

FETAL BOVINE SERUM (FBS) HISTORY, ANOTHER LESSON LEARNED

HISTORY

FBS is critically important for research, diagnostics, vaccines, and biopharmaceuticals. Its use has resulted in significant contributions to the improvement of human and animal health. The use of FBS in cell culture started in the USA in the 1960s, based on serum collections in North America. In Europe, FBS was mainly imported from New Zealand and Australia until the 1980s. Supply was tight and prices were high. European Union (EU) import rules differed from country-to-country which made smuggling and misrepresentation of origin fairly simple and profitable

for those willing to ignore the rules. "Serum brokers" were specialists in imports into the EU, as described in an article published by *Der Spiegel* in 1993.

Collection in Latin America started in 1979 in Mexico. FBS from Mexico and Central America was allowed into the USA. FBS from South America was only allowed into Europe where the serum industry, instead of purchasing directly from producers as in Mexico and North America, collaborated with serum brokers as described in the *Spiegel* article. This network of brokers became the main route for FBS from South

America into European FBS companies. Biowest was one of the few companies buying FBS directly from serum producers in South America. While Biowest had originally been formed in cooperation with German brokers to produce FBS in France, that cooperation ended and Biowest continued its serum collection activity directly with French abattoirs.

ANOTHER LESSON LEARNED

In 1994, the Serascandia group became a sleeping partner in Biowest, who owed it money for serum supply and could not pay. Accepting a proposal to convert debt to shares was the best solution for Sera Scandia to avoid a loss; and served the additional purpose of keeping Biowest alive and active as a customer.

Due to the adverse market conditions in the EU FBS market, the economic problems of Biowest continued; and in 2003, it was decided to sell the company. Around six months later the new owner came across evidence that the previous manager had been operating a parallel, illegal activity, with Biowest as one of his victims. Biowest had purchased and resold misrepresented product! The new owner backed out of the deal. Sera Scandia had to take over, denounced the case to the French police and to USDA and informed the affected serum customers.

Prior to the detection of the irregularities, the former manager of Biowest resigned his position convinced that the irregularities would not be detected. However, by pure chance, he was proven wrong. This shows how difficult it is to detect this kind of illegal activity; as also has been the experience of other companies in similar circumstances.

This unfortunate learning experience resulted in Biowest proposing that the leading serum companies create an industry organization to prevent similar illegal activities, which was the genesis of ISIA. ■

NOTE

Dotted lines for note-taking