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*Boucher et al study:*

**Highly experimental study in cell cultures with several limitations is not relevant for human risk assessment**

A recently published in vitro study<sup>1</sup> by Boucher *et al.* examines the effect of a Bisphenol A metabolite (BPA-glucuronide, BPA-G) on the differentiation of pre-adipocytes into adipocytes - fat cells). The authors report that BPA-G induced adipogenesis, leading them to conclude that “BPA-G is not an inactive metabolite as previously believed but is in fact biologically active.” This would be in contrast to previously published in vitro and in vivo data which demonstrate that BPA-G has no such biological activity. The scientific evidence shows that BPA when ingested is efficiently converted in the body to inactive metabolites, primarily BPA-G, that have no known biological activity and are rapidly eliminated from the body in urine.

*In this context the Polycarbonate/Bisphenol A and Epoxy Resin groups of PlasticsEurope would like to make the following statement:*

**This in vitro study is not relevant for risk assessment – BPA-G, as the primary metabolite of BPA, is intrinsically tested in all in vivo experiments including large multigeneration guideline studies**

Body weight is a regularly measured parameter in toxicological in vivo studies. Comprehensive multi-generation studies investigated potential effects of BPA after oral ingestion, covering a broad range of dose levels. After ingestion, BPA is quickly converted into glucuronated BPA; potential effects of BPA-G would have been observed. However, none of these large-scale studies conducted according to internationally accepted guidelines showed effects on the body weight at realistic dose levels.

The European Food Safety Authority (EFSA) in its most recent comprehensive assessment of the available studies on BPA concluded that there is no consumer health risk from BPA, exposure from all sources is very low and well below the new safe limit for all age groups. Regarding the question of body weight, EFSA found “there is no convincing evidence that BPA is obesogenic after intrauterine exposure or in longer-term studies”.<sup>2</sup>

Further factors limiting the relevance of the study include:

- The authors report an effect only at a very high BPA-G concentration, while realistic human BPA-G levels measured in human studies are orders of magnitude lower.
- Evidence of distinction between an effect caused by BPA-G versus an effect caused by free-BPA is missing. Unconjugated “free” BPA could likely be present either because BPA-G chemically degraded back to BPA during the course of the experiment, or is present as an impurity. Indeed, it would be much more plausible that the biological effects seen in the cells were caused by the presence of free BPA rather than by BPA-G.

The study by Boucher *et al.* in cells does not change the overall conclusion of regulatory safety authorities such as EFSA and the US-FDA that BPA is safe in its intended uses.

Polycarbonate/Bisphenol A group  
Epoxy Resin Committee

<sup>1</sup> *In Vitro Effects of Bisphenol A  $\beta$ -D-Glucuronide (BPA-G) on Adipogenesis in Human and Murine Preadipocytes*, Jonathan J.G. Boucher, A. Boudreau, S. Ahmed and E. Atlas, published online in Environmental Health Perspectives <http://www.environmentalhealthnews.org/>  
<http://dx.doi.org/10.1289/ehp.149143>

<sup>2</sup> EFSA 2015 Executive Summary of the Scientific Opinion p.18 “there is no convincing evidence that BPA is obesogenic after intrauterine exposure or in longer-term studies”;  
<http://www.efsa.europa.eu/en/efsajournal/doc/3978.pdf>

EFSA explains their BPA-assessment report here:  
<http://www.efsa.europa.eu/en/corporate/pub/factsheetbpa150121.htm>

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