What about rules and regulations?

The rules and regulations that processors of bovine serum must respect are complex and are frequently changing. It is only possible to provide a brief overview here.

Some regulations are targeted directly towards processed bovine serum that is offered for sale and supplied by serum producers. These, or similar regulations, apply to other materials of animal origin as well. They address the possible risk that serum (or other products) might transfer a disease from one country or region to another that was previously free from that disease. They are in place to ensure that the movement of the products from one country to another, and their subsequent manipulation, does not pose a risk to animal or human health.

Additional requirements become applicable when bovine serum, or other materials of animal origin, are used in the manufacture of products such as pharmaceuticals that are themselves subject to regulation. These rules are in place to ensure that the material can safely be used in its intended application.

Thus this regulatory framework is not unique to processed bovine serum. It applies to many other animal-derived materials as well.

Movement

Export and import of animal by-products such as bovine serum necessarily involves collaboration between different national and international regulatory bodies. Information on the animal health status of countries/regions provided by the OIE (see also: *Is bovine serum safe?*) forms the basis upon which decisions relating to the movement of animal by-products are made.

Veterinary controls worldwide are to a great extent based upon the rules and regulations established by the United States Department of Agriculture (the USDA) and by the European Commission – the two largest global markets for animal-derived products being the USA and Europe.

Use in the manufacture of human and animal medicinal products

Serum (together with other animal-derived materials) destined for use as a raw material in the manufacture of medicinal products is, necessarily, subject to particularly stringent additional requirements relating to quality and safety. Numerous regulatory bodies worldwide are involved in setting standards and defining requirements that impact upon bovine serum either directly or indirectly.

In the USA these are the USDA, the Food and Drug Administration (FDA) and the United States Pharmacopoeia.

Both the USDA and the FDA have in place regulations that address in detail the control of bovine serum that is to be used in the manufacture of medicinal products. With regard to BSE, the USDA maintains a list of countries from which bovine serum cannot

be derived in order to minimise any risk. The FDA also applies the same geographical restrictions.

In Europe the bodies are the European Commission, the European Directorate for the Quality of Medicines and Healthcare (the EDQM – an organisation responsible, amongst other things, for the European Pharmacopoeia) and the European Medicines Agency (the EMA – which reports to the European Commission and is responsible, with the support of national authorities, for the scientific evaluation of medicines for use within the EU).

These bodies in turn make use of scientific advice issued by supra-national organisations such as the World Health Organisation (WHO) and the World Organisation for Animal Health (OIE).

One of the responsibilities of the EMA is to produce scientific guidelines that cover a whole host of matters relating to the development, manufacture and control of human and veterinary medicinal products.

Two of these guidelines (one relating to products for human use, one to products for veterinary use) are devoted entirely to processed bovine serum. Serum producers ensure that processed bovine serum that is intended for use in the manufacture of pharmaceuticals meets the requirements established in these documents.

There is another guideline that has the force of law within the EU and in some other countries also. It applies to a wide range of ruminant-derived materials, not just bovine serum, and relates to the measures that must be in place to minimise risk due to TSE agents (see also: *"Is serum safe?"*). All processed bovine serum that is sold or used for manufacture of pharmaceuticals in or for Europe must be shown to comply. In order to establish compliance, companies must submit, for expert review, detailed product-specific information covering every aspect of sourcing, collection and processing.

Whatever the purpose behind the regulations, the ISIA and its members liaise closely with authorities to make sure that member companies are compliant. One of the key roles of the ISIA is to provide a recognised and authoritative link between its members and regulatory bodies and the scientific experts that are involved in the development and application of the legislation.