

**Submission re:**

*Proposed Risk Management Approach for  
Phenol, 4,4'-(1-methylethylidene) bis (Bisphenol A)*

*CAS RN: 80-05-7*

Environment Canada and Health Canada, October, 2008

Submitted to:

Existing Substances Division

Gatineau, QC K12A 0H3

[Existing.Substances.Existantes@ec.gc.ca](mailto:Existing.Substances.Existantes@ec.gc.ca)

Submitted by the Crooked Creek Conservancy Society of Athabasca

December 15, 2008

## A) General Comments

This submission includes issues and recommendations regarding the *Proposed Risk Management Approach for Phenol, 4,4'-(1-methylethylidene) bis (Bisphenol A)*<sup>1</sup> for your consideration in finalizing the risk management approach for bisphenol A (BPA).

Considering the contents of the final screening assessment report on BPA and further research on the effects of BPA that has recently been published, but not taken into account in the screening assessment, we expect the risk management approach to be comprehensive and precautionary, and to 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 delineated in the Proposed Risk Management document, fall far short of our expectations.

As indicated in the Proposed Risk Management document, the Government plans to “ban the importation, sale and advertising of polycarbonate baby bottles made with bisphenol A monomer.”<sup>2</sup> It also proposes to “develop stringent migration targets for bisphenol A in infant formula food cans,” and to work with industry to implement codes of practice “aimed at reducing levels of bisphenol A in canned infant formula to the lowest reasonably achievable levels.”<sup>3</sup> *No date is given for the latter two actions to take effect.* No further action is proposed for consumer products, beyond “explor(ing) the option of establishing strict migration targets for bisphenol A in canned foods in general.”<sup>4</sup>

The risk management plan further proposes regulations to “minimize the risks from releases of bisphenol A into the environment,” including “establish(ing) maximal concentrations at the effluent;” requiring best management systems; monitoring industrial releases; and a verification protocol.<sup>5</sup> Finally, there will be efforts to work with provincial authorities to minimize BPA in leachate from landfills, and a number of research and monitoring projects.<sup>6</sup>

We find the proposals in the Proposed Risk Management document beyond banning polycarbonate baby bottles weak and ineffectual. Their descriptions in are full of words such as “explore the option,” “consider imposing,” and “explore with industrial users... how this regulatory approach would be implemented.”<sup>7</sup> *There is no sense of when regulations concerning release into the environment, even if promulgated within 24 months, would actually take effect, and what results might be achieved.*

Our specific concerns and recommendations are outlined in the following sections of this submission, including lack of protection for pregnant women, fetuses and nursing

---

<sup>1</sup> *Proposed Risk Management Approach for Phenol, 4,4'-(1-methylethylidene)bis (Bisphenol A)* (80-05-7). Government of Canada, October, 2008. (Proposed Risk Management Approach)

<sup>2</sup> *ibid.*, p. 13.

<sup>3</sup> *ibid.*, p. 14.

<sup>4</sup> *ibid.*, p. 14.

<sup>5</sup> *ibid.*, p. 14.

<sup>6</sup> *ibid.*, p. 15.

<sup>7</sup> *ibid.*, pp. 14-15.

infants; lack of a serious commitment to finding substitutes or alternatives to BPA in food packaging and other uses; lack of protection for the environment and its biodiversity; woefully inadequate analysis social and economic factors (Section 7.3); and inadequate application of the precautionary approach.

In general, given the results of the screening risk assessment and the paucity of specific, timely actions to minimize human exposure to BPA and the amount of BPA entering the environment, we are very discouraged by this Proposed Risk Management document and feel that it is almost entirely lacking in precaution.

## **B. Lack of protection of the pregnant woman/fetus/nursing infant**

It is particularly discouraging that while there is to be some protection for infants bottle-fed with infant formula, in the form of a ban on polycarbonate baby bottles and the promise of a limitation on allowable concentrations of BPA in infant formula, no protective actions for the other most vulnerable groups, the fetus and the breast-fed newborn and infant, are being proposed.

In light of the facts that

- (a) There is evidence that BPA levels in the fetus are higher than in the pregnant mother. The assessors suggested that repeated BPA exposure could lead to elevated *in utero* exposures<sup>8</sup>
- (b) Intake of BPA by breast-fed infants has been estimated as being less than, but comparable to, formula-fed infants<sup>9</sup>
- (c) Health Canada “continues to recommend exclusive breastfeeding for the first six months of life, followed by the gradual introduction of other nutritious foods in addition to breastfeeding, which should continue up to two years of age or more” <[http://www.chemicalsubstanceschimiques.gc.ca/faq/bisphenol\\_a\\_qa-qr\\_e.html#17](http://www.chemicalsubstanceschimiques.gc.ca/faq/bisphenol_a_qa-qr_e.html#17)> and
- (d) The proposed human health objective of the Proposed Risk Management document, is “to minimize infant exposure to the greatest extent practicable,”<sup>10</sup>

we are very concerned that the Proposed Risk Management document contains no specific measures to protect the fetus or the breast-fed newborn and infant, which requires protecting the pregnant and nursing mother.

Many actions could be taken now to help protect the pregnant woman/fetus and breast-fed newborn and infant, and almost all of them require actions that will have the added benefit of reducing the exposure of all humans to BPA.

---

<sup>8</sup> Environment Canada and Health Canada, *Screening Assessment for the Challenge Phenol, 4,4'-(1-methylethylidene)bis-(Bisphenol A)*. October 2008, pp. 56-57. (Screening Assessment)

<sup>9</sup> *ibid.*, pp. 37-38.

<sup>10</sup> Proposed Risk Management Approach, p. 12.

**Recommendation B (1):** Protecting the fetus should be a key focus of risk management activities preventing harm to human health.

**Recommendation B (2):** The protection of newborns and infants must go beyond eliminating polycarbonate baby bottles and reducing BPA levels in infant formula containers to include reducing breast milk levels.

**Recommendation B (3):** Eliminate the use of BPA in food and beverage containers that create direct exposures.

**Recommendation B (4):** Given the high levels of BPA found in house dust, there should be a particular emphasis on reducing the use of the chemical in household products that contribute to this accumulation.

**Recommendation B (5):** Although it is unclear what levels of BPA might remain in cosmetics, the substance should be added to the cosmetics “Hot List” to prohibit its use in cosmetic products.

**Recommendation B (6):** Research on the use of polycarbonate water pipes and how they might increase human exposure to BPA should be supported.

We feel as well that the advice on the Chemicals Management Plan website concerning precautionary measures that pregnant women may wish to take to reduce exposure to BPA<sup>11</sup> is wholly inadequate and quite frankly cynical, as it covers only containers that are used to heat food, and is likely to be accessed only by very knowledgeable people who have the leisure to find this advice on a relatively obscure website, that is, likely middle class, highly educated people who would also need to be able to do research to find out which plastic containers contain bisphenol A. This advice does nothing to protect a large proportion of the vulnerable subpopulations that rely on the Canadian government to protect them from toxic chemicals.

### C) Substitution/Alternatives

---

<sup>11</sup> See *Questions and Answers for Action on Bisphenol A Under the Chemicals Management Plan: What advice do you have for pregnant/breastfeeding mothers?*

If you have concerns about bisphenol A you may wish to take the following precautionary measures to reduce your exposure:

- Use non-polycarbonate plastic containers to heat food or liquids, or use alternatives to plastic such as glass, ceramic or stainless steel containers;
- Let boiling water cool before pouring into polycarbonate plastic containers when using them to prepare, or store, either food or drink; and
- Remove food from the can before heating.

[http://www.chemicalsubstanceschimiques.gc.ca/faq/bisphenol\\_a\\_qa-qre.html#17](http://www.chemicalsubstanceschimiques.gc.ca/faq/bisphenol_a_qa-qre.html#17)

We are disappointed by the weak and passive approach in the Proposed Risk Management document to the issue of finding non-toxic alternatives to BPA in food packaging and other uses. The excuse given is that “no information on potential substitutes for bisphenol A was brought forward in the voluntary Challenge Questionnaire submissions.”<sup>12</sup> Surely a basic requirement of preparing a risk management approach is a literature search on alternatives to toxic chemicals. The Government is taking an approach that is not protective of human health by relying on industry to come forward with potential substitutes, and even then, only for infant formula can coatings: “The Government will support manufacturers in the evaluation of replacement options for bisphenol A in infant formula can coatings.”<sup>13</sup>

A more precautionary approach would involve supporting research leading to innovative solutions that would benefit the environment, human health, and the economy.

**Recommendation C (1):** The government should actively engage industry, researchers, and stakeholders in developing and/or investigating alternatives to epoxy resins and other products containing BPA.

#### **D) Lack of Protection for the Environment**

The final screening assessment found significant evidence for harm to the environment and biological diversity at present levels of environmental BPA release. The evidence is summarized in the Screening Assessment as follows:

Bisphenol A is acutely toxic to aquatic organisms and has been shown to adversely affect growth and development in both aquatic and terrestrial species. There is evidence that low-level exposure to bisphenol A, particularly at sensitive life cycle stages, may lead to permanent alterations in hormonal, developmental or reproductive capacity. In laboratory testing, these effects have occurred within the range of concentrations measured in Canada, indicating that there is potential for adverse effects in populations, particularly close to point sources. On the basis of expected continued or increasing exposure of biota, and information indicating the potential for long-term adverse effects to organisms within the range of concentrations currently measured in the environment, it is considered appropriate to apply a precautionary approach when characterizing risk. As such, it is concluded that bisphenol A is entering the environment in a quantity or concentration or under conditions that have or may have an immediate or long-term harmful effect on the environment or its biological diversity.<sup>14</sup>

It is disappointing in the extreme that the Proposed Risk Management document is almost entirely lacking in measures to protect the environment and its biological diversity. As noted in Sections B and C above, measures designed to broadly reduce use and release,

---

<sup>12</sup> Proposed Risk Management Approach, p. 11.

<sup>13</sup> *ibid.*, p. 11.

<sup>14</sup> Screening Assessment, pp. i-ii.

including substitution with safer materials, are lacking in firm commitment and detail, and are years from being implemented, if they ever are.

The discussion of landfills is illustrative of the weak approach to environmental protection in the Proposed Risk Management document. Significant reductions in the use of BPA would obviate the necessity to engage provinces in lengthy discussions about how they might reduce levels in landfill leachate.

**Recommendation D (1):** Risk management of BPA should involve a firm commitment with timelines for a broad reduction of BPA use and release, including substitution with safer materials.

### **E) Socio-Economic Considerations**

Section 7.3 of the Proposed Risk Management document is weakened by its exclusive attention to economic considerations from a narrow industry viewpoint. The social impacts of the proposed regulations, including the failure of the proposed regulations to provide protection for human health beyond bottle-fed infants, are completely overlooked. Discussion of potential impacts of the proposed weak regulations on health and safety, security, the environment, and the social well-being of Canadians is missing altogether.

If this were not bad enough, the economic analysis that is included in the Proposed Risk Management document is woefully inadequate. It has been pointed out that

The economic costs of current levels of chemical contamination are often hidden, though they contribute significantly to reduced worker productivity, increased hospital costs, more expensive health insurance, and greater burdens on businesses for hazardous waste storage, disposal, and clean-up fees. Uncounted in the conventional cost-benefit analysis of our chemical regulatory policies is the price we pay for children with developmental disabilities or the toll on families with chemical exposure-linked illness, not to mention eco-system impacts.<sup>15</sup>

Also missing in this section is any reference to researching innovative alternatives to current BPA use and technology, which have the potential to improve the economy as well as the health of humans and the environment.

**Recommendation E (1):** A broader perspective should be taken to the social and economic impacts of regulating BPA, including impacts on the social well-being of Canadians and a more comprehensive approach to economic impacts, including the costs of failing to regulate adequately and the potential economic benefits of researching alternatives to BPA use.

---

<sup>15</sup> Letter of Principles for Toxic Chemical Regulatory Reform, *Rachel's Precaution Reporter* #172, Dec. 10, 2008. <http://www.rachel.org>.

## F) Lack of Precaution

In light of the results of the screening assessment of BPA, the fact that BPA is a known endocrine disruptor, which is active at extremely low concentrations, and recent research that points toward harmful effects of BPA on adult humans,<sup>16</sup> we conclude that the actions being proposed to manage the risks of BPA are almost entirely lacking in precaution. It may be true that no conclusive evidence exists to quantify the harmful effects of this ubiquitous, toxic substance, but enough evidence has accumulated to justify a much broader precautionary approach to preventing harm to the environment and human health. An approach that fails to identify specific regulations with timelines to protect human health and the environment is not precautionary.

**Recommendation F (1):** In light of the serious potential harm to the environment and human health from BPA, a precautionary approach that involves a commitment to specific regulations with timelines should be taken with respect to all potential harms, including harm to human health in general and the environment and its biodiversity.

---

<sup>16</sup> A sample of such studies includes:

- Lang, I.A., Galloway, T.S., Scarlett, A., Henley, W.E., Depledge, M., Wallace, R.B., and Melzer, D. (2008) Association of urinary bisphenol A concentration with medical disorders and laboratory abnormalities in adults. *Journal of the American Medical Association* 300(11):1303-1310.
- Leranath, C., Hajszan, T., Szigeti-Buck, K., Bober, J., and MacLusky, N.J. (2008) Bisphenol A prevents the synaptogenic response to estradiol in hippocampus and prefrontal cortex of ovariectomized nonhuman primates. *Proceedings of the National Academy of Sciences (USA)* 105(37):14187-14191.
- Ho SM, Tang WY, Belmonte de Frausto J, Prins GS. 2006. Developmental exposure to estradiol and bisphenol A increases susceptibility to prostate carcinogenesis and epigenetically regulates phosphodiesterase type 4 variant 4. *Cancer Res* 66(11):5624-5632.
- Dairkee, S.H., Seok, J., Champion, S., Sayeed, A., Mindrinos, M., Xiao, W., Davis, R.W., Goodson, W.H. *Bisphenol A induces a profile of tumor aggressiveness in high-risk cells from breast cancer patients. Cancer Research* 68(7): 2076-2780.