Regulatory Concerns

PRODUCT NEWS

Increasing Regulatory Concerns?
Reassure yourself with FBS from Gibco®

The Biopharmaceutical Industry is facing an increasing number of regulations concerning the use of Foetal Bovine Serum (FBS) in the manufacture of Biopharmaceuticals. Attention is turning further upstream in the manufacturing process. Having confidence in your source is now of utmost importance.

Regulatory Bodies

In Europe, the European Medicines Agency (EMEA) has two committees:

- CVMP – Committee for Medicinal Products for Veterinary Use
- CHMP (previously CPMP) – Committee for Medicinal Products for Human Use

These committees issue guidelines for the manufacture of human and veterinary medicines including guidance on minimising the risk of Animal Spongiform Encephalopathy Agents from FBS in biopharmaceutical products.

Gibco® can provide peace of mind to manufacturers of Biopharmaceuticals by offering FBS that meets the EMEA guidelines:

- EMEA/CVMP/743/00 – Final: Guideline on requirements and controls applied to bovine serum used in the production of immunological veterinary medicinal products.
- CPMP/BWP/1793/02. Note for Guidance on the use of bovine serum in the manufacture of human biological medicinal products.

In addition, the European Pharmacopoeia Commission has drafted a monograph (which will be published shortly) on Bovine Serum, which will become a mandatory quality standard for this material when used in the manufacture of medicinal products. Gibco® is working closely with the EDQM (European Directorate for the Quality of Medicines) on this matter to ensure our FBS will be in compliance with this standard when it is issued.

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Certificates of Suitability

Concern over risk of Transmissible Spongiform Encephalopathy (TSEs)?

The EDQM has issued Certificates of Suitability to Invitrogen which covers various Gibco® bovine sera products (see Table 1).

Table 1—List of serum products covered by Certificates of Suitability issued to Invitrogen

Product Description	Origin	Catalogue Number
FBS, Standard	Australian	10099-141
FBS, Heat Inactivated		10100-147
FBS, Standard	New Zealand	10091-148
FBS, Heat Inactivated		10093-177
FBS, Gamma Irradiated		10094-142
FBS, Dialysed		10227-023
FBS, Certified	USA	16000-044
FBS, Certified, Heat Inactivated		10082-147
FBS, Qualified		26140-079
FBS, Qualified, Heat Inactivated		16140-071
FBS, Dialysed		26400-044
FBS, Ultra Low IgG		16250-078
Adult Bovine Serum	New Zealand	16170-078
Adult Bovine Serum, Heat Inactivated		26170-043
Donor Bovine Serum	New Zealand	16030-074
Donor Bovine Serum, Heat Inactivated		16175-028
Donor Bovine Serum, with Iron		10371-029
Newborn Calf Serum	New Zealand	16010-159
Newborn Calf Serum, Heat Inactivated		26010-074
Newborn Calf Serum, Gamma Irradiated		56010-028

CE Marking

Effective October 30, 2003, Invitrogen began CE marking several hundred Gibco® media, sera and reagent products that are suitable for *in vitro* diagnostic (IVD) applications. We instituted this labelling change in order to comply with the European Union Medical Device directive 98/79/EC that became effective for these products in December 2003.*

EU Import Regulations

As most Gibco® FBS products of US, Australian and New Zealand origin are CE marked, this also means that they are exempt from the Animal byproducts regulation (EC) No 1774/2002† which came into effect in June 2004. The introduction of this regulation has created new import controls which has made the importation of non-CE marked product into Europe more difficult, resulting in supply problems.

Gibco®'s CE marked FBS means uninterrupted supply of FBS for our customers.

Future Regulatory Developments

Our policy is to work closely with our customers and provide them with maximum support to allow both our customers and Invitrogen to be in compliance with any future regulatory requirements.

Confidence in Your Source

Our ability to source serum globally allows us to offer you a wide selection of FBS to meet your regulatory needs.

- GBR I countries**; New Zealand, Australia
- USDA Approved countries: USA, New Zealand, Australia, Central America, Mexico

Superior Traceability

We can trace raw materials back to the original country and abattoir where they were collected and we have full documentary verification of the procedures used to manufacture each batch of finished product.

FBS of Australian, New Zealand and USA origin are final-processed in the country of origin; the ultimate guarantee that the origin of the material is genuine. Our documentation traces the finished product back through the manufacturing cycle to the original raw material, in accordance with EMEA guidelines.

Gibco® has been serving the Biopharmaceutical Industry for over 40 years and has the most respected regulatory compliance programme in the Industry.

Rely on Gibco® to meet your FBS needs.

* Gibco® products bearing a 'CE' mark are intended 'for *in vitro* diagnostic use' and the IVD claim is indicated by the IVD symbol on the label. These products are considered medical devices subject to the requirements of Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on *in vitro* diagnostic medical devices [Official Journal L 331 of 07.12.1998] and to the requirements of the United States Code of Federal Regulations Title 21, Part 820: Quality Systems Regulation.

† Regulation (EC) No 1774/2002 of the European Parliament and of the Council of 3 October 2002 laying down health rules concerning animal by-products not intended for human consumption (OJ L273, 10.10.2002, p1)

** Final Opinion of the Scientific Steering Committee (European Commission) on the Geographical Risk of Bovine Spongiform Encephalopathy (GBR) Adopted on 06/07/2000

GBR Level	Presence of one or more cattle clinically or pre-clinically infected with the BSE agent in a geographical region/country
I	Highly Unlikely
II	Unlikely but not excluded
III	Likely but not confirmed or confirmed, at a lower level
IV	Confirmed, at a higher level

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