

Polycarbonate/Bisphenol A group

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Statement concerning the study from Braniste et al regarding the intestinal impact of BPA

Study fails to reflect realistic exposure scenarios and has very limited relevance to consumers

Recently, media attention on Bisphenol A (BPA) has focused on a newly-published study from Braniste et al.* on the impact of BPA on the intestinal functions of rats. The results of the study have extremely limited relevance for consumers and should be put into the context of the wealth of existing data on BPA. The weight of the scientific evidence shows that there is no basis for health concerns over human exposure to BPA. This has been confirmed by relevant European authorities.

Unrealistic exposure scenarios

The study uses unrealistic exposure scenarios that significantly limit the relevance of its conclusions for consumers. Specifically:

- ❖ The study is based on an artificial animal model which has very limited value for human risk assessment. It measured local effects in the colon of rats after direct application of BPA into the stomach of the animals. This represents an artificial test setting that is in no way representative of human exposure.
- ❖ Experiments were undertaken on adult female rats that were treated with a wide range of BPA doses. From the data presented, it appears that biological observations were found at doses at least ~100 times higher than typical human exposure. Furthermore, the relevance to human health of these observations is unrealistic since the rats had their normal hormonal status eliminated, through the surgical removal of ovaries.
- ❖ BPA was administered to the rats as a single daily dose rather than steadily through the diet. This daily dose was administered by gavage, i.e. by applying the whole dose via a syringe-like instrument through the mouth and oesophagus directly into the stomach of the rats. This leads to immediate high concentrations of the substance in the gastro-intestinal tract. It is therefore in no way a realistic exposure scenario and clearly exaggerates the animal dose versus human exposure.
- ❖ The second set of experiments involved treatment of pregnant female rats with a dose equal to the "No Observable Adverse Effect Level (NOAEL)" for BPA (5 mg/kg-day), which is ~100,000 times higher than typical human exposure, followed by observations on their offspring. The typical low doses of BPA were not examined as part of the study.

Bisphenol A is safe in its intended uses

The information presented by this study must be placed in the context of the large body of existing scientific evidence on BPA, much of which involves actual laboratory testing to observe potential health effects. BPA is one of the most widely studied compounds in the world, and existing scientific evidence from many studies with oral exposure does not "match" the associations found in the new work.

BPA has been the subject of extensive scientific testing and government reviews worldwide. International responsible authorities such as the European Commission, the European Food Safety Authority (EFSA), the US Food and Drug Administration (FDA) and the Japanese Ministry of Health, Labour and Welfare have all assessed the comprehensive database on BPA.

Based on a weight-of-evidence approach, these assessments have consistently concluded that human exposure levels to BPA are low and within the safe limits set by government authorities. The European Commission (June 2008), EFSA (July 2008), and the US FDA (August 2008) re-confirmed their long-standing conclusions that products made from BPA are safe for their intended uses. Over 50 years of research and extensive use throughout the world provide convincing evidence that products made from materials based on BPA are safe for their intended uses.

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*** Impact of oral bisphenol A at reference doses on intestinal barrier function and sex differences after perinatal exposure in rats**, Viorica Braniste, Aurore Jouault, Eric Gaultier, Arnaud Polizzi, Claire Buisson-Brenac, Mathilde Leveque, Pascal G. Martin, Vassilia Theodorou, Jean Fioramonti, and Eric Houdeau; published online in PNAS: www.pnas.org/cgi/doi/10.1073/pnas.0907697107