

Submission on

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Final Screening Assessment and the Proposed Risk Management Approach
for
Phenol, 4,4'-(1-methylethylidene)bis-(Bisphenol A), CAS No. 80-05-7

Submitted to:
Environment Canada
Health Canada

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by

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Re: Submission on bisphenol A (BPA)

A. General Comments

This submission includes comments, issues and recommendations pertaining to the final screening assessment and proposed risk management approach for Bisphenol A, published October 18, 2008.

Firstly, I wish to express my support for the conclusion of the final screening assessment that BPA meets the criteria to be declared toxic under sections 64(a) and 64 (c), of the *Canadian Environmental Protection Act* (CEPA 1999). I also support the Government of Canada's proposal to list bisphenol A (BPA) as a toxic substance under Schedule 1 of CEPA 1999, both for its potential impacts on human health and the damage it could cause to ecosystems.¹

BPA is an acutely toxic reproductive and developmental substance. It is also well recognized as an estrogenic chemical. It is prevalent in numerous commonly-used consumer products, from polycarbonate baby bottles, water bottles and food cans; paints, water pipes, medical devices, computer parts, windshields, dental products, adhesives, and lubricants to the production of some polyesters, polyurethanes and polyvinyl chloride and in cosmetics. Its diversity of uses creates a myriad of exposure routes and leads to widespread contamination of the environment.

The screening assessment report provides a fairly comprehensive coverage of toxicity and exposure data, with prominence placed on infants, as they are the most highly exposed population. The report also indicates the uncertainties associated with much of the information and the application of a precautionary approach in formulating conclusions.

However, the report does not account for the full range of routes and magnitude of exposure including adult and occupational exposure or the potential effects of cumulative exposure. In light of recent studies indicating adult exposure to BPA may be of greater significance than has been previously thought, this is disconcerting.

¹ *Screening Assessment for the Challenge Phenol, 4,4'-(1-methylethylidene)bis-* (80-05-7) October 2008.
http://www.ec.gc.ca/substances/ese/eng/challenge/batch2/batch2_80-05-7_en.pdf

The assessment found that BPA does not meet the criteria for persistence in air, water, or soil, but in sediment, and does not meet the criteria for bioaccumulation. This is a highly questionable finding and would seem contrary to taking a precautionary approach. It is also disturbing as it predicated the path of the risk management approach, that is, rather than subjecting BPA to virtual elimination provisions under CEPA 1999, BPA is to be managed using a “life-cycle approach, to prevent and minimize releases to the environment”.

The Government’s Proposed Risk Management Approach calls for a ban on baby bottles to ban the importation, sale and advertising of polycarbonate baby bottles, consultation with industry in developing codes of practice to reduce levels of BPA found in infant formula packaging to “as low as reasonably achievable”, and regulations to prevent or minimize releases to the environment, and wastewater systems.²

While the ban on BPA-containing baby bottles is a significant action, the proposed risk management approach on the whole is seriously limited. The pregnant woman/fetus, clearly identified as vulnerable populations in the screening assessment, is not included in the risk management approach. No actions are proposed for other BPA-containing products. No consideration is given to exposure of the adult population to BPA from food, the workplace, and other sources. No mention is made of the links of BPA exposure to increased risk in prostate cancer, cardiovascular disease, and other disorders.

Given the insidious and ubiquitous nature of BPA, the risk management approach needs to be far more comprehensive than it presently is, and precautionary. Efforts must be directed toward reducing and eliminating the use of BPA and finding safer alternatives, and not only on preventing and minimizing releases.

The comments and recommendations that follow are intended to highlight those specific elements that speak to the concerns outlined above, and other issues related to data and information on BPA.

B. Studies on BPA – Human Health Effects

New studies continue to mount on the adverse effect of exposure to BPA. In addition there have been several recent studies linking exposure to BPA to Prostate Disease.

New Studies

- A study published in the *Journal of the American Medical Association* in September 2008 found an association between BPA exposure at the high end of normal population levels and adult-onset diabetes and cardiovascular disease.³ Accordingly, the study concluded that “higher BPA exposure, reflected in higher

² Proposed Risk Management Approach for Phenol, 4,4’ –(1-methylethylidene) bis- (Bisphenol A) (80-05-07), Environment Canada, Health Canada October, 2008 p.13, 14.
http://www.ec.gc.ca/substances/ese/eng/challenge/batch2/batch2_80-05-7_en.pdf

³ Association of Urinary Bisphenol A Concentration With Medical Disorders and Laboratory Abnormalities in Adults Iain A. Lang; Tamara S. Galloway; Alan Scarlett; William E. Henley; Michael Depledge; Robert B. Wallace; David Melzer. *JAMA*. 2008;300(11):1303-1310. Published online September 16, 2008

urinary concentrations of BPA, maybe associated with avoidable morbidity in the community-dwelling adult population.”

- According to a study published in April in *Cancer Research*, many genes in non-cancerous breast cells exposed to trace amounts of bisphenol A begin acting in a way that closely resembles gene activity in highly aggressive breast tumours.⁴
- A study published in the *Proceedings of the National Academy of Sciences* in September 2008 showed that, in a primate exposed to a daily dose equal to the current US safe daily limit, bisphenol A interfered with the formation of some types of synapses in the brain: “Because remodelling of spine synapses may play a critical role in cognition and mood, the ability of BPA to interfere with spine synapse formation has profound implications. This study is the first to demonstrate an adverse effect of BPA on the brain in a nonhuman primate model and further amplifies concerns about the widespread use of BPA in medical equipment, and in food preparation and storage.”⁵
- A study by University of Cincinnati scientists (October 2008) stated that BPA actually induces a group of proteins that protect cancer cells from the toxic effects of chemotherapy. The study concluded that BPA at environmentally relevant doses reduces the efficacy of chemotherapeutic agents.⁶
- The U.S. *Food and Drug Administration (FDA)* Science Board Subcommittee peer review on BPA noted that consideration needs to be given to several studies, despite their limitations, of effects of BPA on adult humans and animal species that were published after the FDA assessment was completed.⁷ The peer review report also commented that “the exposure assessment is focused on food contact applications only and does not consider the potential cumulative and interactive effects of non-food contact exposures to BPA. As a result, the human health risks of the food contact applications may be understated when only a single source of exposure is considered and limited data are available regarding other food contact exposures (e.g., polycarbonated sippy cups and sport bottles)”.

Link of BPA to Prostate Disease

A number of animal studies have shown that low-dose exposure to BPA can significantly increase prostate size and initiate the proliferation of human prostate cancer cells. For example, one of such studies published in the issue of *Cancer Research* (June 1, 2006) reported evidence of a direct link between development of prostate cancer and early life exposure to two estrogenic chemicals, the natural human estrogen, estradiol, and

⁴ Shanaz H. Dairkee, Junhee Seok et al: Bisphenol A Induces a Profile of Tumor Aggressiveness in High-Risk Cells from Breast Cancer Patients : *Cancer Research* 68, 2076-2080, April 1, 2008

⁵ Csaba Leranth, Tibor Hajszan, Klara Szigeti-Buck, Jeremy Bober, and Neil J. MacLusky: Biological Sciences - Neuroscience: *From the Cover: Bisphenol A prevents the synaptogenic response to estradiol in hippocampus and prefrontal cortex of ovariectomized nonhuman primates* *PNAS* 2008 105:14187-14191

⁶ E. W. LaPensee, T. R. Tuttle, S. R. Fox, N. Ben-Jonathan: Bisphenol A at low nanomolar doses confers chemoresistance in estrogen receptor alpha positive and negative breast cancer cells *Environmental Health Perspectives* [Online 8 October 2008, doi: 10.1289/ep.11788 available at <http://dx.doi.org/> Abstract: <http://www.ehponline.org/docs/2008/11788/abstract.html>

⁷ Scientific Peer-Review of the FDA Draft Assessment of Bisphenol A for use in Food Contact Applications, October 2008: <http://www.fda.gov/OHRMS/DOCKETS/ac/08/briefing/2008-4386b1-05.pdf>

bisphenol A (BPA). The findings of the study indicate that very low levels of exposure during development to environmental and natural estrogens can affect the behavior of prostate genes and promote prostate disease during aging.⁸ Prior experiments have shown that comparable doses in animals have multiple adverse effects, including alterations in prostate size, mammary gland development, sperm density, behavior and errors in cell division.⁹ These studies add to the weight of evidence that developmental exposure to endocrine disrupting contaminants can cause adverse effects in adulthood.

The findings of such studies have been met with controversy. The assessment report commented that the “limited evidence of the association of BPA to neoplastic transformation in the prostate and mammary gland of adult rats is insufficient to demonstrate that early BPA exposure, acting independently, could lead to neoplastic events”. At the same time, the report stated that “further research was needed in the role of early life exposures to BPA, particularly via routes most relevant to human exposure, in the process of carcinogenesis”.¹⁰

Regardless of how or whether there is resolution as to the controversies over the findings and interpretations of implications of the studies indicated, these studies provide considerable support to the accumulating evidence that BPA is hazardous to human health and that precautionary measures are needed to prevent exposure to BPA.

Recommendations

In applying a precautionary approach to characterizing risk, it is important that recent findings and studies on BPA be considered in the final screening assessment report and risk management approach as they may well have a significant bearing on actions that need to be taken regarding the use of and exposure to BPA.

- Findings from new and emerging studies on BPA need to be reviewed on a continuous basis.
- The screening assessment needs to be updated, and amended accordingly with ongoing research on BPA.
- The risk management approaches need to consider the implications of new studies in formulating its actions.

C. Releases of BPA to the Environment

The National Pollutant Release Inventory (NPRI) is used to track the annual releases, disposal and of BPA. However, there are notable limitations to the information that is obtained via the NPRI. For example,

- The NPRI does not cover all facilities that may be releasing BPA.

⁸ Ho, S-M, W-Y Tang, J Belmonte de Frausto, and GS Prins. 2006: Developmental Exposure to Estradiol and Bisphenol A Increases Susceptibility to Prostate Carcinogenesis and Epigenetically Regulates Phosphodiesterase Type 4 Variant 4. *Cancer Research* 66: 5624-5632.

⁹ <http://www.eh.uc.edu/news/pdfs/BPA%20Ho%20and%20Prins.pdf>

¹⁰ Assessment Report, P. 59

- The reporting criteria for BPA may not necessarily trigger facility reporting and is likely not suitable for BPA.¹¹
- Facilities are not required to measure or monitor their emissions.
- Neither the recipient nor location of off-site disposals is identified.

In fact, the assessment report did note that “only facilities meeting established criteria are required to report to the NPRI, and therefore NPRI data are likely to underestimate total Canadian releases of bisphenol A.”¹²

Because the NPRI provides an annual report of releases of pollutants, it is not possible to account for incidences that could lead to highly significant variation in emissions such as upsets in operations, shutdowns, and purging or maintaining equipment. These incidences may have the largest, immediate impact on local communities.

NPRI data on BPA

Only 6 to 7 facilities in Canada have reported releases of BPA for years 2003-7. These releases, shown in the table below, are to air or off-site disposal (i.e., landfill and/or municipal sewage treatment plants).¹³

Releases of BPA (in tonnes) 2003 -7

Year	Releases to Air	Disposal Off-site	Major Facility Source
2003	8.8	14	Ford Motors-Oakville
2004	4.5	8.5	Ford Motors-Oakville
2005	0.12	1.2	
2006	0.159	2.9	
2007	0.126	9.4	Howmet Aluminum Casting

No releases to water or land were reported, which may well be attributed to thresholds for reporting, as noted in the Proposed Risk Management Approach Document (p.7). Yet BPA has been identified in groundwater samples collected in the vicinity of municipal landfills.¹⁴

The data on BPA may best be described as erratic. For example, Howmet Aluminum Casting (Georgetown) did not report any releases in 2006, but was the primary source of disposal levels in 2007 (7.9 tonnes) and anticipates levels of disposal for 2008-10 to be in the order of 8 to 8.75 tonnes. Ford Motors (Oakville), reported emissions to air of 8.8 and 4.4 tonnes for 2003 and 2004 and disposal level of 11 and 5.7 tonnes but did not report any releases in the following years.

Such disparities question the veracity of the data.

¹¹ Reporting criteria for most substances including BPA are 10 tonne manufactured, processed or otherwise used (M,P,O) at a concentration $\geq 1\%$ by weight and ten full-time employees for a given calendar year.

¹² Assessment Report p.8

¹³ The assessment report (p.10) showed release data for 2001-5 but did not identify the major source.

¹⁴ Proposed Risk Management Approach Document (p.7, 8).

Use Data on BPA

Based on the surveys carried out under section 71 of CEPA 1999, twenty-five companies reported importing approximately 500 tonnes of BPA in 2006 and five companies reported using 100 to 1000 tonnes of BPA either alone or in a product, or mixture or in a manufactured item. The information on use is not specific and inadequate.

Specific information in the survey is treated as confidential, while the NPRI is a public inventory. It is impossible to relate the NPRI release data with results of the survey.

Recommendations - NPRI

The NPRI is the main public tool on pollutant releases. Since it is being referred to and used to examine releases of BPA to the environment, efforts must be made to improve the NPRI in terms of thresholds, data quality and clarity of information (e.g., disposal).

- The threshold for reporting BPA to the NPRI must be examined and set at an appropriate level to be able to account for at least 90 per cent of releases of BPA to the environment.
- The methodology of determining BPA releases needs to be standardized. Facilities must be required to conduct measuring and monitoring of releases.
- Facilities must be required to report the location and recipient of off-site disposal. Additional monitoring tools are needed to assess levels of BPA in water, air, landfill and sewage treatment plants.
- Confidentiality issues related to uses of BPA make it impossible to relate the NPRI release data with use. The public should have access to this information.
- The Domestic Substance List (DSL) inventory update exercise should include specific information on importation and use levels of BPA.

D. Draft Assessment Report - Issues

Vulnerable Populations

The potential exposure of adults and the possible adverse health effects on vulnerable populations, notably the pregnant woman and the fetus, could well be underestimated.

Occupational Exposure

The potential exposure of workers to BPA in occupational settings is inadequately reported. Considering the widespread and diverse use of BPA in industry, more detailed information on occupational exposure data and occupational risk management for BPA should have been included in the assessment document. There are indications that sperm count and quality for the male workers in industries using BPA are of concern.

Additional Sources of Exposure

While dietary intake is a major exposure source for BPA, other sources of exposure, such as transdermal and inhalation, also require adequate evaluation.

No mention is made of the impact of repeated reheating of polycarbonated containers in microwave ovens and potential breakdown that could lead to leaching of PBA into food.

The exposure assessment does not consider the potential cumulative and interactive effects of non-food contact exposures to BPA. As a result, the human health risks of the food contact applications may be understated when only a single source of exposure is considered.

Persistence and Bioaccumulation

The assessment found that BPA does not meet the criteria for persistence in air, water, and soil but in sediment, and based on available information, does not meet the criteria for bioaccumulation as set out in the *Persistence and Bioaccumulation Regulations* of CEPA 1999.

Persistence

The assessment report acknowledges conflicting evidence on the aerobic biodegradation potential of BPA from field tests, modelling and laboratory studies. The evidence from these studies were combined at differing *weights* as a means of arriving at reliable evidence to formulate a conclusion on persistence. This combined evidence suggested that bisphenol A does not meet persistence criterion for air (half-life in air ≥ 2 days), water and soil (half-life in soil and water ≥ 182 days).¹⁵

The assigning of weights to these different methodologies with contradictory findings and poor data is a subjective and contentious means to arrive at a conclusion.

On the other hand, many studies show that BPA does not degrade or degrades only slowly under conditions of low or no oxygen and the measured presence in sediment. a medium which receives no direct release of BPA. Therefore, BPA was found to meet criteria for persistence in sediments (half-life in sediments ≥ 365 days).

Bioaccumulation

The assessment report notes the uncertainty about the measured presence and accumulation potential of BPA in biota. BPA is well recognized as acutely toxic to aquatic organisms. Bioaccumulation factors of up to 650 have been determined for lower trophic level aquatic species, suggesting there may be circumstances or conditions under which BPA may accumulate within organisms. It is also possible that bioaccumulation is occurring with the subsequent potential for food chain transfer and secondary poisoning of predator species.¹⁶

The report also notes that “an increased database of measured concentrations in Canadian biota, including trophic magnification studies, would provide greater clarity on the potential for accumulation within individual organisms and along food webs.”

¹⁵ Screening Assessment Report, p.14,15

¹⁶ *ibid*, P. 34

The conclusion that BPA does not bioaccumulate within organisms or up the food chain in light of the indicated uncertainties and lack of information would seem to conflict with these statements in the report, and with the application of a precautionary approach.

It is also disturbing as it predicates the path of the risk management approach, that is, rather than subjecting BPA to virtual elimination provisions under CEPA 1999, BPA is to be managed using a “life-cycle approach, to prevent and minimize releases to the environment”.

Application of Precautionary Principle

Little information is provided about how the precautionary principle was applied to the conduct and interpretation of the results of the screening assessment. Yet reference is made to how conclusions were based on the application of a precautionary approach. No explanation is provided in either Environment Canada’s *Overview of the Ecological Assessment of Substances under the Canadian Environmental Protection Act, 1999*¹⁷ or in the *Framework for the Application of Precaution in Science-Based Decision Making about Risk*, 2003.¹⁸

Recommendations

- The exposure assessment should consider the potential cumulative and interactive effects of non-food contact exposures to BPA.
- Sources of exposure, such as transdermal and inhalation, in addition to dietary require adequate evaluation.
- The assessment should include Occupational exposures to BPA, including industries using BPA, BPA-derived epoxy resins and polycarbonate fabrication that could pose a risk of exposure to BPA, should be addressed in the assessment.
- The finding that BPA is neither bioaccumulative nor persistent in air, water and land is questionable and needs to be reviewed, particularly in light of conflicting and obscure methods used in coming to this conclusion.
- Demonstration of how the precautionary principle has been applied in formulating decisions should be included.

E. Proposed Risk Management Approach for Bisphenol A

The health objective of the government’s risk management approach is to minimize infant exposure to the greatest extent practical and its environmental objective is to

¹⁷ Environment Canada, *Overview of the Ecological Assessment of Substances under the Canadian Environmental Protection Act, 1999*, June 2007.

http://www.ec.gc.ca/ceparegistry/documents/subs_list/evaleco-ecoassess/OverviewOfEA_en.pdf

¹⁸ *A Framework for the Application of Precaution in Science-Based Decision Making about Risk*, 2003. http://www.pco-bcp.gc.ca/docs/information/Publications/precaution/Precaution_e.pdf

prevent or minimize releases of BPA into the environment (p.12, 13). Main features of the Risk Management Approach proposed by the federal government are to:

- Ban the importation, sale and advertising of polycarbonate baby bottles made with bisphenol A monomer.”¹⁹ This is the most significant feature.
- Reduce BPA levels found in infant formula packaging to “as low as reasonably achievable”, and implement codes of practice for industry.²⁰
- Explore the option of setting limits to migratory levels of BPA in other canned food.
- Impose regulations to prevent or reduce BPA releases to the environment, including: establishing maximum concentrations in effluent; require best management practices; monitoring of industrial releases; and, a verification protocol according to government standards.
- Work with provincial, territorial, and municipal agencies to minimize the amount of BPA release from recycling and disposal of BPA products.
- Other actions include further information gathering, human exposure surveys, environmental monitoring, and research.²¹

F. Issues: Risk Management Approach

The proposed approach is premised on the continuing the use of BPA rather than eliminating the use of BPA in products in the first place as the best route to protect the most vulnerable populations and human health and prevent releases to the environment. Specifically,

- The health and environmental objectives are too limited in scope. While infants are the most sensitive populations, several other populations need to be considered, in particular, the pregnant woman/fetus, exposed workers, etc., as well as aquatic ecosystems.
- There are no plans to take further action for consumer products containing BPA, beyond baby bottles and infant formula.²²
- In seeking lowest levels of BPA in food packaging for infants, there is no mention of the implication of multiple sources of BPA-exposure from several packaged products.
- Codes of Practice for reducing levels of BPA in infant food packaging are voluntary measures and not appropriate for a toxic substance, particularly one as prevalent and hazardous as BPA. Mandatory action is required.
- Recycling/Disposal issues: The proposed action is vague. There must be a uniform strategy in place to deal with the collection and disposal of BPA-

¹⁹ Proposed Risk Management Approach for Phenol, 4,4' –(1-methylehylidene)bis- (Bisphenol A) (80-05-07). October, 2008, Environment Canada, Health Canada p. 13

²⁰ Ibid, p.14

²¹ Ibid, p.16

²² Ibid, p. 7

products. There is no indication how or whether industrial disposal is to be dealt with.

Other actions indicated on monitoring the environment need more detail for commenting.

Recommendations

- The risk management plan should cover the broader use of BPA in order to minimize and prevent environmental and health-related risks.
- The plan should include the elimination of BPA-containing food and beverage containers that create direct exposures.
- Sectors with high occupational exposure in the BPA industry should be identified and efforts put in place to reduce the levels of residual BPA in products.
- The use of BPA-based epoxy resin can linings should be phased out by a regulatory framework with the objective of eliminating BPA-based can linings for infant formula and food. Manufacturers of can linings should be obligated to prove that these linings are safe before they enter the market.
- Risk management of BPA must put more effort into safe BPA substitutes, particularly in situations where there is greater potential for BPA to do harm to human health and ecosystems.
- The risk management approach should provide assurance that BPA-containing products will be collected and disposed of safely through mandatory measures.

Above all, the risk management approach should focus on eliminating the use of BPA and finding safer alternatives as the best way to protecting infants, pregnant women and the fetus and other vulnerable populations from exposure to BPA.

G. Concluding Remarks

While more studies and research will no doubt continue on BPA, uncertainties and controversies are bound to surface. At this stage, after decades of use of this substance, we know well enough that it is dangerous.

In banning baby bottles containing BPA, Canada is the first country to bring in measures to control exposure to BPA. I urge the Government to go further and take a strong precautionary approach toward the elimination of the use of BPA as the ultimate means of protecting human health and the environment.