

Response to *Canada Gazette* Part I, Vol. 142 No. 42
(October 18, 2008) on the proposed risk management
approach document for Phenol, 4,4' -(1-
methylethylidene)bis, (Bisphenol A), CAS No. 80-05-7

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Submitted to:

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The Canadian Environmental Law Association (CELA) and Chemical Sensitivities Manitoba (CSM) submitted individual submissions responding to the draft screening assessment and the risk management scope documents for bisphenol A (Phenol, 4,4'-(1-methylethylidene) bis, Chemical Abstract Service Registry Number (CAS RN 80-05-7)) during the public comment period ending June 18, 2008. The final screening assessment was released October 18, 2008 in *Canada Gazette Part 1, Vol. 142, No. 42*, under subsection 77(6) of CEPA 1999 and was posted on the Environment Canada's website:
http://www.ec.gc.ca/substances/ese/eng/challenge/batch2/batch2_80-05-7_rm.cfm.

We are submitting the following comments and recommendations in response to the government's proposed risk management for bisphenol A (BPA) in this 60 day public comment period ending December 17, 2008.

CELA (www.cela.ca) is a non-profit, public interest organization established in 1970 to use existing laws to protect the environment and to advocate for environmental law reform. It is also a legal aid clinic that provides legal services to citizens or citizens' groups who are unable to afford legal assistance. In addition, CELA also undertakes substantive environmental policy and legislation reform activities in the area of access to justice, pollution and health, water sustainability and land use issues since its inception. Under its pollution and health program, CELA has been actively involved in matters that promote the prevention and elimination of toxic chemicals addressed in the *Canadian Environmental Protection Act*, including the categorization process and implementation of the Chemicals Management Plan.

Chemical Sensitivities Manitoba (CSM), a volunteer organization, was founded in 1997 by four individuals who saw the need to address the affects of toxic chemicals on human health and the possible link between the onset of chemical sensitivities and chemical exposure and, in particular, chronic low-level exposure. CSM raises awareness of the presence of toxic chemicals in the home and the environment and strongly advocates for the safe substitution of these toxins.

Comments on the Final Screening Assessment Results for BPA

CELA and CSM support the final assessment conclusions that BPA can do harm to human health and to the ecosystem. In its assessment report, the government states that BPA "is entering or may be entering the environment in a quantity or concentration or under conditions that have or may have an immediate or long-term effect on the environment or its biological diversity"¹ and concludes that "bisphenol A be considered as a substance that may be entering the environment in a quantity or concentration or under conditions that constitute or may constitute a danger in Canada to human life or health."² We also support the conclusion that BPA be classified as a toxic substance to be added to the Toxic Substances List (Schedule 1) of the *Canadian Environmental Protection Act* (CEPA), as it meets the criteria in Sections 64(a) and 64(c) of CEPA 1999. With this conclusion, the government is required to develop measures on BPA to protect the environment and human health.

Recommendation 1: CELA and CSM support the government finding that BPA is toxic under CEPA.

¹ Environment Canada and Health Canada. October 2008. Screening Assessment for the Challenge Phenol, 4,4'-(1-methylethylidene) bis, Chemical Abstract Service Registry Number (CAS RN) 80-05-7. pg. 76.

² Ibid, pg. 76.

Recommendation 2: CELA and CSM support the proposal by government to add BPA to the List of Toxic Substances in Schedule 1 of CEPA.

Specific Comments on the Proposed Risk Management Approach for BPA

The following table (Table 1) focuses on each of the government proposals to manage BPA as a CEPA toxic substance. Based on the conclusions of the final screening assessment, our organizations are concerned that the proposed measures would not adequately protect human health and the environment. Generally, the government's proposals focused on additional investigations of industrial releases of BPA and the collection of additional information, monitoring and research, as substantive measures to address BPA exposures. Given the evidence of aquatic toxicity effects as well as evidence that may link human health effects from low dose exposure to BPA, a precautionary approach to this substance would be more appropriate.

The proposed approach is weak for several reasons:

1) *Lack of protection to vulnerable populations:* The proposed risk management outlines a human health objective "to minimize infant exposure to the greatest extent possible"³, which excludes any protection to other vulnerable populations such as children, pregnant women and workers from exposure to BPA. It falls short of more stringent measures to further decrease infant exposure as well as exposure to other vulnerable populations and the general population. For example, the proposals do not include a phase out of BPA from consumer products known to contain BPA, particularly from the lining of canned foods and other products containing BPA that come into contact with human bodily fluids.

2) *Proposals to prevent or minimize BPA exposure are inadequate:* The proposed risk management indicates that the environmental objective is to "prevent or minimize releases of bisphenol A into the Canadian environment." The government has not articulated explicitly whether measures will be in the form of regulatory action promoting prevention. In fact, consideration for regulations to BPA releases to the environment and exposure aim to "establish maximal bisphenol A concentration at the effluent" and "ensure best management practices are adopted..." These measures are control measures and do little to support a prevention approach.

a) *Application of Precautionary Principle to act on BPA falls short:* The assessment for BPA outlines sufficient evidence to demonstrate the possibility of long term adverse effects from BPA to human health and to the environment. The assessment results have also documented several uncertainties as it relates to the BPA data already gathered, including:

- i. exposure to all age groups from the use of polycarbonate containers in the absence of Canadian use pattern information and use conditions;
- ii. residual levels of BPA in polymers used in consumer products (e.g. toys and cosmetics) and their use patterns;
- iii. adequacy or inadequacy of the database on reproductive/developmental effects below the established No Observed Adverse Effects Level of 50 mg/kg–bw per day use patterns;
- iv. lack of surveys that measure concentrations of BPA in Canada.

³ Environment Canada and Health Canada. October 2008. Proposed Risk Management Approach for Phenol, 4,4'-(1-methylethylidene) bis, Chemical Abstract Service Registry Number (CAS RN) 80-05-7.

Despite these uncertainties, the government's decision to conclude BPA as toxic under CEPA was made. The application of the precautionary principle is appropriate in making the determination of toxicity under CEPA. However, several of the proposed management measures on BPA do not demonstrate that a precautionary principle was applied. The proposed measures focus on undertaking further observation on options for regulations (e.g. establishing migration targets in canned food, industrial releases, disposal or recycling of products, etc.) and monitoring (e.g. monitoring programs under The Material-Infant Research on Environmental Chemicals (MIREC) Study and Plastics and Personal-Care Product Use in Pregnancy, etc.) that lack immediate actions that will significantly result in the reduction of exposure to BPA to Canadians or the environment in the near future.

Table 1 below documents the government's proposals, lists concerns from CELA and CSM and includes their recommendations.

Table 1: Summary of risk management components, proposed government measures, NGO comments and recommendations

Risk management components⁴	Proposed Government measures	CELA & CSM - comments	Recommendations
Polycarbonate baby bottles (section 9.1.1)*	Proposal to ban the importation, sale and advertising of polycarbonate baby bottles made with BPA monomer.	<p><u>Support</u></p> <ul style="list-style-type: none"> • To date, the manufacturers of BPA-based baby bottles have voluntarily initiated the transition to BPA-free baby bottles. This type of phase out has been extended to other polycarbonate bottles on the market. • It was noted in the government's proposals that some alternative packaging for baby formula exist, including glass bottles, baby bottle liners made of polyethylene (PE) and also, polypropylene (PP). However, the government report does not include additional commentary or data on the safety of these alternatives (glass not included). The report would be strengthened with this type of information as it informs the general public of safe alternatives for BPA containing polycarbonate baby bottles and other polycarbonate containers. 	<p>Rec.: We support the government's proposal to ban polycarbonate plastic baby bottles containing BPA.</p> <p>Rec.: We urge the government to eliminate BPA from all polycarbonate plastic bottles to ensure adequate protection to the general public, in particular, pregnant women and children.</p> <p>Rec.: We urge the government to conduct an assessment on the safety of alternatives for these applications.</p>
Canned infant formula (section 9. 1,2)*	Development of stringent migration targets for BPA in infant formula cans.	<p><u>Do not support</u></p> <ul style="list-style-type: none"> • BPA is a potential hormonal toxicant, which can result in a wide range of health impacts with effects that may occur at low dose levels. This proposed government measure will result in continued exposure to infants relying on formula for their nutritional intake. It does not fully protect babies and infants from exposure 	<p>Rec.: We do not support the government's proposal to establish a migration target. We urge the government to require the elimination of BPA from all packaging coming in contact with food, particularly baby and infant formula.</p> <p>Rec.: Require the identification and promotion of safe replacements of BPA in the packaging of baby and infant canned formula.</p>

⁴ Note: * refer to Section 9 of the Proposed Risk Management Approach for Phenol, 4,4'-(1-methylethylidene) bis, Chemical Abstract Service Registry Number (CAS RN) 80-05-7. October 2008.

See also : Environment Canada, Existing Substances Division: http://www.ec.gc.ca/substances/ese/eng/challenge/batch2/batch2_80-05-7_rm.cfm#3

Risk management components ⁴	Proposed Government measures	CELA & CSM - comments	Recommendations
		<p>to BPA. Also, it does not fully compliment the measures proposed by the government to have BPA-free baby bottles.</p> <ul style="list-style-type: none"> • The government efforts to define what would be considered “stringent migration targets” will be significant and is subject to debate by industry and other stakeholders. Furthermore, establishing these targets will depend on the methodology and technology used to determine these levels. • A government commitment to prevent BPA in food products directed for infant consumption is an appropriate goal if the goal is to protect infants. 	<p>Rec.: Establish a stakeholder task force mandated to assess the safety of alternatives of BPA for this application.</p> <p>Rec.: Require that the migration BPA levels should be zero in food packaging for infants and babies.</p>
<p>Alternative linings - cans for infant food (section 7.1)*</p>	<p>Government will support manufacturers in the evaluation of replacement options for BPA in infant formula can coatings.</p>	<p><u>Support</u></p> <ul style="list-style-type: none"> • Identifying alternatives for infant formula can coatings is essential to address BPA. 	<p>Rec.: We urge the government to identify alternatives to can linings containing BPA for babies and infants, as well as for the general public.</p> <p>Rec.: Establish a taskforce to conduct assessments on the safety of alternatives to ensure that alternatives do not exhibit impacts to human health or the environment.</p>
<p>Other canned food linings</p>	<p>“explore the option of establishing stringent migration targets for canned foods”</p>	<p><u>Do not support</u></p> <ul style="list-style-type: none"> • Protection to the general populations and in particular pregnant women and children, is required from BPA in canned food linings. The government needs to go beyond exploring options for stringent migration targets for canned foods. Sufficient evidence gathered through the assessment of BPA demonstrates the migration of BPA to food products, and is 	<p>Rec.: We do not support the government’s proposal to simply explore options to establish BPA migration targets for canned foods. Safe alternative linings for canned foods should be a priority in addressing BPA exposure.</p> <p>Rec.: As noted previously, the government should phase out the use of BPA in canned food linings.</p>

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		<p>particularly high for some foods such as tomatoes. Furthermore, greater consideration should be given to the chronic exposure of BPA for pregnant women, infants and children.</p>	<p>Rec.: The government should provide immediate assistance to industry on the safe replacements for BPA-based food can linings.</p> <p>Rec.: Establish a stakeholder task force mandated to assess the safety of alternatives of BPA for this application.</p>
<p>Industrial releases of BPA for:</p> <p>- industrial users of BPA (section 9.1.4)*</p>	<p>Government will consider imposing regulations to minimize the risks from releases of BPA into the environment.</p> <p>Regulations may aim to: “establish maximal bisphenol A concentrations at the effluent; and require ...best management practices are adopted...” (The regulatory proposal will be published in the <i>Canada Gazette</i>, Part I, within approximately 24</p>	<p><u>Do not support</u></p> <ul style="list-style-type: none"> • Monitoring and verifying BPA levels are essential for tracking and determining the effectiveness of BPA measures taken to date. However, it is an inadequate tool on which to rely for the purpose of identifying <u>immediate</u> actions on BPA. • Adequate evidence exists to demonstrate the presence of BPA in wastewater, sludge and in ambient air, to name a few. Reliance on current monitoring will delay actions to reduce BPA levels. Rather than focus on BPA concentration levels, the policy discussion should focus on how to ensure that BPA does not enter the environment or human tissue. • The government assessment report provides some commentary on the effectiveness of current waste water treatment plants to address BPA, noting that reduction rates of <1% to 99% were observed from 36 Canadian sewage treatment plants... Plants exhibiting greater than 50% reduction rates were those employing secondary waste treatment.⁵ Discharge from influents and effluents directed to treatments 	<p>Rec.: We do not support the government proposal to minimize the risk from BPA release. We urge the government to eliminate the risks from releases of BPA. This would include the reduction and ultimate elimination of residual monomer BPA in products. Any applications where BPA is required to perform a particular function, a timeline to find alternatives should be identified.</p> <p>Rec.: Government should require pollution prevention measures by industry to promote prevention at source. Prevention measures may include the review and redesign of manufacturing procedures to prevent BPA releases to the environment.</p> <p>Rec.: Government should require the identification and implementation of safe substitutions of BPA in products, in particular, for food contact (including repeat-use bottles, PVC water pipes) and human bodily fluid contact.</p> <p>Rec.: The risk management report should provide specific detailed information on the use</p>

⁵ Environment Canada and Health Canada. October 2008. Screening Assessment for the Challenge Phenol, 4,4'-(1-methylethylidene) bis, Chemical Abstract Service Registry Number (CAS RN) 80-05-7. pg. 8.

Risk management components ⁴	Proposed Government measures	CELA & CSM - comments	Recommendations
	months.)	plants are significant sources of BPA. These sources of BPA may be applied as sludge to agricultural land, etc. The reliance on treatment plants to remove BPA does not result in prevention. Sewage treatments plants across Canada are not identical for processing; some communities may not even have treatment plants available and others may be employing only primary treatment plants, which are inadequate to effectively reduce BPA levels.	of regulatory measures in addressing environmental releases of BPA. The use of the word “will consider” should be replaced by “will undertake” to develop regulations to prevent BPA releases to the environment.”
Disposal/recycling of products or materials containing BPA (section 9.1.4.2)*	<p>“Work closely with provincial, territorial and municipal counterparts to minimize the quantities of bisphenol A released to the environment, from the disposal or recycling of products.”</p> <p>“Options will be explored...regulatory approach at facilities releasing this substance.”</p>	<p><u>Do not support</u></p> <ul style="list-style-type: none"> • While we are pleased to see commentary related to BPA containing products and their recycling/disposal, the government proposals will not result in substantive measures that will eliminate BPA as a toxin in waste streams and soil. Also, incineration was not explicitly mentioned in the disposal/recycle review. The use of incineration practices to address waste raises a number of other problems, including the production and release of other toxic chemicals such as dioxins, furans and heavy metals. 	<p>Rec.: The government should ensure that its efforts to consider disposal and recycling issues do not include consideration of incineration technology as an adequate measure in addressing the disposal of products containing BPA. There are concerns about the range of toxic by-products released from incineration processes being even more toxic than BPA as a result of incomplete combustion. It is essential to consider the range of toxic by-products from BPA in its lifecycle as part of the assessment and proposed management reports.</p> <p>Rec.: Despite the authority of provincial and municipal governments to address disposal matters, a federal commitment to the phase out of BPA should be beneficial to provincial and municipal governments targeting the disposal of BPA products. Government should establish a phase out goal for the use of BPA in industrial and consumer products, so as to reduce BPA exposure to the environment and humans. Should specific exemptions be required, a one time limited exemption should be considered to allow time to identify safe alternatives,</p>

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			reformulation, product redesign or process redesign.
Information gathering (section 9.2)*	- Monitoring to continue under the National Pollutant Release Inventory (NPRI)	<ul style="list-style-type: none"> Although reporting releases of BPA have been required under the NPRI for years, there are many limitations to the NPRI including the reporting requirements by facilities. For example, not all facilities releasing BPA may be reporting to the NPRI program since they may not be meeting the thresholds for number of employees and number of hours worked. Furthermore, the NPRI data released to the public does not provide trends on BPA levels over the years. These are some limitations that exist in the use of NPRI data. 	<p>Rec.: The government should improve reporting requirements for BPA under the NPRI thereby requiring all facilities using or releasing BPA to report, regardless of the reporting thresholds currently outlined for the NPRI program. This will require the threshold for reporting to be lowered.</p> <p>Rec.: To improve understanding on the sources and trends for BPA from Canadian facilities, the NPRI should be utilized more fully in the Chemicals Management Plan (CMP) process to determine levels of releases and trends over time. This data should be presented through an annual report to the Canadian public.</p> <p>Rec.: The government should enhance requirements by facilities reporting to NPRI, in particular, on BPA, to report pollution prevention activities implemented during the year. The pollution prevention information should be included in an annual report to the public.</p>
Information gathering (section 9.2)*	Survey of Class 11, 111, 1V medical devices (in contact with patient or patient bodily fluid) for BPA	<ul style="list-style-type: none"> While there is agreement to gather more information on the stated medical devices, there is a gap with regard to action by the government to prohibit BPA from new devices and, in particular, those devices that are in contact with bodily fluid. This is of great concern since there is direct contact with bodily fluids and the possibility of BPA migration into the body. 	<p>Rec.: Based on the already stated health concerns regarding BPA exposure and with emphasis on this type of exposure, BPA should be prohibited from use in all new medical devices (classes as stated by the government). In keeping with this recommendation, we also recommend that existing devices be replaced with BPA-free devices.</p> <p>Rec.: Establish a stakeholder task force mandated to assess the safety of alternatives of BPA for these applications.</p>

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Information gathering (section 9.2)*	Domestic Substance List inventory update	<ul style="list-style-type: none"> • The DSL is over 20 years old and an update of the inventory is urgently needed. The update to the DSL should be comprehensive and complete to allow the government to make policy decisions as well as maintain an accurate inventory of all users, importers and manufacturers of these chemicals in Canada. • The reporting of releases and transfer of data to the NPRI program since 1994 demonstrates that facilities are well positioned to participate in a full and comprehensive update of the DSL. The NPRI reporting mechanism can provide a model for a comprehensive DSL update. 	<p>Rec.: We urge the government to undertake a comprehensive update of the full DSL substances, including BPA.</p> <p>Rec.: In efforts to undertake an update the DSL, it should be noted that the threshold for reporting on high priority substances such as BPA should be lowered from the current levels of 100 kg required for the DSL.</p> <p>Rec.: We urge the government to use the NPRI program as the model for developing the reporting mechanism for the DSL inventory update.</p>
Monitoring (section 9.2)*	<p>1) Exposures to pregnant women - Maternal-Infant Research on Environmental Chemicals (MIREC) Study & Plastics and Personal-care Product Use in Pregnancy</p> <p>2) Canada Health Measures Survey – BPA will be included as a substance for analysis;</p>	<ul style="list-style-type: none"> • We support the proposal to include BPA as a substance to be monitored in the specified areas. However, additional focus to monitor this substance in specific vulnerable communities is needed to demonstrate the extent of exposure. • We also recognize that monitoring through the various programs is needed to establish baseline data, fill data gaps and identify further research on the fetal effects of BPA. • However, monitoring programs should not result in delaying regulatory action on BPA. There is sufficient evidence that demonstrates the presence of BPA in human tissues and the impacts of BPA exposure, even at low doses, may have long term adverse health effects. Delays in responding to the findings of the BPA final screening assessment will result in on-going exposure to the general population, and 	<p>Rec.: We support monitoring efforts to demonstrate the effectiveness of BPA measures, given the availability of sufficient evidence to indicate the need for a preventative and precautionary approach to BPA, particularly from consumer products that may contain BPA.</p> <p>Rec.: We urge the government to ensure that data should be collected on the use, release, presence and impact of BPA in aboriginal communities. In addition, the various planned monitoring programs should be extended in a comprehensive manner to these communities.</p>

Risk management components ⁴	Proposed Government measures	CELA & CSM - comments	Recommendations
	<p>3) Inclusion of BPA monitoring in the 2009 cycle of the Canadian Total Diet Study (TDS);</p> <p>4) address data gaps for BPA exposure – infant and canned foods included.</p>	<p>in particular, to pregnant women, babies, children and workers.</p> <ul style="list-style-type: none"> • As noted, current proposals lack aggressive actions by the government to further reduce BPA exposures for the most vulnerable populations in our society – babies, infants, pregnant women, and the fetus. • Statistics from other jurisdictions already indicate the widespread presence of BPA, including those areas mentioned for monitoring in the risk assessment. 	
Monitoring (section 9.2)*	Environmental monitoring of BPA including: wastewater effluent, wastewater sludge, fish landfill leachate, wildlife, receiving waters downstream from wastewater treatment plants.	<ul style="list-style-type: none"> • The assessment report presents data showing that BPA is widely present in the environment. Again, while BPA monitoring is acceptable, there are other variables such as the efficiency of wastewater treatment facilities and other pollution facilities, which can affect the concentration of BPA in our waterways. • The presence of BPA in various environmental media and aquatic life, demonstrates the need to reduce BPA in our soil and water supply. 	<p>Rec.: Government should ensure that BPA-containing sewage sludge is not used for agricultural purposes.</p> <p>Rec.: Government should provide necessary resources for upgrades to sewage treatment plants across Canada.</p> <p>Rec.: Government should require the development of sewer use bylaws that require facilities discharging to municipal sewage treatment plants to prepare pollution prevention strategies on toxic substances, such as BPA.</p>
Research (section 9.2)*	Ongoing research: “mechanism of action of BPA and potential fetal exposures to	<ul style="list-style-type: none"> • There is value in on-going research on BPA particularly as it focuses on “mechanism of action of BPA and potential fetal exposures.” However, such activities should not delay government in developing comprehensive protection for the fetus at the present time. This 	Rec.: We urge the government to phase out BPA in consumer products and industrial applications so as to ensure protection for vulnerable populations such as infants, pregnant mothers and children from sources of BPA.

Risk management components ⁴	Proposed Government measures	CELA & CSM - comments	Recommendations
	BPA.”	approach would be consistent with applying the precautionary principle.	
Cosmetics	Not included in the risk management	<p><u>Do not support</u></p> <ul style="list-style-type: none"> • The proposed risk management document does not provide sufficient information as to the extent BPA is found in cosmetic products. However, given that BPA is a potential reproductive toxicant, an explicit comment by government is required to ensure that BPA is not be used in cosmetics and personal care products now or in the future. 	<p>Rec.: Government should impose a ban of BPA in cosmetic and personal care products.</p> <p>Rec.: A ban of BPA in cosmetic products may include adding BPA to the Cosmetics Ingredient Hotlist as a prohibited substance for use in cosmetics and personal care products, with improved compliance mechanisms under the Food and Drug Act</p>
Occupational health	Not included in the risk management	<p><u>Do not support</u></p> <ul style="list-style-type: none"> • The government final screening document and the proposed risk management document do not provide commentary on the occupational exposure to BPA. Although occupational exposure to toxic chemicals is recognized more as a provincial responsibility, the federal government has failed to articulate that BPA is used extensively in industry and as such, exposure to workers should be included in the risk management. This gap is significant. Occupational exposure guidelines for BPA respirable dust are lower in Germany and the Netherlands than in North America. 	<p>Rec.: BPA measures should include the lowering and eventual prevention of workplace exposure level for BPA respirable dust under the Canadian Occupational Health and Safety Regulations.</p> <p>Rec.: We urge the government to include the protection of workers exposed BPA in its BPA management strategies.</p>

Concluding Comments:

CSM and CELA urge the government to consider a comprehensive strategy that leads to the prevention and ultimate elimination of BPA from applications in industrial settings and consumer products. The current proposals by government will not adequately protect even our most vulnerable population, infants. Until the main sources of exposure are targeted for regulatory action, particularly the phase out of BPA from food can linings and other food packaging (including baby formula packaging), Canadians may be vulnerable to the long term adverse effects of BPA.

We look forward to further engagement on the proposed measures taken on BPA in the coming months. Please do not hesitate to contact us should you wish to discuss this submission.

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