

Recent study with dogs on Bisphenol A has severe limitations

Results from highly artificial tests not relevant for human health assessment

Recent media reports about a new study from the French National Institute for Agricultural Research (INRA¹, Institut National de la Recherche Agronomique), claiming “high bioavailability of Bisphenol A through sublingual exposure” must be put into perspective of the chosen methodology and existing scientific knowledge. Industry is concerned about highly experimental exposure studies being presented to the public as evidence of dangers for human health. In this context, the Polycarbonate/Bisphenol A group of PlasticsEurope would like to make the following statement:

The authors’ suggested conclusion that exposure to Bisphenol A (BPA) via sub-lingual administration might be higher than exposure via the gastro-intestinal tract is not relevant for human risk assessment. The authors themselves acknowledge that their study design is artificial.

In their experiment, the authors exposed six dogs via different application routes to different doses of BPA: 0.5 mg/kg bodyweight and 5 mg/kg bodyweight under the tongue (sublingually) and directly into the blood (intravenous), and 20 mg/kg bodyweight directly into the stomach via a stomach tube. In order to manage the sublingual exposure, three dogs were narcotized, BPA was dissolved in alcohol and the solution was deposited under the tongue of the dogs. BPA concentrations were analyzed in blood collected from the jugular vein.

The study has severe limitations. The authors themselves acknowledge that their dosing is artificial and indicate that their artificial sublingual dosing is not relevant for human dietary exposure. In addition, anesthetized dogs don’t swallow, and the authors did not take into account the data of the first blood collections, but started their analysis after an arbitrary delay of 8 minutes because “*The disadvantage of this blood collection site [jugular vein] is that the corresponding plasma BPA concentrations do not properly reflect the BPA systemic exposure... during the absorption phase*”

This highly experimental study design – applying BPA in highly concentrated ethanol to anesthetized dogs - is not relevant for humans, and it is not appropriate to indicate conclusions from such tests as relevant for human risk assessment.

Furthermore, the authors’ general claim that sublingual absorption of BPA may contribute to much higher internal exposure is not substantiated by this study, and is neglecting the actual realistic exposure situation. Contrary to sublingual exposure in dogs, studies in humans (Teeguarden et al) that exposed people via the relevant oral route (diet), as well as data from comprehensive guideline animal studies (Tyl et al, Stump et al) include chewing and swallowing the diet as the normal route of administration to display a realistic exposure situation.

The public should be confident that BPA is one of the most studied chemicals and has a safety track record of 50 years. The European Food Safety Agency EFSA, the US Food and Drug Administration FDA and other regulatory bodies from around the world have concluded that the science supports the safety of BPA in its current uses, including its continued use in food-contact products.

Polycarbonate/Bisphenol A group

Only very recently, in April 2013, the US Food and Drug Administration FDA unequivocally reconfirmed that BPA is safe for its approved uses: **Is BPA safe? Yes. Based on FDA's ongoing safety review of scientific evidence, the available information continues to support the safety of BPA for the currently approved uses in food containers and packaging.**

<http://www.fda.gov/Food/IngredientsPackagingLabeling/FoodAdditivesIngredients/ucm355155.htm>

FDA's current perspective is based on its review of hundreds of studies, as well as its comprehensive research on BPA.

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***High Bioavailability of Bisphenol A from Sublingual Exposure**
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