What about bovine spongiform encephalopathy?

Bovine spongiform encephalopathy (BSE, "Mad Cow Disease") has been very much under the spotlight in recent years. Because humans are susceptible to BSE, one of the questions that is rightly asked is: "*What precautions are in place to prevent the transmission of this disease via medicinal products that have been manufactured using bovine serum*?" A similar question can of course be posed for veterinary medicinal products that are administered to susceptible species such as cattle, sheep and goats.

Importantly, there is no evidence that BSE has ever been transmitted via a medicinal product and experts (including the World Health Organisation) have documented that no infectivity has been found in the blood of afflicted cattle. Of course, precautions still need to be taken, but it is nevertheless reassuring information.

Although BSE is a relatively new disease, similar diseases called transmissible spongiform encephalopathies (TSEs) have been known for a long time in both animals and man. The exact nature of the agents that cause these TSEs is still a matter of scientific dispute, but they are very resistant to many of the chemical and physical treatments that efficiently destroy bacteria, viruses and other micro-organisms. In practice, it is not possible to effectively "treat" a material like bovine serum to inactivate the BSE agent, so precautions must be taken to ensure that the material is free from the BSE agent at the outset and that it is manipulated in such a way as to avoid its introduction. Safe sourcing, safe collection and safe processing in a protected environment are thus of great importance.

The OIE (see also: *Is bovine serum safe?*) monitors the incidence of BSE in the world and publishes this information on a regular basis. Regulatory authorities and processors use it as one of the critical determinants in deciding which countries may be used as a source of serum. The OIE Terrestrial Animal Health Code Chapter 11.4 on BSE now states that blood and blood by-products 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 pitching process.** (Section 11.4.1). The code also clarifies that "blood and milk are not considered to play a role in the transmission of BSE (Section 11.4.27)

The OIE Animal Health Code Chapter 11.4, the supporting documentation used by the OIE to arrive at these conclusions and the WHO analysis of the levels of infectivity of different tissues can all be found in the resources section of this website.

In March of 2014, USDA accepted the OIE standards. Federal Register Vol. 78, No. 233. Wednesday December 4, 2013. See page 73005. Following OIE Standards, USDA accepts the importation of FBS from all three BSE category countries, with varying degrees of concern for the mixing of blood with SRM (Specific Risk Materials). The certification statements used by USDA for the three risk categories cab also be found in the resources section of the website

For countries classified as

1. “negligible risk”, USDA has no BSE related restriction for cattle of any age.
2. “controlled risk”, only cattle over 30 months age are subject to the BSE related stunning prohibition and precautions relating to SRMs.
3. “undetermined risk” countries”, all cattle over 12 months of age are subject to the BSE related restrictions.

The FDA recently published a final rule on BSE, in which they concluded that: “there is no evidence that blood from infected cattle can transmit the BSE agent to humans when the blood is incorporated into human food or cosmetics. Therefore, the final rule does not prohibit use of cattle blood or impose any special requirements on cattle blood materials that might be used in human food, including dietary supplements, and in cosmetics.”
https://www.gpo.gov/fdsys/pkg/FR-2016-03-18/pdf/2016-06123.pdf

The EDQM follows also follows OIE guidelines, as it relates to animals not being subjected to a stunning process prior to slaughter. EDQM states that blood is safe when coming from “negligible BSE risk” and “controlled BSE risk” origins. EMA/410/01 rev. 3. 2011. Note for Guidance on Minimizing the Risk of Transmitting Animal Spongiform Encephalopathy Agents. 2011. See 6.3 Bovine Blood and Blood Derivates. Pp 10-11