

Melzer et al:

LIMITED EPIDEMIOLOGICAL BPA-STUDY MAKES UNSCIENTIFIC LEAP

Study Suggesting Links between Bisphenol A and Heart Disease Lacks Sufficient Evidence

A study by Melzer et al*, recently published in the online journal PlosOne, purports to link BPA to cardiovascular disease in adults. In this information paper the Polycarbonate/Bisphenol A industry group comments and adds scientific facts to put the claimed effects into perspective.

New study does not replicate earlier findings

The new study is a follow-up to a study published in September 2008, which was based on an analysis of data from the US-CDC NHANES* program using the 2003-2004 data set. The new study includes an analysis of the most recent set of CDC data (2005-2006).

In their initial study the authors state: "These first reports clearly need to be replicated in independent study samples, to ensure that the findings are robust and to refine estimates of effect sizes". Now in their repeat study the authors largely failed to replicate their earlier findings, which suggests that the earlier findings are not robust:

- The statistically significant findings for diabetes and three liver enzyme levels reported for the 2003-2004 data set all disappear with the 2005-2006 data set.
- Of the four statistically significant parameters relevant to heart disease, two are no longer statistically significant and the other two are of marginal statistical significance.
- For several endpoints, no association was found in the 2005/2006 data. The authors suggest this is a result of low statistical power. However, it could equally be a lack of association. One cannot know which is the case.

The use of pooled data, and health parameters partly generated by self-reporting without medical confirmation, question the results – no cause-response-relationship

In their new study the authors choose to pool data from the 2003-2004 with the 2005-2006 data sets and then analyse the aggregated data. When doing so, the authors report that all but one of the earlier findings are still statistically significant. However, pooled data cannot confirm an earlier finding because the pooled data set is a derivative of the earlier finding and is not independent of it.

Furthermore, the study itself does not establish a cause-effect relationship between BPA exposure and heart disease. The BPA measurements were taken at the same time as the health information was collected. The analysis assumes that measures of BPA and other factors such as BMI (body mass index) at the time of the survey are equivalent to those that lead to the health effect. However, there is no evidence to support this, as the BPA measurements reflect very recent exposure over the last day, while the onset and development of heart disease occurs over much longer time periods. Therefore, the biological plausibility of the statistical associations reported for the two heart disease parameters is uncertain. In addition, fewer than 50 participants self-reported health conditions without medical confirmation both in the 2003-2004 and the 2005-2006 dataset, as can be seen from the description of the data generation. The robustness of the limited findings is therefore questionable.

Bisphenol A is safe in its intended uses

“Studies of this type are very limited in what they tell us about potential impacts on human health. While they can provide information on where to focus future research, by themselves they cannot and should not be used to demonstrate that a particular chemical can cause a particular effect. The public should be confident that BPA is one of the most studied chemicals. Regulatory bodies from around the world have recently completed scientific evaluations and found BPA safe in food-contact products, including canned foods and beverages,” stated Jasmin Bird, of the Polycarbonate/BPA Group of PlasticsEurope

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* **Association of urinary bisphenol A concentration with heart disease: evidence from NHANES 2003/06**; David Melzer MB, Neil E Rice, Ceri Lewis, William E Henley, Tamara and S Galloway
PlosOne, online (online journal)

**** US-CDC NHANES**

United States of America, Center for Disease Control, National Health and Nutrition Examination Survey