

A Response to the Proposed Risk Management Approach for Phenol, 4,4'-(1-methylethylidene) bis (Bisphenol-A) under the Chemicals Management Plan

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Introduction

Health and Environment Canada released the draft screening assessment for bisphenol-A on April 18 under Batch 2 of the Challenge under the Chemicals Management Plan. The final screening assessment was subsequently published on October 18, and the Proposed Risk Management Approach announced on the same date, beginning a 60-day commenting period. The comments in this paper are addressed to that Proposed Risk Management Approach.

Toxic Free Canada (formerly the Labour Environmental Alliance Society) was founded in 1998 to foster cooperative initiatives between environmentalists and workers, particularly around issues that link human health and the environment. Our mission is “to create alliances and initiatives that promote healthy workplaces, healthy homes and communities and a healthy environment.” An important focus of our work is toxics use reduction aimed at reducing consumer and workplace use of toxic chemicals and their replacement wherever possible by safer, environmentally-preferable alternatives. Among consumers, we conduct regular educational work using our CancerSmart Consumer Guide, which encourages the substitution of toxic household and home maintenance products. In the workplace, we have initiated numerous projects, notably among school districts, to reduce the use of hazardous products and encourage green procurement policies. Toxic Free Canada has been involved in the chemicals management stakeholder process and continues to participate as work on the Challenge chemicals continues.

Bisphenol-A Risk Management

Toxic Free Canada fully supports the proposal of the Government of Canada to list Bisphenol-A as a toxic substance under Schedule 1 of the Canadian Environmental Protection Act. Further we support the government's proposals to ban the sale and importation of polycarbonate baby bottles, to develop stringent BPA migration targets for infant formula cans, and to develop further methods to monitor BPA as it affects the environment and as it affects health.

However, we believe that additional measures are needed in the risk management approach, to protect the health and the environment of Canadians. That is particularly true of the fetus and pregnant women, identified as "sensitive subpopulations" in the final screening assessment. But is also generally true for all Canadians who are now known to be exposed to BPA on a continual basis. The screening assessment states that BPA does not meet the CEPA criteria for virtual elimination, but the clear objective of the risk management approach should be to reduce exposure to BPA across the population wherever possible and to eliminate sources of that exposure where sensitive subpopulations are involved. That should be coupled with increased monitoring, covering both environmental releases and human health effects, and additional risk management proposals should be considered in the event that monitoring finds exposures increasing or new research finds human health effects occurring at current levels of BPA exposure.

The final screening assessment states that that the pregnant woman/fetus should be considered a sensitive population based on current BPA exposure levels and the absence of "pharmacokinetic models to quantitatively characterize absorption, distribution, metabolism and excretion of bisphenol-A and its metabolites in test animals and humans.." We believe that the final screening assessment underestimates current levels of exposure to BPA, potentially increasing the risk to all Canadians, but posing a particular risk to the pregnant woman/fetus subpopulation.

The assertion that exposure levels have been underestimated is based on the following:

1. There are additional routes of exposure to BPA that were not considered in the draft assessment. Recycled office papers, thermal papers used for credit card and cash register receipts, as well as recycled toilet and facial tissue are all sources of BPA and have come into widespread use in recent years, increasing the potential exposure. The amount of BPA in each has not been extensively quantified, but some studies have shown BPA in recycled toilet paper ranging from .3.2–46 mg/kg (Gehring, 2003) and assorted waste paper from 0.093–4.23 mg/kg dry mass. Another study showed the BPA content of recycled paper towels ranging from 0.55–24.1 mg/kg (Ozaki 2004). Dermal absorption is a factor in BPA absorption and BPA so absorbed would not be subject to the first pass conjugation that occurs with oral ingestion (Vandenberg 2007). While exposure from papers may not itself be a significant source of exposure, it would certainly contribute to aggregate exposure and the omission of that data would obviously lead to an underestimation of exposure levels and risk.
2. The figures used in the draft assessment to calculate BPA leaching from food cans were based on average levels, which may seriously underestimate the actual levels to which individual consumers or groups of consumers may be exposed. We believe that a worst-case scenario should be considered in estimating potential exposure. For example, BPA was found in canned soups at levels ranging from non-detectable to 385 ppb. In canned pasta the BPA levels ranged from non-detectable to 247 ppb. Using the geometric mean

average (Table 11) does not represent the real-life risk posed by individual consumers or groups of consumers consuming only one brand or brands of products that may contain BPA at the upper end of that range. A precautionary approach would indicate using the upper figure for risk management purposes, especially for sensitive subpopulations such as the pregnant woman/fetus. The significant discrepancy among various countries' statistics in quantifying exposure to BPA from dietary sources would further emphasize the need for such precaution.

3. Recent U.S. research estimating the human exposure to bisphenol-A (Vandenberg 2007) was used in preparing the final screening assessment. But one of the key findings in the research was not reported, namely that current circulating levels of BPA in humans cannot be fully explained by current exposure sources. "The consistent finding that BPA is detected in almost all individuals in developed nations implies that humans are exposed to BPA continuously. Because of the rapid metabolic clearance of BPA, and the measurable levels of BPA that have been detected in human blood and urine, Welshons and colleagues have identified two potential issues: 1) BPA intake may be actually much higher than has been suggested, and/or 2) long-term, daily intake leads to bioaccumulation of BPA, (my emphasis) leading to steady-state levels that are not represented by any of the current models for BPA metabolism based on single, acute administration." (Vandenberg 2007)

The final screening assessment also did not take into account the first epidemiological research recently completed that showed an elevated risk for cardiovascular disease and Type 2 diabetes for those with higher urinary levels of BPA (Lang 2008). The research was based on existing population levels of BPA and while it did not establish a causal link, it provides the first epidemiological evidence that BPA at levels found in the population may be conferring an elevated disease risk.

The final screening assessment itself acknowledges that the confidence in the exposure estimates is only moderate. Given the high degree of uncertainty about exposure that we have outlined, and the 40 studies completed to date that have shown adverse effects of BPA at levels below the EPA reference dose, the current risk management measures do not provide a margin of safety for the pregnant woman/fetus population. Similarly, based on recent epidemiological evidence (Lang 2008), there may not provide a safety margin for the general population. A precautionary approach would dictate that additional steps be taken.

Recommendations:

- The government should immediately develop health advisories, disseminated through Health Canada offices and clinics, advising women on health concerns related to BPA as outlined in the final screening assessment and offering ways to avoid potential sources of BPA, including such sources as polycarbonate water bottles and canned foods.
- The government should conduct further investigation to determine all possible sources of exposure and pathways, especially for vulnerable populations. Further study should also be directed at investigating whether blood and urine levels of BPA are the result of higher than estimated exposure or some other mechanism.
- The ban on polycarbonate baby bottles should be extended to all polycarbonate reusable water bottles and children's sippy cups.

In fact, this action has been taken unilaterally by many retailers and some manufacturers, which have replaced polycarbonate bottles with those made from alternative materials, including stainless steel, high-density polyethylene and a new polymer, Tritan copolyester. However, many retailers continue to sell polycarbonate bottles, many of which are imported into the country from offshore manufacturers. A ban would have little socio-economic impact on Canadian industry because there is no manufacturer of polycarbonate in Canada (Industry Canada) and little evidence of polycarbonate bottle fabricating in Canada.

- The government should develop a regulatory framework, beginning with a consultation with industry, to phase out the use of BPA-based epoxy resin can linings. That framework, which should have as its first objective a reduction in, and eventual elimination of BPA-based can linings for infant formula and food, should set timelines for reduction and eventually elimination of BPA from can linings.

At present, alternatives such as oleoresinous coatings, used by at least one food manufacturer, are available for some uses, but regulation is important in developing new alternatives. The experience from the salmon canning industry, which was required under European Commission regulations in 2000 to reduce NOGE migration from can linings into food, demonstrated that regulations and timelines were highly effective in encouraging innovation and developing NOGE-free coatings. Toxicity testing of alternatives must be an important part of the regulatory framework.

- The government should develop regulations, either as stand-alone legislation or through adoption of the Globally Harmonized System for consumer product labelling, to ensure that BPA is labelled as a potential reproductive and developmental toxicant on any consumer product that potentially exposes the consumer to BPA.
- Health Canada should harmonize regulations with the European Union and add BPA to the Cosmetics Hotlist, to prohibit the addition of BPA monomer to any cosmetics products and to set strict limits on residual BPA from BPA polymers.

BPA and occupational exposures

In its human health assessment of BPA, the final screening assessment makes no reference to occupational exposures to BPA, either as a result of direct manufacturing of BPA or use of products, such as epoxy resins, that could expose workers to BPA. The proposed risk management approach notes only one existing occupational risk management regulation, the requirement under the provisions of the Ingredient Disclosure Act that any BPA in excess of one per cent in a product be reported on a Material Safety Data Sheet.

There are few data available on occupational exposures to BPA but one study did show that urinary BPA levels were significantly higher in 42 men exposed occupationally in working with epoxy resins compared to the non-exposed control group. (Hanaoka, 2002). What makes occupational exposures a particular concern is that they are compounding identified consumer exposures. Since the aggregate exposure estimate outlined in the final screening assessment is based entirely on potential consumer exposures, it stands to reason that occupational exposures will result in elevated BPA levels — and elevated potential risk as well. The findings of Lang 2008 that showed an increased risk of cardiovascular disease and Type 2 diabetes for those with the highest

levels of circulating BPA underline that concern.

The industrial uses of BPA outlined in the final screening assessment demonstrate that there are numerous areas of potential occupational exposure to BPA including can manufacturing, automotive painting and repair, CD and other polycarbonate fabricating and concrete sealing. Yet there is no exposure data from those areas and while the risk management approach emphasizes the importance of monitoring there is no provision for monitoring of occupational exposures. Similarly, workers in those affected occupations work without any exposure limits, since the American Conference of Governmental Industrial Hygienists — the body whose standard is used by the Canada Labour Code and most provinces — has not developed any limits for BPA.

Recommendations:

- The draft risk management approach should include monitoring of occupational exposures in selected workplaces where there is potential for exposure to BPA from polycarbonate manufacturing, for example, or emissions from paints or adhesives that contain BPA. That monitoring should include bio-monitoring of workers to provide an assessment of circulating BPA levels in workers relative to the general population.
- 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 and encourage provincial workplace safety authorities to adopt them.

Releases to the environment

Toxic Free Canada supports the development of standards and regulations to control at-source releases of bisphenol-A into the environment. Since bisphenol-A use is expected to increase 6-10 per cent annually (Lang 2008), it is imperative that those regulations be developed well within the 24 month-period proposed under the risk management approach.

We also support proposals to conduct national monitoring of wastewater effluent and wastewater sludge. However, we believe the objectives of that monitoring should go beyond merely determining the ambient levels of BPA in the environment, assessing the effectiveness of risk management actions and helping to determine the fate of BPA in waste streams.

As the final screening assessment notes:

“Evidence of disruption to reproductive and developmental processes following exposure to bisphenol A at concentrations below those causing acute effects has been reported in fish, aquatic invertebrates, amphibians and reptiles.... differing sensitivities are evident between groups of organisms, with endpoint values for fish generally higher than those for aquatic invertebrates. Considered together, the data provide strong evidence that bisphenol A is capable of eliciting adverse effects: (1) following prolonged exposure at levels below those usually seen to elicit effects in standard toxicity tests (i.e., tests based on recognized methods which evaluate endpoints such as survival, reproduction and growth); (2) following brief low-dose exposure, particularly at sensitive developmental stages, with effects apparent later in the life cycle; (3) on filial generations following parental exposure; and (4) using more than one mode of action.”

Those finding are of special significance in marine waters that provide a rearing ground for juvenile fish and where wastewater treatment facilities provide only primary treatment, such as Iona and Lions Gate in Metro Vancouver. The assessment notes that a “significant fraction” of BPA in

wastewater remains in the dissolved phase, with partitioning to the solid phase above 50 per cent only occurring in plants providing secondary or better treatment. According to Table 9a in the assessment, the highest BPA levels in effluent from a municipal wastewater treatment plant were from an unidentified plant in Vancouver sampled in 2003.

Similarly, the assessment cites data from Norway showing that marine fish had the highest levels of BPA among species sampled, suggesting that either environmental exposures were higher or some bioaccumulation is occurring.

The data all indicate a higher risk for marine fish, including reproductive toxicity for juvenile fish, in areas around primary-only wastewater treatment plants. No research data is available to determine whether or not the toxicity meets the bar required for action under the Fisheries Act to eliminate or mitigate the risk, but that should certainly be included under the proposed risk management approach.

Recommendations:

- Expedite development of standards and regulations to control at-source releases of BPA and to implement best-practices management in facilities where BPA is used.
- Conduct further research on Pacific salmon, Atlantic cod and other species potentially affected by BPA from wastewater treatment plants to determine toxic effects and threshold levels, if they exist.
- Maintain annual monitoring of effluent from treatment plants, with priority given to primary treatment plants
- Ensure compliance with applicable legislation, especially the Fisheries Act.

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