

## Material of Animal Origin

Commission Directive 2003/32/EC of April 23, 2003, defines detailed specifications as regards the requirements laid down in the Council Directive 93/42/EEC with respect to medical devices manufactured utilizing tissues of animal origin.

This Med-Info gives you helpful advice on how to prepare for this legal requirement including a practical to-do list.

### To whom is this news bulletin applicable?

- Medical device manufacturers using tissues of animal origin
- Suppliers of medical device components using tissues of animal origin

### Does the new regulation apply to all animal tissue?

No. It applies to material from bovine, ovine, caprine species, deer, elk, cat, and mink only. Products manufactured using tallow, gelatine, and collagen must meet requirements as set out for human consumption.

### What is now required from affected manufacturers?

#### Here is a brief to-do checklist:

- The manufacturer has to produce documentation justifying the need to use animal tissues or derivatives in the production process
- The manufacturer must conduct an assessment of the clinical benefit/potential risk/possible alternatives
- The manufacturer must produce studies of the elimination/inactivation of BSE/TSE agents or alternatively literature research on the subject
- The manufacturer must produce a well-documented strategy in risk analysis and risk management. Furthermore, the manufacturer must demonstrate a high level of protection for patients as well as the benefit of the material
- The manufacturer must prove that all relevant aspects of the TSE agent have been considered and that measures are in place and that these ensure that infection is minimized
- The manufacturer must document the control of raw material, finished products, and subcontractors
- The manufacturer must install a control mechanism related to the sourcing of the materials

For further information, please feel free to contact us.

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#### **What is assessed by the Notified Body?**

TÜV SÜD Product Service as Notified Body has to establish an evaluation and conclusion report and needs to seek the opinion of the other member states via their competent authority. This report includes an assessment of the risk analysis and risk management evaluation and studies of TSE/BSE inactivation. TSE certificates of suitability issued by the EDQM have to be taken into account for the starting materials as well as, if appropriate, the opinion of the CPMP (Board of Medicinal Specialties).

After consulting the other competent European authorities, and before the EC certificate according to Annex II.4 or III is issued, the Notified Body has to consider the statements which were given by the authorities within 12 weeks. If a TSE certificate of suitability issued by the European Directorate for the Quality of Medicines is available the consultation of the competent European authorities is no longer necessary. In this case, only the responsible German authorities must be consulted.

#### **Links to informative websites:**

[http://www.oie.int/eng/en\\_index.htm](http://www.oie.int/eng/en_index.htm)

<http://www.efsa.eu.int>

<http://www.emea.eu.int/>

<http://www.pheur.org/>

<http://www.rki.de/>

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