UPDATE – STATUS REACH AFTER ENVI VOTE

Consequences for the Medical Devices and IVD industry

30th October 2006.

On October 10th 2006 ENVI Committee of the European Parliament voted on amendments to the REACH proposal in Second Reading.

Amendment 110 was presented before the Committee for the exclusion of medical devices from part of the scope – this amendment was defeated by the narrowest possible margin with the ENVI Committee being split 30-30.

An analysis of the other amendments passed by ENVI Committee show that now, more than ever, the exemption for Medical Devices is more pertinent than ever –

- **Testing requirements for low volume substances have been substantially increased** by the introduction of a requirement of a chemical safety report for substances in the 1-10 tonne category. (Previously this had been a requirement only above 10 tonnes). Proportional to other industries, a larger proportion of the substances used by the Medical Devices and IVD Industry will be falling into this category.

- **Obligation for substitution has been strengthened without taking into account existing risk control measures.** The approach has been based exclusively on the intrinsic properties of a substance. This measure is of particular concern in the field of Medical Devices as it means that a manufacturer can be obliged to change a substance in a product for another, potentially resulting in a decreased performance of the device and consequential risk to patient safety, even if the risks related to the use of the original substance is adequately controlled.

- **Rather than accept a case by case approach based on risk, authorization has fixed for a 5 year time frame.** This will cause uncertainty for medical device manufacturers whose use of authorized substances will be questioned every five years, irrespective of risk mitigation strategy, non-availability of substitutes and socio-economic benefits.

Taken together, these amendments result in a significant increase of the regulatory burden of REACH, particularly for SMEs, which are particularly important in the Medical Devices (including IVD) sector.

Furthermore, these amendments result in an even greater imbalance between the consideration of risk and that of benefits to patients. The medical devices directives provide a framework to address this crucial issue through its risk management process, which can address all kinds of risks, including risks to the environment.

Because of the wide ranging impact which these new measures will have, it is critical to have an exemption as put before the ENVI Committee for medical devices within the REACH proposal.

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