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Claims that BPA exposure might cause obesity are not supported by available valid scientific data

Recently, media reported that obesity might be an alleged effect of BPA exposure. However, there is no consistent evidence that any dose of BPA produces obesity in animals or humans.

The above mentioned claims are based on studies which used a small number of animals per group, a limited number of dose levels, an artificial (i.e. non-oral) route of exposure, or a combination of these factors, or which showed a lack of consistency in the results (e.g. some researchers reported a *decrease* in body weight, while others reported an *increase* in body weight). Although studies with such characteristics are also being included in the regulatory assessments, the European authorities have based their opinion on the results of most comprehensive studies respecting Good Laboratory Practice (GLP) and following accepted test guidelines. From guideline multi-generation studies in rats and mice, performed in accordance with GLP, which also report body weights of animals exposed to dietary BPA, there is strong evidence that BPA exposure does not result in obesity in rats and mice.

The recently published draft US - National Toxicology Program (NTP) brief on BPA (April 14, 2008) concluded that "there is currently insufficient evidence to conclude that bisphenol A exposure during development predisposes laboratory animals to develop obesity or metabolic diseases such as diabetes, later in life ... The NTP concurs with the CERHR Expert Panel on Bisphenol A that the effects of bisphenol A on body weight at "low" doses are inconsistent".

Overall conclusion: There is no consistent evidence to support the hypothesis that low doses of BPA affect body weight in animals or humans.

The PC/BPA group of *PlasticsEurope* believes that the weight of the scientific evidence supports the safety of polycarbonate plastic and epoxies in their intended uses.

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Additional information:

In the guideline multi-generation studies in rats and mice, performed in accordance with GLP, only animals in the highest dose groups (at or above 50 mg/kg/day for rats and ~600 mg/kg/day for mice) showed a significant *decrease* of body weight; no effect on body weight was observed at lower doses^{1,2}.

Recent reviews by Gray et al.³, Goodman et al.⁴, Rhomberg et al.⁵, the “European Panel on Food Additives, Flavorings, Processing Aids and Materials in Contact with Food” (EFSA)⁶, the Center for Evaluation of Risks to Human Reproduction (CERHR)⁷, Willhite et al.⁸ and Health Canada⁹ examined the BPA mammalian toxicology literature on reproduction, including large studies (meeting or exceeding GLP guidelines) by the oral route, as well as small studies that utilized both oral and non-oral (parenteral) routes of administration. All of the reviewers’ evaluations cited above were consistent with the conclusion that BPA exposure does not produce obesity in rodents.

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2 Two-Generation Reproductive Toxicity Study of Dietary Bisphenol A (BPA) in CD-1(R) (Swiss) Mice Rochelle W. Tyl, Christina B. Myers, Melissa C. Marr, Carol S. Sloan, Nora P. Castillo, M. Michael Veselica, John C. Seely, Stephen S. Dimond, John P. Van Miller, Ronald N. Shiotsuka, Dieter Beyer, Steven G. Hentges, and John M. Waechter, Jr. *Toxicol. Sci.* published 29 April 2008, 10.1093/toxsci/kfn084

3 . Gray, G. M., Cohen, J. T., Cunha, G., Hughes, C., McConnell, E. E., Rhomber, L., Sipes, I. G. and Mattison, D. Weight of the evidence evaluation of low-dose reproductive and developmental effects of bisphenol A. *Human and Ecological Risk Assessment* 2004; 10: 875-921.

4 Goodman JE, McConnell EE, Sipes IG, Witorsch RJ, Slayton TM, Yu CJ, Lewis AS, Rhomberg LR. An updated weight of the evidence evaluation of reproductive and developmental effects of low doses of bisphenol A. *Crit Rev Toxicol* 2006; 36: 387-457.

5 Rhomberg, L. R., Goodman, J. E., McConnell, E. E., Sipes, I. G., Witorsch, R. J., Slayton, T. M., Yu, C. J., and Lewis, A. S. (2007). An updated weight of evidence evaluation of reproductive and developmental effects of low dose of bisphenol A. *The Toxicologist*, 96, 427.

6 EFSA. Opinion of the Scientific Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food on a request from the Commission related to 2,2-bis(4-hydroxyphenyl)propane (bisphenol A). *EFSA J* 2006; 428: 1-75

7 Chapin R, Adams J, Boekelheide K, Gray L, Hayward S, Lees P, McIntyre B, Portier K, Schnorr T, Selevan S, Vandenberg J, Woskie S (2007) NTP-CERHR Expert Panel Report on the Reproductive and Developmental Toxicity of Bisphenol A. <http://cerhr.niehs.nih.gov/chemicals/bisphenol/bisphenol.html>

8 Willhite CC, Ball GL, McLellan CJ (2008) *J Toxicol Environ Health B Crit Rev.* Derivation of a bisphenol A oral reference dose (RfD) and drinking-water equivalent concentration. 11(2): 69-146

9 Draft Screening Assessment for Phenol, 4,4'-(1-methylethylidene)bis- (80-05-7) April 2008