PlasticsEurope
Association of Plastics Manufacturers

Polycarbonate/Bisphenol A group (PC/BPA-group)/ Epoxy Resins Committee (ERC)

29. January 2014

SCENIHR preliminary opinion finds margin of safety for polycarbonate and epoxy resin medical devices

The Polycarbonate/Bisphenol A Group and the Epoxy Resin Committee of PlasticsEurope group note the publication of the preliminary opinion on the safety of the use of BPA in medical devices prepared by the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR). The draft opinion was prepared following a request by the Commission in December 2011 and it is now open for consultation until March 26, 2014.

The SCENIHR draft opinion evaluated potential exposure to BPA from a wide range of medical applications that are characterized by type of use (e.g., external, dental, implants, hemodialysis, surgical procedures, intensive care unit) and length of contact (i.e., short to long contact times). In general, **SCENIHR found that available exposure data is very limited** and it is uncertain whether the data is reliable or representative of current medical applications. Accordingly, SCENIHR's exposure estimates are based on "conservative assumptions and extrapolations" and, as noted, should be "viewed and used with some caution."

Within the constraints of the available data, SCENIHR generally found that exposure to BPA from all medical applications is low, often in the range of the very low consumer exposures through the diet. Exposures from many medical uses occur for a limited period of time and are estimated to be well below the conservative temporary TDI (Tolerable Daily Intake for an individual's lifetime) recently proposed by EFSA. For other applications, in particular for neonates being treated with multiple devices in intensive care units, SCENIHR concluded "there may exist some risk for adverse effects," but **a margin of safety exists** even for these applications. As with dietary intake, the Committee noted that BPA is rapidly eliminated from the body following exposure from medical applications.

Given the limitations of the existing data, SCENIHR notes that there is a need for more and better information on the release of BPA from medical devices in actual use conditions. As also noted by SCENIHR, many of the uncertainties regarding potential health hazards of BPA are currently being addressed in a chronic toxicity study being conducted by the US Food and Drug Administration's National Center for Toxicological Research.

Very importantly, SCENIHR states "that **the benefit of medical devices has also to be considered**" and, in particular, the survival of premature infants often depends on the availability of medical devices made with BPA. Accordingly, replacement of BPA in medical devices must "be considered against their efficiency in the treatment, as well as the toxicological profile of the alternative materials."

Jasmin Bird of the PlasticsEurope Polycarbonate/Bisphenol A industry group stated "The long track record of proven life-saving benefits from polycarbonate medical devices coupled with the margin of safety demonstrated by SCENIHR's evaluation should give confidence to patients and medical professionals in the continued use of these products."

ASSOCIATION OF PLASTICS MANUFACTURERS IN EUROPE AISBL
Avenue E. Van Nieuwenhuyse 4/3 - B -1160 Brussels – Belgium
Tel (32-2) 675 32 97 - Fax (32-2) 675 39 35
VAT BE 416 155 338 - WWW.PLASTICSEUROPE.ORG

Industry will provide its comprehensive scientific input after having had the opportunity to review in detail the comprehensive 150 page dossier with its experts.

For further information please contact:

Jasmin Bird
Communications Manager
PC/BPA-Group
PlasticsEurope
Tel: +32 2 676 17 38
Fax: +32 2 675 39 35
Email: jasmin.bird@plasticseurope.org
Website: www.bisphenol-a-europe.org