

**STATEMENT OF EFSA
on a study associating bisphenol A with medical disorders¹**

Prepared by the Unit on food contact materials, enzymes, flavourings and processing aids (CEF) and the Unit on Assessment Methodology (AMU)

(Question N^o EFSA-Q-2008-702)

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SUMMARY

The European Food Safety Authority (EFSA) received a request on 29 September 2008 from the European Commission requesting an assessment of the implications to the hazard and risk assessment of bisphenol A (BPA) of a study published in the *Journal of the American Medical Association (JAMA)* on 16 September (Lang *et al.*, 2008), correlating urinary BPA concentrations to medical disorders in adults.

The former EFSA Panel on food additives, flavourings, processing aids and materials in contact with food (AFC) carried out a comprehensive risk assessment on bisphenol A (BPA) in 2006 and set a full Tolerable Daily Intake (TDI) of 0.05 mg/kg body weight (bw)/day.

EFSA concluded that this single study does not provide sufficient proof for a causal link between exposure to BPA and the health conditions mentioned in the study, i.e. heart disease, diabetes and elevated liver-enzyme activities. Therefore, EFSA considers that there is no need to revise the TDI as derived by the AFC Panel in 2006.

Keywords: Bisphenol A, CAS no. 80-05-7, cardiovascular disease, diabetes, liver-enzyme abnormalities.

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BACKGROUND

The former AFC Panel carried out a comprehensive risk assessment on bisphenol A (BPA) in 2006 and set a full Tolerable Daily Intake (TDI) of 0.05 mg/kg body weight (bw)/day derived from the No Observed Adverse Effect Level (NOAEL) of 5 mg/kg bw/day. The Panel also concluded that dietary exposure to BPA was well below the TDI for all groups of the population. (EFSA, 2006)

A study published in the Journal of the American Medical Association (JAMA) on 16 September (Lang *et al.*, 2008), correlates urinary BPA concentrations to medical disorders in adults.

The authors concluded that “higher urinary concentrations of BPA were associated with an increased prevalence of cardiovascular disease, diabetes, and liver-enzyme abnormalities. These findings add to the evidence suggesting adverse effects of low-dose BPA in animals. Independent replication and follow-up studies are needed to confirm these findings and to provide evidence on whether the associations are causal.”

The European Commission asked EFSA to assess the relevance of this study and its implications for hazard and risk assessment of BPA as soon as possible.

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EVALUATION

The study recently published in the Journal of the American Medical Association relating urinary BPA concentrations with medical disorders (Lang *et al.*, 2008) makes use of the existing US National Health and Nutrition Examination Survey (NHANES) for 2003-2004 (CDC, 2004), which comprises measurements of BPA in urine samples of individuals sampled once at the time the participants were asked about their health status. These data can be used as an estimation of the exposure to BPA within 24 hrs of sample collection. However, there is no information on exposure during the time needed for development of diseases such as diabetes and cardiovascular conditions or changes in plasma liver-enzyme activities. Although the study authors attempted to rule out several commonly identified confounders of studies of this type, the observed association between urinary BPA elimination and the conditions mentioned above may have been a chance finding or may be due to non-identified confounders.

CONCLUSION

This single study does not provide sufficient proof for a causal link between exposure to BPA and the health conditions mentioned above. Therefore, EFSA considers that there is no need to revise the TDI as derived by the AFC Panel in 2006.

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