INTERNATIONAL SERUM INDUSTRY ASSOCIATION

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Request for Public Comment on Ways to Reduce Regulatory Burdens

To whom it may concern at the High Level Regulatory Cooperation Forum, the Transatlantic Economic Council and the High Level Working Group on Jobs and Growth

The membership of the International Serum Industry Association (ISIA) is worldwide, and comprised of collectors, processors and users of animal serum and animal derived products worldwide. These products are used extensively in the growth of cells in culture for research and in the production of diagnostic kits, biopharmaceuticals, vaccines and other medicinal products. It is estimated that the ISIA membership provides more than 90% of the global supply of animal serum for technical use in the healthcare sector.

The ISIA understands and respects the control of imported animal derived materials whether directed at protecting human and animal health in the EU, or animal health in the USA.

The majority of bovine derived raw material used in the health care sector is collected as a by-product of the meat industry. The US, Australia Canada and New Zealand are the sources of choice for material used in biopharmaceutical and vaccine production. It is recognized that there are concerns surrounding the potential presence of adventitious disease agents however bovine serum, particularly Fetal Bovine Serum (FBS), is still the material of choice for growing specific mammalian cells for the production of biopharmaceuticals and vaccines worldwide.

Since the demand for bovine blood products for technical purposes in the European market cannot be satisfied by the domestic production of these materials, the European healthcare industry depends heavily on importation from 3rd countries, in particular from the USA, Australia and Canada for industrial applications, and from South America for research purposes.

As most major healthcare companies have both US and European facilities a steady flow of trade, and the ability to compare of research results between the two continents in essential. Although the monetary value of the trade in animal sera is relatively small, the critical role it plays as a necessary raw material in medicines production amplifies its importance. Slowing and/or disruption of trade due to burdensome, confusing and unnecessary rules and regulations poses a serious threat to the multi-billion Euro and Dollar healthcare industries.

Common-sense harmonization of rules and regulations will ensure that trade is not disrupted. The critical agencies involved in the regulation of these products are USDA/APHIS and DG SANCO.

Recent changes in European regulation covering the importation of animal by-products starting with Regulation No. (EC) 1774/2004, followed by Regulation No. (EC) 1069/2011 and it's implementing Regulation No. (EU) 142/2011 and ongoing revisions, have caused significant

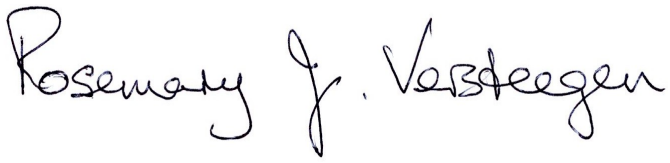
delays in trade and, on occasion, loss of product due to its perishable nature during import into the EU. Harmonization as simple as Animal Health Certificate and Export/Import document formats and common, understandable definitions should be possible through thoughtful dialogue among the parties.

The US should be encouraged to continue its efforts to become more aligned with the rest of the world in terms of adopting a philosophy better harmonized with global bodies such as the OIE. This would go a long way in reducing delays and the expense associated with additional administrative effort and confusion.

We appreciate any effort that you can undertake to support harmonization of the regulations in this area between the EU and USA. We will continue to work actively with the regulatory bodies concerned to encourage this objective. Please feel free to contact us should you need further information or answers.

We regret our delay in responding to the request for comment; but the US weather conditions had a significant impact on our timing, as several points were discussed across the Atlantic.

Respectfully Submitted



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