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Request for Comments Concerning Proposed Transatlantic Trade & Investment Agreement

To whom it may concern at the Office of the United States Trade Representative

SUBJECT : ANIMAL SERUM : Biowest USA and sister companies are sourcing and exporting animal serum worldwide. EU and USA are both big importers and exporters. Stakeholders are: Academia and Researchers; Bio Pharmaceutical- and Veterinary vaccine manufacturers; and patients depending on products from the mentioned stakeholders

We would like to bring your attention to this extremely critical raw material. Animal serum in general and Fetal Bovine Serum (FBS) in particular, has serious challenges in commerce. Resolution of these problems is rarely addressed because this situation is always overshadowed by issues related to the movement of animal materials between the United States and the European Union. However, special consideration must be made to address the challenges faced in the export and import of this raw material where disruption of supply could force the slow down of research and closure of biopharmaceutical manufacturing, jeopardizing the health and well being of millions. Adequate supply of FBS is essential for life science research as well as manufacturing of human and animal vaccines and biologicals used to treat serious, chronic human diseases.

The plea we make is to simply harmonize the import and export regulations governing animal serum for research and further manufacturing use. To obtain this, we strongly recommend the following changes be made.

1. No longer try to regulate animal serum within the same regulation governing the commerce of meat and other animal by-products used for human and animal food. Because of its unique nature and importance, serum must be regulated separately.
2. Reach common definitions based on intended use and risk considerations; taking into account the special nature of the products being traded.
3. Both parties should adhere to the animal disease guidelines provided by the World Animal Health Agency (OIE) , making certain that regulations governing the import and export uniformly apply OIE criteria and other scientifically-based data.
4. The US should adopt the EU practice of accepting for import FBS produced in countries which are free from Foot and Mouth Disease by vaccination; by implementing the proposed rule change 1994, 9CFR Docket No 89-174-1. 40% of the world supply of FBS comes from countries controlling FMD by vaccination. Exclusion of this resource drives up the cost and may jeopardize adequate supply.
5. The US should adopt the EU practice of accepting serum processed in countries different from the country of origin of the serum. Currently the US does not allow import of any serum processed in the EU, not even of US origin serum.
6. Harmonize testing requirements; and update test methodologies to reflect current science. The US-required blue tongue testing for imported FBS using live sheep is expensive and time consuming; and unique, when compared to all other countries.

• 8301 NW 101st Terrace Ste # 12 Kansas City, MO 64153 •
• PH# 877-219-1260 • Fax # 816-841-4708 •
www.biowestusa.com

7. Harmonize formats and wording of certifications.
8. Manage all certificates by on-line electronic means; minimize use of paper.

Harmonization contributes to improved and more uniform availability across the world; intensified competition, as EU based serum supply companies get access to the US market (which is today not the case); reduction of price variances between origins and thus reduced risk of illegal practices; logistical flexibility for FBS users with operations in USA and EU; and smoothening of cyclical price fluctuations. Since 1989 (according to USDA) prices for fetal bovine blood in the US have fluctuated between 20 and 120 USD per liter! Overall prices will be lower through trade and competition, according to studies made by USDA in the context of the proposal from 1994, referred to above.

To understand the importance of harmonized regulations for FBS; it is important to take into account the nature of the sourcing: Killings of pregnant animals are unplanned events. The frequency is influenced by economic factors and weather conditions affecting the herd size; and by techniques for cattle breeding and milk production. The US cattle herd was reduced from over 130 million to below 100 million over the last decades, and same development is seen in most other countries. FBS supply is likely to continue shrinking. Demand for FBS is expected to increase, as new applications are gaining ground. So, the benefits obtained by harmonization of trade rules will increase over time.

It is further important to be aware that historically the lack of harmonization of trade rules has led to the formation of separate supply/demand constellations for sub segments of the FBS world market. FBS can be abundant and affordable in some segments while at same time short and expensive in others; creating up to 5-10 fold price differences between different origins of FBS. This represents a traceability risk, counterproductive for all stakeholders worldwide; and will be dramatically reduced by harmonization of trade rules.

Respectfully submitted,



Biowest USA

Ole Bødtker Nielsen, CEO