biowest®
The Serum Specialist

No risk of BSE in FBS

BSE (Bovine Spongiform Encephalopathy) was first discovered in the UK in 1986[1]. Little was known about the cause of the disease or how it was transmitted. Countries throughout the world responded by banning the importation of all bovine products, including blood products, from affected countries.

With the occurrence of BSE in the 1980´s, many regulations have been established to reduce the risk of bovine derived products in human consumption and other applications. These regulations have influenced the preferences and selection of FBS in cell cultures. Since then a lot of scientific work has been done in this field and today, much more is understood about the occurrence and transmission of this disease.

Based on the improved knowledge of the questions surrounding BSE and according to the OIE (World Organization for Animal Health) and other regulatory entities in the USA and EU, it has been concluded that BSE is irrelevant when selecting origins of bovine serum.

«High-quality FBS needed for the reproducibility of scientific research, can come from any country of origin, as long as regulatory and industry standards are adhered to.»[2]
P.W.Hawkes, GEN, 2017

What is the BSE ?

Bovine Spongiform Encephalopathy. «Mad cow disease» is a prion disease.[3] It is a degenerative infection of the central nervous system of bovines. It is a fatal disease caused by a particular molecular infectious agent called Prion. Everything started in England when BSE was transmitted to cows through feedstuff supplemented with offal from scrapie-infected sheep.[3] In 1985, the epidemic became evident. By 1992, the epidemic was at its highest rate due to the long incubation period, and in that year alone roughly 37,000 animals were affected.[3]

What is a Prion disease?

Stanley Prusiner was the first to discover the existence of prion proteins as the causative agent of BSE. It is a resistant form of this protein that is responsible for the disease. Prions possess an innate capacity to convert their structures into highly stable conformations that ultimately result in the formation of harmful particles, the causative agents of several deadly dementia-type brain diseases of humans and animals. The sensational discovery concluded that the prion protein, designated PrP, could fold into two distinct conformations, one that resulted in disease (scrapie PrP = PrPSc) and the other normal, that didn't result in disease (PrP = PrPc). It was subsequently shown that the disease-causing prion protein had infectious properties and could initiate a chain reaction so that the normal PrPc protein could also be converted into the more stable disease-causing PrPSc form. The PrPSc prion protein is extremely stabile and is resistant to proteolysis, organic solvents and high temperatures (even greater than 100°C).[3]

And what about now?

The number of BSE cases has fallen dramatically, from 37280 cases in 1992 in the UK alone to only seven cases worldwide in 2015, four of which were atypical or spontaneous BSE cases.[4]
In recent years, 2 distinct forms of the disease have been described, classical BSE and atypical BSE.[5] Classical BSE which is pratically eradicated from the world does not occur spontaneously, while atypical BSE does occur spontaneous in all cattle populations, according Stanley Prusiner.

The BSE surveillance system outlined by the OIE, is not designed to detect spontaneous or atypical cases of BSE. It's only designed to detect the typical cases of BSE that occur from feeding MBM to cattle. In order to detect atypical or spontaneous cases of BSE, the surveillance system would need to be 10 times more sensitive that the international standard set by the OIE, and capable of detecting one case in one million head of cattle.[5]

Since the atypical form of BSE occurs spontaneously in all cattle populations, it will sooner or later be found in all countries with effective Veterinary Control.

FBS is BSE-free everywhere in the world !

Blood and blood by-products are exempt from BSE restrictions

OIE

The OIE has established 3 BSE risk categories: «negligible BSE risk», «controlled BSE risk» and «undetermined BSE risk». These BSE classifications are of relevance for meat and many bovine products, with the exception of blood, milk and several other products not considered to transmit BSE. The OIE has determined that blood and blood by-products should not be subject to any importation restrictions relating to BSE. [6]

FDA

Bovine blood and blood products are also considered safe by FDA as ingredients in animal feeds FDA.[7]

EDQM

EDQM (European Directorate for the Qualities of Medicine) follows OIE guidelines relating to how animals are stunned prior to slaughter. EDQM says blood is safe when coming from "negligible BSE risk" and "controlled BSE risk" origins. [8]

USDA

Effective March 4, 2014, USDA adopted the OIE Standards regarding BSE. 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." As with the OIE, this is the only USDA restriction relating to BSE for blood and blood products derived from bovines.[9]

Additionally, studies have shown that BSE from infected mother cows is not transmitted to the offsprings (fetus).[10]

«Bovine blood does not transmit BSE». Bovine blood, embryo and fetus tissues are listed as a tissues with absence of detectable infectivity.[11]

The Geographical Origin is no longer a standard of quality as long as it is collected, imported, and processed following all the applicable regulatory and industry requirements.[2]

1 http://bmb.oxfordjournals.org/content/66/1/185.full.pdf+html

2 http://www.genengnews.com/gen-exclusives/high-quality-fbs-may-come-from-any-authorized-country-of-origin/77900896

3 http://www.nobelprize.org/nobel_prizes/medicine/laureates/1997/press.html

4 http://www.oie.int/animal-health-in-the-world/bse-specific-data/

5 https://wwwnc.cdc.gov/eid/article/14/2/07-1141_article

6 OIE Terrestrial Animal Health Code Chapter 11.5. See article 11.5.1

7 FDA Regulation 21 CFR 589.2000. Animal Proteins Prohibited in Ruminant Feed

8 http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2009/09/WC500003700.pdf

9 https://www.gpo.gov/fdsys/pkg/FR-2013-12-04/html/2013-28228.htm Animal Spongiform Encephalopathy Agents. 2011. See 6.3 Bovine Blood and Blood Derivates. Pp 10-11

10 Wrathall AE1, Brown KF, Sayers AR, Wells GA, Simmons MM, Farrelly SS, Bellerby P, Squirrell J, Spencer YI, Wells M, Stack MJ, Bastiman B, Pullar D, Scatcherd J, Heasman L, Parker J, Hannam DA, Helliwell DW, Chree A, Fraser H.: Studies of embryo transfer from cattle clinically affected by bovine spongiform encephalopathy (BSE). In: Vet Rec. 2002 Mar 23;150(12):365-78. PMID:11936410

11 WHO Guidelines on Tissue Infectivity Distribution in TSE's. 2006. Annex I. pp 19-22 See first paragraph

Biowest Europe
2 rue du Vieux Bourg
49340 Nuaillé - France
Tel.: (+33) 241 464 242
Email: biowest@biowest.net
www.biowest.net

Biowest USA
422 NW Business Park Lane
Riverside, MO 64150 - United States
Tel.: (+1) 816 249 2569
Email: service@biowestusa.com
www.biowestusa.com

biowest®
The Serum Specialist