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Re: Canada Gazette Notice Part 1 Vol. 142, No. 16 — April 19, 2008

Publication after screening assessment of a substance — Phenol, 4,4 □ -(1-methylethylidene)bis- (bisphenol A), CAS No. 80-05-7 — Specified on the *Domestic Substances List* [subsection 77(1) of the Canadian Environmental Protection Act, 1999*]*

The Learning Disabilities Association of Canada is pleased to submit these comments regarding the draft screening health assessment, and on the risk management scoping document for Bisphenol A.

General comments

The draft screening health assessment is thorough and comprehensive, including in detail the most recent research re the toxicokinetics, metabolism, toxicity and exposure data on BPA, with appropriate emphasis and calculations regarding infants and children, and their exposures from various media. In general we applaud the government's action on bisphenol A to protect infants and children. However we have serious concerns that the fetus will not be protected unless the risk management scope is expanded to reduce exposures to pregnant women. We support the conclusion based on the information in the draft screening assessment , and applying a precautionary approach, that bisphenol a meets the criteria under paragraphs 64 (a) and 64 (c) of CEPA 1999.

We support the Government's proposal to prohibit the importation, sale and advertising of polycarbonate baby bottles

We support the Government's proposal to adopt a precautionary approach for bisphenol A in food packaging, to adopt the ALARA (as low as reasonably achievable) principle for bisphenol A (BPA) in food packaging, with emphasis on infant formula.

In addition, we would support the Government taking action to establish regulations under the Food and Drugs Act to set stringent standards for the presence of bisphenol A in infant formula and cereals. Experience from other jurisdictions has shown that regulations have the effect of driving innovation – in this case necessary changes in food packaging.

The presence of BPA in house dust and soil was found to be surprisingly high in the Canadian house dust study, and this source was calculated in the health risk assessment as one of the largest sources of exposure to infants and young children. The migration from products into house dust is poorly understood, and should be included as a high priority in research needs.

Specific comments

Exposure to pregnant women/fetus

The draft screening assessment notes that the dataset of neurodevelopmental and behavioural studies, though limited, when subject to a weight of evidence analysis, is suggestive of potential effects at doses **well below the NOAEL** of 5 mg/kg/bw/day. The evaluation also describes animal studies assessing potential health impacts that show effects at levels similar to those at which humans are being exposed (0.2 to 2 µg per kg of body weight per day)

As the assessment references, bisphenol-A crosses the placenta and is present in fetal serum and amniotic fluid. Research reported in the evaluation showed

that during pregnancy the fetal environment can have levels of BPA five times as high as the levels in the mothers' blood. This accumulation in the fetal compartment, and the likelihood that the fetus is more vulnerable, point to pregnancy as a key period of human health risk. Contrary to the statement in the risk management scoping document, Infants may not be the most highly-exposed population. The government's proposed risk management focuses on infants and children and ignores the fetus. The pregnant woman/fetus is at least equally important to consider as potentially sensitive populations.

In many cases, the prenatal and perinatal period of organ development has been found to be the most sensitive to toxicants. This is particularly true for neurodevelopment, In the human brain the "brain growth spurt" occurs during perinatal development - the third trimester of pregnancy and continuing throughout the first two years of life. Exposures to a low dose of an environmental agent during this critical period for brain development - has been shown to lead to irreversible changes in adult brain function in the mouse, exposed during the corresponding brain growth spurt in rodents, the first 3-4 weeks of life[1]. The prenatal developmental test does not provide this information regarding neurodevelopment as the pups are sacrificed before they are born.

In addition to the many studies cited in the draft assessment, a study published in Endocrinology[2] reported that prenatal exposure to BPA at environmentally-relevant levels, affects anatomical and functional measures of brain development and sexual differentiation. Data from these studies revealed significant [normal] sex differences in the [placebo] -exposed offspring, that were not observed in the BPA-exposed offspring – showing weakened gender differences in the bisphenol A exposed group.

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[1] Eriksson p. (1996) Developmental neurotoxicity of enviornmental agents in the neonate. NeyuroToxicology 18 (3) 719-726.

[2] Rubin BS. Lenkowski JR et al. (2006) EVIDENCE OF ALTERED BRAIN SEXUAL DIFFERENTIATION IN MICE EXPOSED PERINATALLY TO LOW, ENVIRONMENTALLY RELEVANT LEVELS OF BISPHENOL **A. Endocrinology**

A synopsis of the conclusions of 38 international scientific experts [3] included this reference to prenatal exposures and effects: "Specifically, prenatal and/or neonatal exposure to low doses of BPA results in organizational changes in the prostate, breast, testis, mammary glands, body size, brain structure and chemistry, and behavior of laboratory animals."

Reducing exposures to the general population from bisphenol A in food packaging, polycarbonate water bottles and other containers would reduce exposures to pregnant women. In addition specific advice from Health Canada to pregnant women on reducing their exposures from these and other sources of BPA – such as dental materials is necessary and important.

Categorization criteria for bioaccumulation and persistence

Bisphenol A did not meet the categorization criteria for bioaccumulation. However a recent study noted that lipid-water partitioning cannot serve as a universal model for identifying bioaccumulative substances in wildlife and humans[4]. As noted in the risk scoping document BPA is more likely to partition to soil, so bioaccumulation in soil-dwelling species would be more relevant to measuring and defining bioaccumulation potential.

RM scope for BPA in food and water

BPA has been found in non-canned food; has been widely detected in sewage sludge and surface waters; and has been found to degrade slowly in anaerobic conditions such as soil. The assessment notes that concentrations as high as

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[3] vom Saal, FS, SM Belcher, LJ Guillette, R Hauser, JP Myers, GS Prins, WV Welshons, JJ Heindel et al. 2007. Chapel Hill Bisphenol A Expert Panel Consensus Statement: Integration of mechanisms, effects in animals and potential impact to human health at current exposure levels. Reproductive Toxicology,

[4] Kelly BC, Ikonomou G, Blair jd, Morin AE & Gobas FAPC. (2007) Food web-specific biomagnification of persistent organic pollutants. Science, Vol 317, 236-238.

40,000 ug/kg dw were reported in municipal wastewater sludges collected from sewage treatment plants.

This raises the question about the safety of applying sewage sludge to pastures and fields where crops and vegetables are grown. Uptake into plants and crops grown for food has not been researched to date. We would support the risk management proposal that would consider BPA in wastewater streams as part of the federal government's regulatory framework for wastewater. In addition it will be important to involve the provincial and territorial governments in setting standards for bisphenol A in sewage sludge spread on farmland, and research to determine possible uptake into plants and vegetables from the use of sewage sludge.

The migration of BPA in inks used in food packaging into food needs to be considered toward reducing this dietary source of BPA.

A recent report focused on the BPA contamination of recycled paper, including toilet paper, and corrugated paper made from recycled paper. The concentration of BPA in toilet paper ranged from 0.93- 4.23 mg/kg D.M. [5] which the authors stated is an important source of xenoestrogens to wastewater.

A study of BPA levels in paper food containers found between 190 and 26,000 nanograms per gram in eight of the 12 food containers made from recycled paper, including sandwich and fried chicken packaging. The highest levels of BPA-26,000 nanograms per gram in a sandwich box- were considered to be equal to BPA levels found in polycarbonate plastic food packaging. Upon further examination, the researchers found microscopic traces of ink and copy paper

[5] M. Gehring, D. Vogel, L. Tennhardt, D. Weltin & B. Bilitewski Bisphenol A contamination of wastepaper, cellulose and recycled paper products. Waste Management and the Environment II, witpress.com.

among the fibers of items made from recycled pulp, which could explain the source of the contamination[6].

In Conclusion

We applaud the government's action in designating bisphenol A as toxic under CEPA: the decision to ban polycarbonate baby bottles; and the proposal to reduce exposures from epoxy linings in formula cans. However we disagree with the Government of Canada's intention, as stated in the risk management scooping document, not to take action on other sources of exposure to BPA and the reasoning given - that exposure is low and poses little risk to the general population. The presence of levels of BPA up to 23.8 µg/g in house dust from the Canadian House Dust Study gives evidence of other important sources of exposure in the home, especially to infants and children. In addition, pregnant women are part of the general population. The risk management scoping document does not reflect the scientific evidence contained in the draft assessment regarding fetal levels of BPA and the vulnerability of the fetus during development. While we welcome the government's concern for infants and children, this concern should be equally applied to the developing fetus in determining risk management practices.

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[6] Asako Ozaki, (2002) Osaka City Institute of Public Health and Environmental Sciences