INTERNATIONAL SERUM INDUSTRY ASSOCIATION

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Note for Guidance on Minimizing the Risk of Transmitting Animal Spongiform Encephalopathy Agents via Human and Veterinary Medicinal Products: Revision 4

McHenry Maryland USA
June 29, 2009

The International Serum Industry Association is pleased to respond to the above document, and would like to draw attention to a few issues and concerns.

1) The Association would like to draw the attention of CHMP and CVMP to the recent progress made in the revision of Regulation EC 1774/ 2002. Its revision, (COM)345/2008, has already been voted on by the Commission and is in translation and legal review with a view to publication late in 2009. Full implementation is anticipated to occur late in 2010. This document contains certain aspects that would seem to require that the draft under comment will need to be further revised in the near future to accurately reflect these developments.

2) Section 3.2.1 of the above referenced document states "Where there is a choice, animals should be sourced from countries with the lowest possible BSE risk (Category A countries) unless the use of material from countries with a higher TSE risk is justified." It also advises that "Some of the materials identified in Section 6 can be sourced from Category B countries". Fetal bovine serum (FBS) sourced from, for example, the USA (a Category B country) would fall into this latter category.

As developed, the wording in the draft implies that an explanation/ justification would have to be provided by the applicant as to why, if FBS was sourced from the USA, material from a Category A country had not been used. It is well-known that it is necessary to source FBS from certain Category B countries as well as from Category A countries in order to meet demand. The safety of FBS is well established and the USA is universally considered to be acceptable as an FBS source country. The ISIA concludes, therefore, that it is not the intent of the CHMP/CVMP to oblige a formal

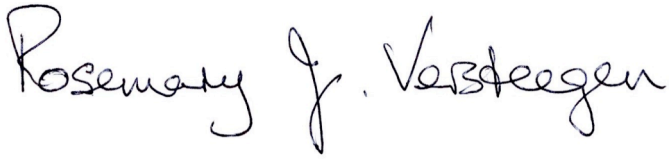
justification of geographical origin of FBS in each marketing authorization application.

We would like to further note that a clear statement that a Certificate of Suitability (as issued by the EDQM) establishes compliance with this Section would avoid any possible misunderstanding.

3) With regard to Section 6.3 it is clear that captive bolt is the standard method of kill in the USA. This has led most manufacturers of serum and blood derived proteins to use source materials from Category A countries to produce products for use in human and animal medicinal products, thus avoiding concerns around the age of the animal at the time it is killed. We understand, however, from certain member companies that there may be some issues associated with the assurance of continuous supply of certain blood derived proteins such as Bovine Serum Albumin due to the age restriction proposed, and have recommended that these companies comment directly on such issues.

Please do not hesitate to contact ISIA if there are any further questions arising from this matter.

Yours sincerely



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