

## Toxicokinetics of Bisphenol A

### Scientific Opinion of the Panel on Food additives, Flavourings, Processing aids and Materials in Contact with Food (AFC)

(Question No EFSA-Q-2008-382)

Adopted on 9 July 2008

#### SUMMARY

The Panel has been asked to reconsider the possible age-dependent toxicokinetics of BPA in animals and humans and their implication for hazard and risk assessment of BPA in food. The Panel concluded that the exposure of a human fetus to free BPA would be negligible due to the maternal capacity for conjugation whereas the fetal rat would be exposed to free BPA from the maternal circulation. Taking account of data in human neonates on compounds structurally related to BPA which undergo glucuronidation/sulphation, the Panel considers that there is sufficient capacity in the neonate to conjugate BPA at doses below 1 mg/kg bw (the Panel noted that exposures at the TDI of 0.05 mg/kg bw are 20 fold lower than this).

Therefore, the Panel concluded that there is sufficient capacity for biotransformation of BPA to hormonally inactive conjugates in neonatal humans at exposures to BPA that were considered in the EFSA opinion of 2006 and the European Union Risk Assessment Report (EC, 2003, 2008).

In addition, the Panel notes that because of the metabolic differences described, exposure to free BPA in adult, fetal and neonatal rats will be greater than in humans and that rats would therefore be more susceptible to BPA-induced toxic effects than humans on an equivalent dose basis.

The Panel therefore considers that its previous risk assessment based on the overall NOAEL for effects in rats and using a default uncertainty factor of 100 can be considered as conservative for humans. The Panel concluded that the differences in age-dependent toxicokinetics of BPA in animals and humans would have no implication for the EFSA 2006 risk assessment of BPA.

**Key words:** Bisphenol A, BPA, 2,2-bis(4-hydroxyphenyl)propane, 4,4'-isopropylidendiphenol, CAS no. 80-05-7, toxicokinetics, neonate, glucuronidation.