Bisphenol A in Food Cans: An Update

The bisphenol A manufacturing industry and suppliers have followed closely the current research on can coatings and have conducted their own testing to provide data that support their position. They have also been active in providing exposure data related to bisphenol A from can coatings.

The paper states that the active level of bisphenol A in food cans was measured at 2 and 20 micrograms per kilogram body weight per day (μg/kg/day) and a "near" or "thus" related to the range of reported human exposure. This data appears to be based on human exposure data derived from a paper by Brown et al. (1995) in Environmental Health Perspectives. The paper concludes that bisphenol A exposure is a concern for human health.

In late 1996, our industry's Ecstasy Can Coating Group of the Interindustry Group on Bisphenol A and Allelophyls concluded a second study on potential human exposure to bisphenol A from epoxy-leached food cans. The first study from this work group (4), completed in 1995, was referenced by Nagel et al. (4). The second study was undertaken using the improved analytical methodology that minimizes the interferences which were observed in the first study and likely occurred in the study of Brown et al. (2).

The findings of the 1996 report, "Potential Exposure to Bisphenol A from Epoxy Can Coatings" (6), provide new improved exposure data. This 1996 study with more accurate data was not referenced by Nagel et al. (6). These new data, which have now been provided to the U.S. Food and Drug Administration and the National

Corrections and Clarifications

In the article by Nagel et al. (1995) in The Growth Foundation in Iowa Community, with Herbicide-contaminated Drinking Water Supplies published in EHP in Volume 105, Number 3, 1997, Table 1 was incorrect. For all variables, both mean and median should be given in micrograms per liter. The corrected table is shown below:
Academy of Sciences Committee on Hormone-related Tumours in the Environment, indicate that the estimate of dietary exposure is approximately 0.1 μg/kg/day under the most conservative conditions. Obviously, this is a level far below the lowest dietary exposure used by Nagel et al. (5). It is therefore quite clear that epoxy acrylate-coated metal food and beverage containers present no public health hazard.


References

In the news article about the BEST Program that appeared in the February issue of EHP (105:176-177), Mariam Johnson-Thompson, Assistant to the Director for Educational and Biomedical Research Development, was not identified as the program's chief organizer and the NIEHS BEST contact person. Additionally, Larry Champion, Laboratory of Molecular Genetics, should be identified as an individual who coined the term BEST.

Furthermore, the unique characteristics of the BEST Program that formally is a partnership between the NIEHS and Duhamel Public Schools engages several other important domains. These are represented by the continuous and active involvement of the school's students, parents, faculty, and staff, community-based organizations and volunteers, businesses, other RTP area federal and private scientific organizations, local and state government officials, local universities, and the N.C. School of Science and Math. Confusions in this innovative concept is the "It Takes a Village approach."

Finally, since the February publication of the article, additional school, C.C. Spaulding Elementary School, home of the new Epoxy Magnet Center, has joined the BEST Program.

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Response
In a paper published earlier this year (5), we described biological effects in vivo on the rodent prostate caused by frequent exposure to low doses of the environmental estrogenic bisphenol A. Females were exposed by feeding pregnant female mice bisphenol A at average maternal doses of 2 and 20 μg/kg maternal body weight per day (2 and 20 μg/kg) and these lowest levels produced increased prostate (similar to effects seen with low doses of estrogen and diethylstilbestrol) (5) measured in subsequent adult males. Our conclusion that these doses of bisphenol A were "near or within the reported range of human exposure" was based on exposures to bisphenol A following application of some dental sealants as reported by Oles et al. (2), where up to 913 μg of bisphenol A were reported released into saliva in the first hour after application of sealant. This 913 μg of bisphenol A in a 60 kg human would be equivalent to 9.13 × 60, or 55 μg/kg body weight, well above the lowest dose of 2 μg/kg/day at which we observed a biological effect in mice in the developing prostate. In a very recent report, Sallam et al. (4) detected biological effects of bisphenol A at a concentration down to 1 nM or 0.23 μg/l.

In their letter addressing several conclusions drawn in our study, Hoye and Budweiser noted that the Epoxy Can Coating Work Group's final report, "Potential Exposure to Bisphenol A from Epoxy Can Coatings" is now available and that newer methods for measuring bisphenol A are more sensitive and therefore revise downward the estimated exposure to bisphenol A. However, the revised value in the final report for estimated daily intake (EDI) of bisphenol A extracted from epoxy can linings, using the improved methods, was reduced only 35%, from 9.6 to 6.3 μg/person/day, compared to the preliminary report. The final report expressed the EDI as a potential exposure level of 0.105 μg/kg/day. However, the authors of the study state that solvents were used to stimulate the effects of food to target bisphenol A from the lining of cans, whereas in the study referred to by Hoye and Budweiser in their letter, Breton et al. (5) extracted bisphenol A actually present in the liquid phase of vegetables cooked in cans, and values published in this study ranged from 0.023 to 0.23 μg bisphenol A in a can of peas.

For chemists such as bisphenol A, the FDA calculates an acceptability index (ADI), which is assumed to be safe. To calculate the ADI, safety factors originate from the analysis of uncertainty with regard to extrapolating from animal data to estimation of risk to humans. There are three multiplicative uncertainties that apply here: 1) a 10-fold safety factor is applied when the lowest dose used in the experiment results in an adverse effect; 2) a 10-fold safety factor is normally also applied; and, in the human population, there is assumed to be a distribution of susceptibility and intake levels; and 3) because of uncertainty in extrapolating from experimental animals to humans, another 10-fold safety factor is standard. Dividing the lowest dose (2 μg/kg) in our study (that led to an adverse effect) by a safety factor of 1,000 provides an ADI of 0.002 μg/kg using current methods and 0.001 μg/kg using the ADI calculated above.

For Hoye and Budweiser to support the suggestion that "It is therefore quite clear that epoxy acrylate-coated metal food and beverage containers present no public health hazard" is completely misleading. The NIEHS BEST Program, a scientifically rigorous and relatively modest effort involving individuals who have coined the term BEST, is the "It Takes a Village approach."

Finally, since the February publication of the Best Program article, an additional school, C.C. Spaulding Elementary School, home of the new Epoxy Magnet Center, has joined the BEST Program.
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REFERENCES

The National Institute for Occupational Safety and Health (NIOSH), in association with its public and private sector partners, will host the

National Occupational Injury Research Symposium
from October 15-17, 1997 at the Appalachian Laboratorides for Occupational Safety and Health in Morgantown, West Virginia.

Be sure to visit the symposium homepage at
http://www.cdc.gov/niosh/noir.html
and visit the NIOSH homepage at
http://www.cdc.gov/niosh/homepage.html

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