



January 30, 2009

National Center for Environmental Assessment
Environmental Protection Agency
c/o EPA Docket Center, Mail Code 2822T
EPA West Building
1301 Constitution Ave., NW
Washington, DC 20005

Docket ID: EPA-HQ-ORD-2008-0663

RE: Comments on NCEA's Exposure Assessment of PBDEs (November 2008 draft)

To Whom It May Concern:

Environmental Working Group is pleased to submit these comments on the November 2008 draft National Center for Environmental Assessment (NCEA) report "*Exposure Assessment of Polybrominated Diphenyl Ethers.*" This important and timely document represents careful work by EPA scientists to assess the magnitude of current exposures in the U.S. to the ubiquitous fire retardants PBDEs (polybrominated biphenyl ethers). The need for a thorough exposure assessment could not be more acute, given that the widespread, long-term use of these chemicals in common consumer products like furniture and electronics has led to PBDE pollution in human blood and breast milk nationwide, and given that numerous studies show PBDEs to be toxic at low levels, particularly for the fetus, infant and young child.

Although the only U.S. manufacturer of 2 major commercial formulations of PBDEs (Penta and Octa) ceased making the chemicals in 2005 when studies reported it at high levels in breast milk from American mothers, a third form (Deca) remains on the market. Maine and Washington have banned the use of Deca in consumer products, but it remains in use in most of the country. Young children remain at risk from continuing exposures to Deca, in combination with the withdrawn forms of PBDEs that remain ubiquitous pollutants in human blood and breast milk.

We are pleased to see in EPA's draft assessment an examination of PBDE

exposures and behavioral characteristics that put infants and children at risk for increased PBDE intake. But we have concerns that the assessment underestimates exposures for the fetus, infant and young child. To fully represent risks to young children, EWG recommends:

- EPA should assess and document the full range of exposures for the fetus, breastfed infant, and young child. In particular, EPA should estimate high-end exposures for these vulnerable populations, including those up to the 99.9 percentile, so that risk management actions can identify and protect these highly exposed populations. Additionally, EPA should estimate the percentage of the population exposed at levels above the reference dose, so that the ramifications of continued exposures can be more fully understood.
- EPA should discuss risks to the fetus. PBDE exposures begin in utero; exposure assessments for infancy and early childhood should consider the background levels in newborns from transfer of a mother's PBDEs across the placenta.
- EPA should incorporate the full range of available exposures measures into the assessment. EWG finds that some studies included in the draft were not used for exposure calculations, resulting in potential underestimates of exposures.

Finally, EWG urges the Agency to take quick action to reduce risks from PBDE exposures. The draft exposure estimates presented in this report show that at least half of all breastfed infants in the U.S. may be exposed to PBDEs at unsafe levels. We urge EPA to take action to phase Deca out of use in consumer products so that Americans will no longer face continued exposures to these toxic chemicals.ⁱ

Exposures to the fetus and newborn:

The draft report finds intense PBDE exposures during pregnancy and early life. The calculations provided show that breastfed infants are the most highly exposed of any population with typical exposures of more than 1,400 ng PBDE/day. This indicates that many breastfed babies could exceed the reference doses for PBDE-47, -99, -153, some by a dramatic margin.

Exposures in the womb may pose even greater risks. It is important to note that pregnancy may be the period of greatest risk of toxicological harm. Estimates of infant and childhood exposures should account for the “background” concentration of PBDEs in infants at birth. The findings of this draft assessment indicate that adult women’s intake may need to be much less than the current reference dose in order to protect her developing fetus or nursing infant from excessive exposure.

To our knowledge only 2 samples of infant formula have been tested for PBDEs (Schechter 2006). Deca PBDE was reported in high levels in soy formula. Further testing is warranted to determine whether soy or milk-based formulas could be an exposure source for newborn babies. EPA should acknowledge this data gap in their discussion of infant exposures via food.

Exposures to young children:

The Agency confirms the conclusions of other studies, namely that children are a high-risk group and that their exposure is dominated by ingestion of PBDE-laden house dust. EPA’s intake calculations suggest that typical PBDE intakes for 1 to 5 year olds is 751 ng/day or 50 ng/kg-day. However the draft intake estimate ignores findings from Stapleton’s hand wipe study (2008), which reports median intakes of 1380 ng/day for children. Hand wipe sampling is an accepted exposure measure that may better reflect dust intake than other more indirect types of household dust studies (like vacuum bag studies). EPA should use this data to estimate children’s PBDE exposure, which would double the current estimate.

Despite a lengthy discussion of the variability of PBDE levels in Americans’ bodies and in environmental media (including household dust), the draft report fails to quantify high-end exposures for all age groups. This is particularly problematic when considering risk of dust ingestion for children. Several dust studies highlight intense exposures for the top 5% of children. Stapleton’s hand wipes find the 95th percentile dust exposures 6,090 ng/day, 8 times greater than EPA’s estimate (Stapleton 2008). Jones-Otazo (2005) and Allen (2008, as cited by Stapleton 2008) estimate even greater PBDE ingestion, 19,000 and 18,700 ng/day respectively. These measurements are about 25 to 30 times EPA’s mid-range value.

Exposures to the top 5th percentile, which equates to roughly 1 million

American children between the ages of 1 and 5 year old, is a serious gap in the report. Very high-end exposures, such as at the 99.9th percentile, should also be estimated, so that the full range of children's exposures can be fully understood. Children who live in houses or attend daycare centers with excessive PBDE levels, or whose behavior places them at higher risk for PBDE exposures must also be protected, and will not be without a careful consideration of their unique risks.

High-end exposures are of critical concern as the Agency considers the safety of present-day exposure to PBDEs. Further modeling should be performed to estimate what proportion of young children exceed EPA's reference doses for the common PBDEs based on dust ingestion, breast milk ingestion or other unusual exposures. The Agency should calculate the number of women whose PBDE exposures put their developing fetus or nursing infant at risk. The evidence presented makes a strong case that the Agency will need to consider actions to PBDE exposures for women of childbearing age if it wants to assure that babies do not exceed the reference dose during gestation or nursing.

Finally, we would like to call your attention to a recent Environmental Working Group and Stockholm University study of 20 American families. We analyzed paired blood tests from mothers and their 1 to 4 year old children. Consistent with EPA's modeling, we found children had significantly higher PBDE levels than their mothers. The average difference in total PBDEs was 3-fold elevation in children. Children's PBDE levels for specific congeners exceeded maternal measurements 86% of the time. Our data are being prepared for publication, and a summary can be found at: www.ewg.org/reports/pbdesintoddlers

Sincerely,

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References:

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Jones-Otazo HA, Clarke JP, Diamond ML, Archbold JA, Ferguson G, Harner T, Richardson GM, Ryan JJ, Wilford B. 2005. Is house dust the missing exposure pathway for PBDEs? An analysis of the urban fate and human exposure to PBDEs. *Environ. Sci. Technol.* 39 (14), 5121–5130.

Schechter A, Pöpke O, Harris TR, Tung KC, Musumba A, Olson J, Birnbaum L. 2006. Polybrominated diphenyl ether (PBDE) levels in an expanded market basket survey of U.S. food and estimated PBDE dietary intake by age and sex. *Environ Health Perspect.* Oct;114(10):1515-20.

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U.S. EPA, Lorber M, Cleverly D. 2008. An Exposure Assessment of Polybrominated Diphenyl Ethers (External Review Draft). U.S. Environmental Protection Agency, Washington, D.C., EPA/600/R-08/086A.

ⁱ The draft report's estimate for typical PBDE exposure level for breastfed infants is 1,400 ng/day, which is about 300 ng/kg/day for a 10-pound infant. Breastfed infants exposed at this level may exceed the reference doses for PBDE-47, -99, and -153. For instance, a 10-kg infant drinking breast milk contaminated with a mixture of PBDEs made up of 50% PBDE-47, would be exposed to around 150 ng/kg/d PBDE-47, 50% higher than the reference dose for this chemical.)