

September 24, 2008

Martin Philbert, PhD BPA Subcommittee Chair
c/o Office of Science and Health Coordination
Office of the Commissioner (HF-33)
Food and Drug Administration
Rockville, MD 20857

Re: Canadian study and exposure calculations for BPA in formula

Dear Dr. Philbert:

We would like to submit to the sub-Committee a recent publication of BPA levels in Canadian infant formula (Cao 2008, attached). These tests include 21 liquid formula types purchased in 2007. Four formula companies—Abbott Nutrition, Mead-Johnson, PBM and Nestlé—dominate the U.S. and Canadian market, so the results would be reasonably reflective of exposures for American infants. These tests underscore the need for examining high-end BPA exposures for babies. Health Canada's exposure assessment addresses 2 of the 4 gaps identified by the sub-committee and the panel, and results in a tripling of the exposure estimate for hungry children fed from the worst brands.

I'd like to note a couple of key findings from the Canadian government's tests:

Eighty percent (80%) of the formulas tested exceed the BPA concentration used by FDA in their draft assessment. FDA's exposure estimate uses an average BPA level of 2.5 ppb in canned formula, and 17 of 21 formula-types exceed this value. Three ready to eat formulas were tested, but only 1 was for infants younger than 12 months.

The tests also suggest differences between brands. One company had consistently elevated levels compared to the others. The authors postulate that it could be due to the thickness of the epoxy lining used in company cans. The chemists tested at least 2 separate cans of each formula type and found high concordance among duplicate samples with an average difference of just 7.5%. Brand variability and can consistency underscores the need to calculate exposure based on the high-end formula measurements, assuming that a child is fed the same brand of formula throughout infancy.

Health Canada estimates high-end exposures by including maximum ingestion volumes and maximum BPA measurements in their calculations. These steps result in an intake estimate for BPA from canned formula that is 3 times higher than FDA's estimate over the first 7 months of life. Exposures >1 ug/kg-day from formula alone could continue through the entire first 7 months of infancy for hungrier infants, those fed ready-to-eat formula, or those whose parents choose the brand with the greatest BPA concentrations.

Health Canada's high-end exposure estimates for infants are 3 times FDA's estimate. (*ug/kg-day*)

	Exposure criteria	0 to 1 months	2 to 3 months	4 to 7 months
FDA	avg bodyweight, avg intake, avg BPA in formula, assumes dilution	0.44 – 0.46	0.36 – 0.44	0.23 – 0.33
Health Canada	avg bodyweight, high-end intake, max BPA in formula, assumes dilution for most samples	1.35	1.31	1.02

Exposures from polycarbonate bottles are not included

Health Canada's estimates do not estimate increased intensity of exposure for lighter babies, nor do they fully explore risks for those fed undiluted or 'ready-to-eat' formula. FDA should also include these 2 exposure factors in their analysis of highly exposed infants.

The authors did not detect BPA in any of the 56 canned powdered formulas tested (with a detection limit of 1 ppb), suggesting that safer alternatives exist for most infants. EWG shares the concerns raised by panelists about infants who require liquid formulations (due tap water quality or medical concerns). In our opinion the risks posed by BPA ingestion during infancy indicate that parents should select powdered formula or liquid formulas packaged in non-metal containers while safer can linings are developed.

Sincerely,

[signed]

Sonya Lunder, MPH
Senior Analyst
Environmental Working Group
Sonya@ewg.org

Attached: Cao XL, Dufresne G, Belisle S, Clement G, Falicki M, Beraldin F, Rulibikiye A. 2008. Levels of bisphenol A in canned liquid infant formula products in Canada and dietary intake estimates. J Agric Food Chem. Sep 10;56(17):7919-24. Epub Aug 15 2008.