PlasticsEurope
Association of Plastics Manufacturers

Polycarbonate/Bisphenol A group
Epoxy Resin Committee

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SCENIHR opinion on BPA

The Polycarbonate/Bisphenol A Group and the Epoxy Resin Committee of PlasticsEurope comment as follows on the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) opinion on the safety of the use of BPA in medical devices, published 27.2.2015.

SCENIHR confirms safety of many BPA-based medical applications

Since 2012, SCENIHR had evaluated the safety of the use of BPA in medical devices. In its final opinion published end of February, SCENIHR confirmed the safety for many medical applications based on BPA.

SCENIHR found that available exposure data from medical devices is very limited. As a consequence of consistently using conservative worst case assumptions for exposure to account for the lack of data, and relating uncertainties, SCENIHR considers there may be a risk related to some parenteral exposure scenarios for certain medical devices, namely neonates in intensive care, infants under prolonged medical procedures, and dialysis patients.

However, the Committee underlines that such potential risk has to be seen in context of the essential benefits that these devices provide for the therapy of the patients. SCENIHR cautioned not to rush to potential alternative materials: these must be evaluated in terms of *"efficiency in the treatment, as well as the toxicological profile of the alternative materials."* According to SCENIHR, there is currently not enough data available for this evaluation.

More specific exposure data is needed to allow for a robust identification of margins of safety

The PC/BPA-group understands the need for more specific data on exposure from medical devices in their specific use patterns in order to allow for a more robust identification of the respective margins of safety. This would allow for a more substantiated derivation of potential risks. The PC/BPA group will further evaluate available relevant data related to polycarbonate products and would welcome engagement from the other medical devices industry partners in order to reduce the data gap in this area.

"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." says Jasmin Bird of the PlasticsEurope Polycarbonate/Bisphenol A industry group.

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Additional background information from the SCENIHR report

- *Exposure scenarios:*
  SCENIHR investigated 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-term contact) for different types of patients, including highly sensitive groups undergoing multiple therapeutic regimes.

- *Exposure data*:
  SCENIHR found that available exposure data is very limited and it is uncertain whether the available data is reliable or representative of current medical applications. Accordingly, SCENIHR's exposure estimates are based on few worst case data, on conservative assumptions and extrapolations. „*The information available is very limited and in many cases due to the lack of experimental data, only estimations were used. The uncertainties related to the exposure assessment indeed represent the weakest part of this evaluation.*"

- *Relevant plastics materials*:
  SCENIHR identified several materials containing BPA which are used in medical devices, including Polycarbonate and Polysulfone as well as Epoxy resins, where BPA is used as a monomer and firmly bound in a polymeric structure. Furthermore PVC is a relevant material, where BPA is used as an additive. Based on current data, the contribution of polycarbonate to migration of BPA from medical devices is considered significantly lower than the worst case assumptions used by SCENIHR.

- *Effect level derivation:*
  SCENIHR followed the EFSA methodology to derive effect levels based on a weight of evidence approach and adopted the relevant EFSA thresholds. For parenteral exposure routes, these are adapted by an additional factor of 100 to account for higher bioavailability.

- *Safety factor*:
  SCENIHR used the EFSA safety factor of 150 as a maximum starting point and adapts it for medical device specific parameters in order to set specific margins of safety with respect to acute / short term / long term applications.