BSE and FBS
30 years later

WITH THE OCCURRENCE OF BSE IN THE 1980S, MANY REGULATIONS HAVE BEEN ESTABLISHED TO REDUCE THE RISK OF BOVINE-DERIVED PRODUCTS IN HUMAN CONSUMPTION AND OTHER APPLICATIONS. THESE REGULATIONS HAVE STRONGLY INFLUENCED THE PREFERENCES AND SELECTION OF FBS IN CELL CULTURES. SIGNIFICANT SCIENTIFIC WORK HAS BEEN DONE IN THIS FIELD, AND MUCH MORE IS UNDERSTOOD NOW ABOUT THE OCCURRENCE AND TRANSMISSION OF THIS DISEASE.

BACKGROUND INFORMATION

When BSE was first discovered in the UK in 1986[1], little was known about the cause of the disease or how it was transmitted. As a result, countries throughout the world responded by banning the importation of all bovine products, including blood products, from affected countries. After the discovery of the prion by Stanley Prusiner[2] as the causative agent of BSE and his report detailing how it is spread by feeding Meat and Bone Meal (MBM) to cattle, the World Animal Health Organization (OIE) and regulatory authorities throughout the world established standards that banned the feeding of mammalian MBM to cattle and adopted slaughter practices that minimize the risk of BSE transmission.

Thanks to these efforts, the number of BSE cases has fallen dramatically, from 37,280 cases in 1992 in the U.K. alone, to only seven cases worldwide in 2013, two of which were atypical or spontaneous BSE cases[3].

Despite the dramatic reduction (almost elimination) of BSE cases in the world and proper risk-reduction procedures being implemented in cattle-exporting countries, many importing countries maintain disproportionate BSE-related bans on bovine blood and blood byproducts.

BSE REGULATIONS

In 2011, the European Union recommended the use of the OIE classification[4] to replace the former GBR risk-class system[5]. Presently, there are 25 countries in the "negligible-risk level", including Australia, Brazil,

Chile, Colombia, Denmark, New Zealand, Panama, Paraguay, the USA, and Uruguay (See Table 1[4]).

The European Union states that blood is safe when coming from "negligible BSE risk" and "controlled BSE risk" origins[6].

Since 1998, the EU has had a mandatory BSE-monitoring program in place – ID passports for all animals and BSE-testing for cattle, covering 100% of animals in predefined risk groups. The traceability system is also useful for the tracking of other animal diseases and making EU origin the preferred choice in some applications.

For Fetal Bovine Serum (FBS), the BSE risk has been known for many years to be ZERO, regardless of origin. The incubation time for BSE is recognized to be several years, which has been taken into consideration in the EU BSE control program, initially covering animals older than 24 months[7]. Additionally, studies have shown that via embryo transfer, BSE from infected mother cows is not transmitted to the offspring[8].

BLOOD AND BLOOD BYPRODUCTS ARE EXEMPT FROM BSE RESTRICTIONS

At the beginning of the BSE outbreak, the understanding of the disease was low, and consequently meat and blood products were handled under the same regulations and restrictions, some of which are still in place.

Based on the improved knowledge of the questions surrounding BSE, in 2006, the OIE updated the Terrestrial Animal Health Code standards for BSE and clarified that: "Blood and blood byproducts should not be subject to any importation restrictions relating to BSE, regardless of the BSE status of the exporting country, except that the cattle being slaughtered were not subjected to a stunning process, prior to slaughter, with a device injecting compressed air or gas into the cranial cavity, or to a pithing process."[9] The OIE also clarified "that blood and milk are not considered to play a role in the transmission of BSE."

REGULATIONS FOR SERUM USAGE FOLLOW THESE DEVELOPMENTS

Other authorities follow the OIE recommendation and have adapted their regulations as well. The latest version of the 9 CFR 95.12 states that blood and blood products derived from bovines must come from animals that were "not subjected to a pithing process or to a stunning process with a device injecting compressed air or gas into the cranial cavity." This is the only USDA restriction relating to BSE for blood and blood products derived from bovines.

CONCLUSION

According to the OIE and other regulatory entities in the USA and EU, it can be concluded that BSE is irrelevant when selecting origins of bovine serum. ■

Table 1

Countries recognised as having a negligible BSE risk in accordance with Chapter 11.4 of the Terrestrial Code.
Argentina
Australia
Austria
Belgium
Brazil
Chile
Colombia
Denmark
Finland
Iceland
India
Israel
Italy
Japan
Netherlands
New Zealand
Norway
Panama
Paraguay
Peru
Singapore
Slovenia
Sweden
USA
Uruguay

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