin Act or the corresponding regulations, VS would likely not obtain regulatory authority over all FBS without major statutory change and rulemaking. Also, current budgets for VS do not allow expansion of mission into other areas such as regulatory oversight of FBS, which would require significant resources to be effective. VS can directly regulate the import and movement in interstate commerce of FBS. However, VS would need additional regulatory authority, rulemaking, personnel, and budget to regulate the movement of FBS, both imported and solely domestic, for issues beyond the introduction and spread of infectious livestock diseases - such as labeling/mislabeled and/or adulteration with materials not posing a livestock disease risk.

Nonetheless, APHIS is examining ways to strengthen regulatory oversight within its existing scope of authority. VS' Center for Veterinary Biologics (CVB) has recently tightened policy on sourcing of all ingredients of animal origin used in the manufacture of veterinary biologics in an effort to increase the safety of licensed products. Additionally, CVB is currently working with the veterinary biologics industry to update existing testing requirements for ingredients of animal origin including FBS. The net result of these CVB initiatives will be more rigorous regulatory oversight of all ingredients of animal origin, including FBS. In addition, VS' National Import Export Services is reassessing its import requirements for FBS and will consider new/revised ways to ensure that imported FBS truly reflects the country of origin indicated on the authorizing import permit, to the extent that current authority, budget, and technology allow. The International Serum Industry Association is developing new methodology for verifying country of origin of bovine serum, and VS is keeping abreast of these developments.