biowest
The Serum Specialist

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November 21, 2012

Request* for Public Comment on Ways to reduce Regulatory Burdens

To whom it may concern on the High Level Regulatory Cooperation forum , The Transatlantic Economic Council and the High Level Working Group on Jobs and Growth: Regulatory agencies: USDA/APHIS and DG SANCO

Biowest is a European company, sourcing and exporting animal serum worldwide and a founding member of ISIA. We fully support the comments made by ISIA, and want to add a few points we find relevant from a European perspective.

Around 50% of the world supply of Fetal Bovine Serum (FBS) is collected in South- and Central America and EU ; the other 50% is collected between North America and Oceania. EU and USA are both big importers and exporters of FBS. Harmonization of regulations will ensure that trade and competition is stimulated and product getting more accessible for researchers and industries worldwide. Of main concern to EU serum companies are following regulatory differences

1. The lack of uniform criteria for allowing imports of FBS. EU takes guidance from the OIE criteria, while USDA allows imports based on a positive list with BSE related exceptions.

2. USA does not allow imports of FBS after processing in EU, not even of US- and other origins accepted by USDA. Whereas EU accepts imports from USA of the same origins.

These two points are addressed in detail in the attachment, along the guidelines stipulated in the invitation*

Please feel free to contact us should you need further information. We appreciate the opportunity; and regret our delay in responding to the request for comment; caused by US weather conditions, as the issues were discussed among ISIA members across the Atlantic and we were waiting for the ISIA comment to be submitted before sending ours.

Respectfully submitted

Ole Bødtker Nielsen
President of Biowest

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U.S., EU Invite Public Comment on Ways to Reduce Regulatory Burdens
The U.S. and the European Union are requesting public comments by Oct. 31 on ways to promote greater transatlantic regulatory compatibility.....As authorities work on these issues within the High Level Regulatory Cooperation Forum, the Transatlantic Economic Council and the High Level Working Group on Jobs and Growth, they are also inviting from the private sector **concrete ideas** on how greater compatibility could be achieved in particular economic sectors.
For each sector, commenters should provide the following information.
- names of the relevant U.S. and EU regulatory agencies
- citations to the relevant regulatory and/or statutory provisions for each jurisdiction
- **a description of the regulatory differences** to be addressed (...information on **negative effects** and **stakeholders affected**)
- **possible solutions** for bridging these differences (including the **substance** of the solution and the **proposed procedure** for reaching it)
- **any steps that the EU and/or U.S. should consider** to address horizontal and/or sectoral differences .....
- an assessment of the **effects of enhanced regulatory compatibility** (quantified benefits and costs, if possible, or else qualitative descriptions), the likelihood of these effects occurring and the time period over which they would occur

Attachment to Biowest letter dated November 21, 2012

U.S., EU Invite Public Comment on Ways to Reduce Regulatory Burdens

1) Regulatory Difference:

a) EU allows imports of bovine serum originating in OIE listed countries, under defined conditions. US works with a limited positive list of FMD free countries, with BSE related exceptions This is especially affecting the trade in Fetal Bovine Serum (FBS).

b) EU accepts imports of FBS after processing in US of raw serum originating in countries on OIE list , i.e. USA and countries on USDA's positive list. Whereas USA does not accept import of FBS origins on USDA's positive list after processing in EU; not even of US origin FBS having passed though EU.

2) **Negative effects:**

a) Limitation on movement and use of same batches of FBS in and between the USA and EU.

b) Restricting supply for critical industries, including vaccine manufacture for the global market

c) Distortion of competition between US and EU companies. Material processed in the EU has an important market withheld, even when the origin of the material being USA or USDA approved

d) Artificially isolated supply/demand situations, i.e. FBS abundant and affordable in some countries while short and expensive in others; thus enhancing price fluctuations in the individual market segments.

3) Entities or stakeholders affected

a) Academia and Researchers

b) Bio Pharmaceutical and Veterinary vaccine manufacturers

c) Companies servicing the mentioned stakeholders

4) Proposal for bridging these differences

a) USDA to investigate the possibility of US origin- and US acceptable material being imported into the USA from EU, provided full traceability has been demonstrated, thus establishing reciprocity i.e. each party accepting imports from the other after processing of mutually accepted origins

b) The coordination of country acceptance criteria for all other countries based on OIE principles; with elaboration of common list of exceptions and treatments for countries considered "higher risk".

5) Proposed procedure

a) Reciprocity related to the countries of origin already accepted by both parties can be obtained by USDA establishing guidelines to be followed by EU companies wanting to export to USA. Veterinary Certification by Veterinary Officers registered in the country of export could be devised to ensure that safe handling and full traceability of material to be exported.

b) A resolution to the issue of coordination of country acceptance criteria for all other countries could be achieved by implementing USDA's recent proposal to bring U.S. regulations in line with OIE in matters related to BSE; and the proposal made by USDA in 1994, 9CFR Docket No 89-174-1, to allow the importation into the US of FBS from countries free from FMD WITH vaccination,

6) Assessment of the effects of enhanced regulatory compatibility

a) Improved availability, logistical flexibility, and competition in the FBS markets.

b) Reduction of price variances between origins; reducing risk of misrepresentation.

c) Reduction of cyclical price fluctuations which are dramatic in particular for FBS , due to the characteristics of the sourcing. Since 1989, according to public information provided by USDA, prices per liter fetal bovine blood in the US have fluctuated between lower than 20 to higher than 120 USD. Mitigation of these cycles will be useful for stakeholders in US, EU and worldwide.

7) the likelihood of these effects occurring:

The positive effects are certain; based on generally accepted knowledge about how markets work in general, and the characteristics of the serum industry, hereunder the number of processing plants in USA and EU. The positive effects are further supported by the studies made by USDA in the context of the proposal from 1994, referred to above.

8) The time period over which they would occur

Positive effects will be seen in the short term. It is difficult to monitor the exact impact ; but safe to predict that by implementing the proposed harmonization, FBS costs and prices will be at lower levels and more stable, than in case of no harmonization. The reason is found in the sourcing of FBS.

Killings of pregnant cows and heifers are in most cases unplanned events , with quantities influenced by

- land areas used for extensive cattle farming in different countries
- cycles and outlook for meat and dairy markets, causing herd buildup or -reduction
- Animal breeding and milk production technique, including genetics.
- Gestation monitoring techniques

Development in each of these parameters imply that supply of FBS is likely to continue shrinking worldwide, as has actually been the case during the last several years. At the same time demand for FBS is expected to remain firm, and possibly increase as new applications are gaining ground. It can therefore be predicted with a high degree of certainty that due to this expected development in supply and demand, the present negative effects will be aggravated over time, in case no harmonization takes place. And with same certainty that over time, harmonization of the trade rules between US and EU will enhance the positive effects mentioned in point 6 - especially if also harmonizing with other countries' regulatory entities.

Summary: The harmonization of trade rules for bovine serum will be positive in the short run and especially in the longer run as the global demand increases. In the special case of Fetal Bovine Serum , the increasing demand will encounter a steadily decreasing supply. This product is critical for research and as manufacturing components in many industries including the pharmaceutical industry and the manufacture of vaccines.

Harmonization as proposed will contribute to Improved availability, logistical flexibility, and competition in the FBS markets; - to reduction of price variances between origins; and hence to reduced risk of misrepresentation; - and to reduction of cyclical price fluctuations which are dramatic in particular for FBS.

On the other hand, failure to harmonize will lead to aggravation of the negative side effects: Restricted supply and logistic flexibility in research and industries; distortion of competition between US and EU companies; and an artificially divided world market with dissimilar supply/demand situations in the different segments, thus enhancing price differences between segments and price fluctuations in each individual segment.