

Joint NGO Submission

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

Submitted to:
Environment Canada
Health Canada

Submitted by the following Organizations:

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Labour Environmental Alliance/Toxic Free Canada
Reach for Unbleached
Saskatchewan Environmental Society
STORM Coalition
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Re: Joint non-government organization (NGO) submission on the draft screening assessment of bisphenol A (BPA) and on the risk management scope document, April 19, 2008.

A. General Comments

This joint submission includes comments, issues and recommendations regarding the documents cited above for your consideration in finalizing the screening assessment and developing the appropriate risk management approach for Bisphenol A.

Firstly, NGOs fully support the Government of Canada's proposal to list bisphenol-A (BPA) as a toxic substance under Schedule 1 of the *Canadian Environmental Protection Act* (CEPA 1999), both for its potential impacts on human health and the damage it could cause to ecosystems.¹

We further support the application of a precautionary approach in formulating the conclusion of the draft screening assessment that BPA meets the criteria under sections 64(a) and 64 (c), CEPA 1999 to be declared toxic.

We find the draft screening assessment to be fairly comprehensive in terms of toxicity and exposure data on BPA, with emphasis on infants and children. However, we wish to note that it does not fully account for the full range of routes and magnitude of exposure, including occupational exposure.

BPA is an acutely toxic reproductive and developmental substance. It is prevalent in numerous commonly-used 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 use makes it all the more pervasive.

Considering the nature of BPA and its pervasiveness, we expect the risk management approach to be comprehensive and precautionary, and place protection of human health and the environment as the foremost principles in developing appropriate action on such a toxic substance. However, the proposed actions by the Government, as indicated in its Risk Management Scope document, fall far short of our expectations.

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

As indicated in the Scope document, the Government proposes to prohibit the sale and importation into Canada of polycarbonate baby bottles. As well, it proposes to consult with industry on reducing levels of BPA found in infant formula packaging to “as low as reasonably achievable”.²

Despite evidence of significant risk to health and the environment described in the draft assessment, the government has not indicated any plans to take further action. No risk management actions are intended for specified products which include automotive parts, dental materials, two-component epoxy adhesives, optical lenses, and polycarbonate water bottles.³

B. Draft Screening Assessment - Highlights of Findings

The findings in the screen assessment report are compelling. For example;

- In a study of humans, BPA levels were found to be 5-fold higher in amniotic fluid than the mother’s blood by the middle of her pregnancy.⁴ The assessors suggested this was evidence that repeated BPA exposure could lead to fetal accumulation of the chemical and noted that the fetus and infant may be at higher risk due to a reduced ability to clear the chemical.
- Human exposure to BPA in Canada results primarily from dietary intake (i.e., migration from food packaging and from repeat-use polycarbonate containers), as well as from environmental media (e.g., ambient air, indoor air, drinking water, soil and dust), and from use of consumer products and other sources
- Levels of BPA in canned infant formula were found as high as 10.2 parts per billion (ppb). Likewise, maximum concentrations of BPA in formula from polycarbonate baby bottles (based on tests with boiling water) were estimated at 10 ppb.⁵ Human breast milk levels were found to be as high as 7.1 ppb, excluding women with any occupational exposure to BPA.⁶ BPA levels in food included a maximum of 385 ppb found in canned food.⁷
- Preliminary data from the ongoing Canadian House Dust Study detected BPA in the house dust of 99% of Canadian households.
- BPA has been associated with obesity, endometrial hyperplasia, recurrent miscarriages, and polycystic ovarian syndrome in research looking at humans, but that none of the studies were considered to be particularly strong.

² Draft Risk Management Scope for Phenol, 4,4’ –(1-methylethylidene) bis- (Bisphenol A) (80-05-07). April 2008, Government of Canada. p. 7

³ Ibid, p. 7

⁴ *Draft Screening Assessment* , p.56

⁵ Ibid, p.42

⁶ Ibid, p.38

⁷ Ibid, p.35

- The persistence of BPA in sediment, combined with the high levels of human production and use, could create environmental stores of BPA that could act as future sources of exposure to organisms.
- Some animal studies on the potential health effects of BPA showed an increased likelihood of developing prostate and breast cancer, and early puberty, both at very low doses of exposure. Though there has been controversy about how BPA can cause these effects seen in animal studies, the draft assessment suggested it may be happening at the cell membrane. BPA may be as potent as estrogen itself at certain cell membrane receptors.⁸
- The draft assessment report concludes that there is “strong evidence” that BPA can cause harmful effects to organisms (fish to reptiles) with chronic exposure “at levels below those usually seen;” with brief low-dose exposure, particularly at sensitive developmental stages; to subsequent generations; and using more than one mode of action.⁹
- BPA is acutely toxic to aquatic organisms and adversely affects reproduction in earthworms, growth in terrestrial plants, and development in birds. In addition to acute toxicity, BPA can impact the normal development of individual organisms and influence the development of their offspring. In laboratory testing, these effects have occurred at concentrations below those shown to cause acute effects, and these effect concentrations have been measured in the Canadian environment.¹⁰

In proposing to list BPA as toxic to health under CEPA 1999, the assessors noted that despite the uncertainty, animal studies suggest there may be potential effects at the levels we are being exposed, or one or two orders of magnitude higher. They also noted that the risks appear to be highest to the fetus and during child development.

C. Draft Assessment Report - Issues

- Some vulnerable populations as well as the population at large were not adequately evaluated in the draft screening. The potential exposure of adults and the possible adverse health effects on vulnerable populations, notably the pregnant woman and the fetus, could be well underestimated.
- While the assessment includes an extensive list of uses for BPA in the production of some polyesters, polyurethanes and polyvinyl chloride, it does not include levels of BPA that might remain in these polymers.¹¹

⁸ Ibid, p.69

⁹ Ibid, p.20

¹⁰ Ibid, p.33

¹¹ Ibid, p.10

- The assessment asserts that releases of BPA from products made of polycarbonate through leaching from the product surface “are expected to be limited”.¹² At the same time, the report conceded that BPA may enter the environment through breakdown after disposal.
- While recognizing that a major exposure source for BPA is through our dietary intake, other sources of exposure such as transdermal and inhalation also require adequate evaluation.
- A significant percentage of human exposure to BPA is from its release from epoxy-lined food and drink cans and the use of polycarbonate bottles. In the case of food or drink cans, labeling does not indicate the presence of free BPA in the can lining nor its potential health effects. It is not clear why BPA migrates from the matrix of the molecule, particularly as some documents suggest that it is tightly held within the matrix of the molecule. Apart from temperature and possibly pH, other contributing factors to BPA migration were not identified.
- Data from the draft assessment document indicated that some foods have significantly higher residual BPA levels than others. There is a very noticeable wide range of measured BPA for some foods. Without further statistical details for these commonly used foods, interpretation of the data is difficult.
- Several studies have indicated that the human metabolic elimination pathways for BPA are more rapid than those for rodents. This could possibly indicate that actual human exposure is greater than what many studies have indicated. Also, a few studies are indicating that different routes of exposure can result in different health outcomes and the metabolism of acute BPA exposure as compared to low dosage BPA differ in laboratory animals. Data from laboratory animals with chronic low level exposure to BPA would be more pertinent to real life BPA exposures for humans.
- 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 draft assessment document. There are indications that sperm count and quality for the male workers in industries using BPA are of concern.
- BPA-based polymers may be used in the production of cosmetics, such as lipsticks, face and eye makeup and nail lacquers, but the amounts remaining in cosmetic products are unknown and were assumed to be low by assessors.¹³ Cosmetics are applied directly to the skin, and repeatedly. There were no scientific references to qualify this assumption of minimal harm and neither were there any explanations as to the rationale for the presence of BPA-based

¹² Ibid, p.4

¹³ Ibid, p.51

polymers in cosmetics. Also not known or mentioned in is the packing composition of some cosmetics and whether they are BPA-based.

- BPA does not meet federal criteria for bioaccumulation. However, assessors noted that BPA is moderately fat soluble and has “some potential to accumulate in organisms.”¹⁴
- Little information is provided about how the precautionary principle was applied to the conduct and interpretation of the results of the screening assessment. No explanation is provided in either Environment Canada’s *Overview of the Ecological Assessment of Substances under the Canadian Environmental Protection Act, 1999*¹⁵ or in the *Framework for the Application of Precaution in Science-Based Decision Making about Risk, 2003*.¹⁶
- The Challenge Advisory Panel report on BPA (March 28, 2008) indicates only that the Panel agrees that the weight of evidence and the application of precaution supports the conclusions reached by Health Canada and Environment Canada, and that one panel member disagreed. However, there is no indication of how the panel reached that determination.
- A recently published paper stated that many gaps in our understanding of endocrine-active chemicals need to be addressed “prior to effective risk assessment and risk management of these chemicals” and that “when considering risk management of endocrine-active chemicals “the use of the precautionary principle may outweigh reliance on scientific risk assessments” (Phillips et al, 365; 363).¹⁷

D. Risk Management Scope Document for Bisphenol A

Given the findings of the draft screening assessment for BPA, especially a statement that “an emerging trend from the developmental neurotoxicity studies is that prenatal and/or neonatal bisphenol A exposure may cause organizational effects in the brain leading to disruptions in the sexually dimorphic behaviours in mice and rats”, and the uncertainty noted by assessors on potential heightened risks of exposure, the proposed management actions in the risk management scope document are disappointing.

While NGOs support the ban of polycarbonate baby bottles, this is only one step in the whole issue related to the use and exposure of BPA.

¹⁴ Ibid, p.16

¹⁵ 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

¹⁶ *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

¹⁷ Phillips, Karen P., et. al. “Assessing and Managing Risks Arising from Exposure to Endocrine-Active Chemicals,” *Journal of Toxicology and Environmental Health, Part B*, 11:3, 351-372.

E. Recommendations

Based on many of the issues raised in both the draft screening assessment and the scoping document, NGOs are submitting the following recommendations. We strongly encourage the Government to give them due consideration in moving forward to finalizing the draft assessment and developing the risk management strategy for BPA.

- 1) The Government of Canada should list BPA as toxic under CEPA, both for its impacts on ecosystems and its risk to human health.
- 2) Vulnerable Populations:
 - Based on the uncertainty surrounding exposure levels, further investigation is needed to determine all possible sources of exposure and pathways, especially for vulnerable populations. Further study should also be directed at investigating whether blood levels of BPA are the result of higher than estimated exposure or some other mechanism.
 - Given evidence that BPA may accumulate in the fetal compartment and levels of exposure may be higher than for other stages of life, protecting pregnant women and the fetus from exposure to BPA should be a key focus of risk management activities.
 - Given that levels of BPA in breast milk can be almost as high as those found in infant formula, the protection of infants must go beyond the elimination of polycarbonate baby bottles and infant formula containers and include reducing breast milk levels.
- 3) The risk management plan should cover the broader use of BPA in order to minimize and prevent environmental and health-related risks. This plan should include the elimination of BPA-containing food and beverage containers that create direct exposures.
- 4) A regulatory framework should be developed to phase out the use of BPA-based epoxy resin can linings. Its first objective would be the elimination of BPA-based can linings for infant formula and food, and include timelines for reduction and eventually elimination of BPA from can linings. Manufacturers of can linings should be obligated to prove that these linings are safe before they go on the market.
- 5) Risk management of BPA should include the consideration of safe BPA substitutes particularly in situations where there is greater potential for BPA to do harm to human health.
- 6) Given the high levels of BPA found in house dust, a particular emphasis should be placed on reducing the use of the chemical in household products which contribute to this accumulation.

- 7) BPA-containing municipal sludge should not be used for agricultural purposes. Given the high levels that may be found in sludge, this activity spreads BPA more widely and can impact ecosystems and create another source of human exposure through food.
- 8) More research is needed on the use of polycarbonate water pipes and how they might increase human and environmental exposure by BPA dissolving in water.
- 9) The risk management approach should provide assurance that BPA-containing products will be disposed of safely through mandatory measures.
- 10) Public Awareness:
 - In the short term, the government should develop regulations that ensure that consumers are informed, through hazard labelling on consumer products, any time that a consumer product that they purchase may expose them to BPA. A hazard labelling initiative should also extend to other hazardous ingredients as identified by the International Agency for Research on Cancer and other authoritative agencies.
 - All food and drink cans that have internal epoxy linings should be appropriately labeled indicating the presence of BPA and its potential to be a reproductive toxicant. Similarly, all other consumer products with BPA should be appropriately labeled.
 - Health advisories and information sessions, disseminated through Health Canada offices and clinics should be developed to advise pregnant mothers and mothers with babies and infants, ways in which they can avoid potential sources of BPA, including polycarbonate water bottles and canned foods.
- 11) Occupational Exposure:
 - The draft assessment should include an assessment of occupational exposures to BPA, including industries using BPA, BPA-derived epoxy resins and polycarbonate fabrication that could pose a risk of exposure to BPA.
 - The government should consider amendments to the Occupational Health and Safety Regulations under the Canada Labour Code to provide for occupational exposure limits to BPA.
 - Because of the potential of BPA to be a reproductive toxicant, even at low concentrations, material safety data sheets (MSDSs) under Canada's Workplace Hazardous Materials Information System (WHMIS), should disclose the presence of BPA, regardless of concentration. Potential health risks should also be identified, including the potential to be a reproductive toxicant.
 - 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.

- 12) Cosmetics:
- Preferably, the use of BPA in cosmetics should be prohibited. As an interim measure, the following actions should be pursued:
 - The government and the cosmetics industry should clarify the following:
 - the level of free monomer (BPA) in cosmetics
 - bioavailability of the free BPA when the product is used as intended,
 - safe alternatives to BPA-based polymers,
 - cosmetic packaging that may be based on BPA polymers.
 - Cosmetics which contain BPA-based polymers should indicate this on the label with an appropriate warning that BPA is a potential reproductive toxicant.
- 13) Weight of Evidence – Precautionary Principle:
- Environment Canada’s *Overview of the Ecological Assessment of Substances* document should explain the weight of evidence approach in more detail, including the criteria used in weighing the available evidence and how assessors “calculate” the weight of evidence;
 - Assessors should explain in the final draft of the screening assessment how they applied the weight of evidence approach and the precautionary principle.
 - Any guidance documents for assessors that explain how to apply the weight of evidence approach and the precautionary principle in risk assessment should be made available to the public.
- 14) Challenge Advisory Panel:
- In the interest of transparency in government decision-making, the report of the Challenge Advisory Panel on BPA should summarize the deliberations that led to their agreement that the weight of evidence and the application of the precautionary principle support the conclusions reached by Health Canada and Environment Canada, including the minority opinion.
- 15) Risk assessment of endocrine-active chemicals:
- The final draft of the screening assessment should respond to the implication that there cannot be an effective risk assessment for bisphenol A at this point. (See reference to Phillips et al, 365; 363)¹⁸
- 16) The draft and final screening assessments that are written as part of the Chemicals Management Plan must include tables of contents.

¹⁸ Phillips, Karen P., et. al. “Assessing and Managing Risks Arising from Exposure to Endocrine-Active Chemicals,” *Journal of Toxicology and Environmental Health*, Part B, 11:3, 351-372.