

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. Serum for biopharmaceutical use is only derived from countries that are deemed to be acceptable by regulatory authorities and their expert advisers.

BSE is a disease of older animals. This gives rise to an additional safeguard. Source animals for bovine serum must be less than three years old – a cut-off that is based upon scientific input and consensus.