

CANADIAN ENVIRONMENTAL LAW ASSOCIATION L'Association canadienne du droit de l'environnement

CELA response to:

Canada Gazette Part I Vol. 142, No. 16 — April 19, 2008 Phenol, 4-4'-(1-methylethylidene)bis-(Bisphenol A)

Submitted to: Executive Director Existing Substances Division Environment Canada Gatineau, Quebec K1A 0H3

Submitted by: Fe de Leon Researcher, Canadian Environmental Law Association And Theresa McClenaghan Executive Director and Counsel, Canadian Environmental Law Association

June 18, 2008

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CELA provides the following submission with respect to the Canadian government's proposed decision with respect to the toxicity of Bisphenol A. CELA is a federally incorporated, legal aid clinic, with a mandate to provide legal representation, client services, and advocacy with respect to law reform matters, as well as public legal education and outreach in the areas of environmental law. In particular, CELA has undertaken extensive substantive, policy and client services with respect to, among other things, matters of environmental health, access to environmental justice, and toxics and pollution since its inception in 1970.

Support Proposed Decision for Toxicity under CEPA s. 64 (a) and (c)

CELA supports the government's decision to propose that Bisphenol A meets the criteria in paragraph 64(a) and 64(c) of CEPA, 1999. Based on this support, CELA is providing the following comments on the draft assessment report and draft management document to ensure that the government's action on Bisphenol A is protective of the environment and human health. Based on the draft assessment results and the level of details provided on the level of exposure to and the impacts to human health and aquatic wildlife populations, it is appropriate for the government to add Bisphenol A to Schedule 1 of CEPA to confirm the government's efforts to develop regulatory actions which aims to eliminate over time the use and release of Bisphenol A in Canada.

Recommendation: CELA supports the finding that Bisphenol A meets the criteria in paragraph 64(a) and 64(c) of CEPA, 1999.

Recommendation: Bisphenol A should be added to Toxic Substances List (Schedule 1) of CEPA 1999 to trigger the development of regulatory actions that would aim to eliminate the use and release of Bisphenol A.

Specific Comments on Screening Level Risk Assessment for Bisphenol A

Address exposure to developing foetus, children and other vulnerable communities

Developing foetus and growing children

CELA agrees with the approach of the draft assessment report that outlines principle exposure routes of BPA to children. This is a distinct approach from the other assessments conducted so far, on substances identified through the CMP process, which have lacked a substantial focus on exposure to children. CELA encourages a similar approach for all assessments pertaining to substances under consideration in the CMP. The assessment includes information regarding exposure of children to Bisphenol A effectively demonstrating the unique vulnerabilities of children such as that due to their body weight, feeding patterns and particular stages of development.

Recommendation: CELA supports a focus on exposure to children as demonstrated in the draft assessment report. CELA urges that this approach should be applied for all substances assessed under the CMP.

However, despite the inclusion of consideration of exposure of children to BPA from various consumer products, CELA is concerned that the draft assessment report and the corresponding government management report did not also provide additional emphasis on the unique vulnerabilities of pregnant women and developing foetuses to Bisphenol A. Despite a wealth of knowledge and scientific evidence demonstrating the potential for significant impacts to the developing foetus *in utero* from exposure to toxic substances in general, and scientific evidence of significant foetal vulnerability to Bisphenol A specifically, the government assessment and management report have not proposed adequate and necessary steps to protect the developing foetus. CELA urges the federal government to conduct this additional assessment for these additional vulnerable populations.

At the moment, the government's proposals to promote and find a reformulation of baby formulae and prohibit use of BPA in baby bottles are important announcements but represent only part of the solution of prevention and precaution of BPA. Numerous additional sources of direct BPA exposure arise for children and pregnant women in the form of hard plastic water bottles, other hard plastic food and drink containers and the lining of most canned foods. The narrow focus on baby bottles and infant formula avoids consideration of exposures *in utero* and throughout childhood and among adults. As the draft assessment report notes, there is evidence of a five-fold magnification of BPA levels in amniotic fluid over BPA levels in the mother's blood. Levels in breast milk are comparable to levels found in canned foods and early results from the Canadian House

Dust Study found BPA levels in 99% of homes tested. This evidence of pervasive exposure demands a corresponding management strategy that addresses multiple exposure sources, particularly during the most vulnerable period of fetal development.

Recommendation: CELA supports the aggregate work summarized under Table 20 for Bisphenol A. This table should also include estimates for exposure for vulnerable populations such as for a pregnant woman and her developing foetus and accounting for the degree of magnification across the placenta.

Recommendation: The government should ensure that protection of the foetus be included in the management strategy to be developed on Bisphenol A.

Recommendation: The proposed management regime for Bisphenol A should be dramatically revised to ensure government prohibits the use of Bisphenol A in polycarbonate baby bottles and in epoxy resins used in any consumer products that are expected to come into contact with food and drink containers.

Workers

The introduction of the assessment report included a qualifying comment to note that the evaluation of exposure to the general population did not include consideration of exposures to workers. The exclusion of workers in assessments completed on substances targeted under the industry challenge remains a significant gap in the government's approach. CELA recognizes that exposure to workers to substances such as Bisphenol A are reviewed under programs such as WHMIS. However, it is imperative that the chemical assessments be significantly improved by the inclusion of information regarding worker's exposure to these substances. Workers working with Bisphenol A may experience additional burdens of exposure from their place of employment. The assessment results should recognize this significant exposure route in its deliberation on the Bisphenol A and propose a mechanism to address these sources of exposure. At the current time, Canadians cannot know from the assessment the extent to which workers are exposed to Bisphenol A nor to what degree this information may be available since no references are included in the assessment on this topic.

Recommendation: The assessment report should include additional information estimating of exposure of workers to Bisphenol A and outline a management strategy that ensures the protection of workers. In addition, the assessment should outline what applicable legislation will used to develop measures that will protect workers from exposure to Bisphenol A.

Recommendation: Data should be collected on the use, release, presence and impact of Bisphenol A on the aboriginal community. This data collection should be included in the survey conducted under CEPA 1999.

Challenge survey and questionnaire

CELA has provided in depth comments on the use of surveys through section 71 of CEPA during the categorization process. These comments remain relevant as they relate to Bisphenol A. We have provided the link to this submission as follows and reiterate these comments:

<u>http://cela.ca/uploads/f8e04c51a8e04041f6f7faa046b03a7c/537EC_surveys.pdf</u>. It is our view that the limitations of the survey and its accompanying questionnaire may have significant impacts to the outcome of the assessment. It is our view that the surveys should be more explicit in the type of data requested.

- 1) In responding to the industry challenge, facilities and interested parties were not required to describe or outline the type of break- down or by-products resulting from Bisphenol A. This type of information is very useful particularly if consumer products that contain these substances will be disposed of through landfills or by other technologies (such as incineration). The survey requested information on the substance released into air, water and land as well as transferred off-site.
- 2) These surveys are only applicable to one year of data, 2006. The response to the survey will not include those facilities that may have used the substance prior to, but not during the year2006. For Bisphenol A, the lack of data prior to 2005 may be a significant gap and will not demonstrate the full scope of use of this substance. This gap will have a significant impact on how the government responds with its management strategies on Bisphenol A and other substances covered under the industry challenge.
- 3) There was a failure to request toxicity data for endocrine disruption and neurodevelopmental toxicity. These toxicity endpoints were not a focus during categorization. If this information is in the possession of facilities or other stakeholders, the government should highlight this information in the assessment report. In the case of Bisphenol A, the assessment report highlights sufficient data to demonstrate neurodevelopmental toxicity and disruption to hormonal systems. Consideration of these health endpoints has proven to be a very important source of information in making this proposed determination of toxicity under CEPA s. 64. However, no other assessments under CMP have yet provided such data but should all should be required to do so.

Recommendation: The surveys to be conducted for other CMP substances should be revised to include:

- explicit data requests for toxicity information on neurodevelopmental toxicants and endocrine disruption.
- Data should be collected for more than one year.
- Data should be required on break-down products including information on the by-products released from waste disposal methods.

Lack of consideration of by-products

The assessment report is very limited in the descriptions it provides for by-products produced from the use of Bisphenol A in diverse consumer products. The assessment report notes that "Bisphenol A may enter the environment through physical and chemical degradation of end products during disposal and recycling operations... losses could occur at elevated temperatures, for example, during heating of end products." The assessment report provides substantial evidence on the presence of Bisphenol A in sewage sludge and in waste water effluent which are critical sources of Bisphenol A that should be addressed. However, the assessment does not investigate the quality of the leachate and the potential level of exposure and impact to the environment or human health. Furthermore, the assessment report fails to provide any insight on the by-products that may be produced should consumer products containing Bisphenol A be incinerated as a waste disposal method. Given the use of Bisphenol A in production of polycarbonate plastics and other epoxy resin coatings, formation of other toxic substances such as dioxins and furans may be released from the burning of plastic wastes. The assessment report should be revised to include this type of information as this information would be extremely valuable particularly for decision makers in developing management strategies

Recommendation: The assessment report should include information on the type of break-down products produced at all stages of use, production, release and disposal of products containing Bisphenol A given that some of these break down products may be as toxic or more toxic than Bisphenol A. In particular, the assessment report should estimate exposure levels and release levels for toxic substances (i.e., dioxins and furans, hexachlorobenzene, etc.) expected to be released through incineration activities for products containing Bisphenol A, and should be included in the assessment results to support a full life cycle approach.

Levels of Bisphenol A in waste water and sludge

As noted the assessment report provides sufficient data that demonstrates significant and measurable levels of Bisphenol A in waste water and in sludge that may be used for agricultural application. The fugacity model application to Bisphenol A suggest that the release of Bisphenol A in waste water effluent should be a cause for concern for aquatic organisms found in the receiving water and to water quality. Given that sewage treatment plants in Canada have different treatment capacity and technology in use it makes it difficult to ensure effective mechanism for capturing Bisphenol A at the end of pipe, the government should ensure that the management regime focuses on the prevention of Bisphenol A. The current management proposal fails significantly to address this matter since it does not promote prevention at source. There are various CEPA sections that would support the need for pollution prevention strategies which have not been proposed. For example, such a strategy may include mandatory pollution prevention planning to promote reduction and phase out over time in Bisphenol A use in industrial applications as well as use in consumer products. It should include

identification and promotion of safer alternatives to Bisphenol A in its various applications.

Recommendation: The risk management response to data presented on levels of Bisphenol A in waste water effluent and sludge quality have not been adequately addressed. The management regime should focus on measures that promote prevention at source. This may include need for pollution prevention planning by industry using Bisphenol A, prohibiting the use of Bisphenol A in PVC piping for water delivery, and other similar contexts.

Recommendation: Government should ensure that **BPA-containing municipal** sludge is not used for agricultural purposes.

Consideration of aggregate exposure

CELA is please to see that the draft assessment report on Bisphenol A included a section investigating the aggregation of several exposure sources for Bisphenol A for children and adults. Unlike other assessments conducted to date under the CMP, the consideration of aggregated exposures will provide useful information that will help in the development of appropriate management options for Bisphenol A. The consideration of aggregate exposures outlines the main source of exposure from consumer products as well as environmental media. The exposure data is summarized in table 20.

Recommendation: Following the example of the Bisphenol A assessment report, CELA strongly urges the government to incorporate an approach of aggregating of exposure data for all assessments completed under the CMP.

The assessment report, however, does not include consideration of cumulative impacts from other chemicals similar to Bisphenol A. This is a gap in the assessment. The receiving environment and the human populations continue to be exposed to many toxic substances in our daily lives but risk assessments do not account for these cumulative impacts. To fully understand the impacts to our health and to our environment this type of analysis is urgently required.

Recommendation: The assessment report should be strengthened to include analysis on the cumulative impacts of Bisphenol A and other members of this class of substances to the environment and human health.

Recommendation: Recognizing that methodologies for assessing cumulative impacts of multiple chemical exposures remain controversial and complex, all CMP assessment reports and resulting risk management approaches should recognize the reality of multiple exposures to diverse chemicals, and, accordingly, respond with broadly precautionary actions. For Bisphenol A, such actions should include bans on the use of BPA in food and drink containers and aggressive measures to reduce BPA in those areas where the assessment report indicates high levels of exposure: in house dust, in municipal

wastewater effluent and sewage sludge. Cumulative assessment of the class of chemicals similar to BPA should proceed alongside these immediate precautionary measures and not await further assessment.

Issues relevant to Management of Bisphenol A

All sources of Bisphenol A not managed effectively in proposed management proposal

Despite the extensive data collected for the assessment of Bisphenol A to demonstrate widespread exposure as well as impacts on aquatic species, wildlife and human health, particularly *in utero*, the government's proposed management response falls short of a comprehensive approach to address Bisphenol A in Canada. The proposed management approach does not reflect the level of action required to address the threats to the environment and to human health. The proposal to prohibit the use of Bisphenol A in polycarbonate baby bottles is an important proposal but only represents one element of a substantive effort needed to reduce use of Bisphenol A in Canada. The piece-meal approach currently being undertaken by Canada will continue to neglect different sources of exposure to Bisphenol A to the general Canadian population. The information on the leaching of Bisphenol A from canned linings is one example of source that will not be adequately addressed with the proposed management regime.

This gap will result in the continued exposure of Canadians to Bisphenol A. It is our position that Canada should respond with a regulatory regime that will ensure the protection of Canadians at all ages, including the developing foetus.

Recommendation: The government should revise its proposed management approach to prohibit the use of Bisphenol A (polycarbonate or epoxy resin) in any consumer products that come into contact with food or beverages. This would include polycarbonate plastic used for baby bottles, repeat use water bottles, other polycarbonate plastic containers for food and beverages as well as linings of canned food.

Recommendation: The government should work with industry and other stakeholders to identify safer alternatives to Bisphenol A in various consumer products and industrial applications to reduce use of Bisphenol A over time with an ultimate goal of elimination.

Recommendation: CELA urges the government to use CEPA and its statutory tools to develop regulations that lead to the prevention, prohibition and reduction of use of Bisphenol A under CEPA, 1999 to ensure that industrial applications and use of Bisphenol A in consumer products can be effectively addressed.

Recommendation: The government should establish a stakeholder task force that would be mandated to establish a process to assess the safety of alternatives to toxic substances such as Bisphenol A.

Using the assessment results to trigger action under Canadian legislation

Under the CMP, the federal government's efforts to assess substances should be better integrated with federal and provincial legislation where applicable. For example, "the federal government is responsible for over 25 different laws covering environment and environmental health issues" including the Food and Drugs Act, Pest Control Products Act, Transport Canada, Canadian Environmental Protection Act (CEPA), Hazardous Products Act. However, the Workplace Hazardous Materials Information System (WHMIS), Canada's national hazard communication standard, is not listed in the hierarchy of approaches that may be relevant to protection of environment and health. WHMIS and other legislation geared to the workers protection should be integrated into the hierarchy of approaches and statutes in Canada that will be relevant to the CMP. The use, production and release of toxic substances in the workplace provides important information and data on the substances' behaviour, impact and fate that would be difficult to gather in the current regime where toxicity data and testing data for existing substances are not currently required under CEPA. If CMP is truly to move Canada ahead of other countries in addressing legacy substances, its efforts should take into consideration data generated in the workplace and the results of assessment should be used to flag action under CEPA and any other relevant Canadian statutes and programs. Canada states that:

Canada has a clear roadmap for assessing and managing chemical substances that will better protect our health and environment. The Government of Canada continues to work with partners in provinces and territories, industry, health and environmental communities and other countries to ensure that the best approaches are taken.¹

However, the draft assessment for Bisphenol A doesn't include any information on worker's exposure in general, and doesn't consider worker's exposure in the aggregation information that was gathered. This result of such a gap means that decision makers and the public cannot know whether the proposed action is adequate. Also lost is the means to provide a signal that action under other legislation may be required on Bisphenol A to ensure that the general public and workers are protected from sources of this substance. CELA would consider one of the important sources of information emanating from the draft assessment report on these substances is to highlight the need to trigger action under other Canadian legislation. At the moment, the management document doesn't provide this level of detail. It has been mentioned through additional meetings that the government proposed to use the Hazardous Products Act to address Bisphenol A in polycarbonate baby bottles. The use of the Hazardous Products Act to address BPA sends a signal that integration with CEPA is not contemplated and thus the government does not intend to apply the scope and tools available in CEPA to address BPA in industrial settings, in consumer products or their disposal. Consideration of integration of CEPA tools and the applicability of the Hazardous Products Act should be initiated without delay.

¹ See - <u>http://www.chemicalsubstanceschimiques.gc.ca/substance/what-quoi/index_e.html</u>

Recommendation: The draft assessment report and risk management report should articulate adequate detail of information on the scope of regulatory and non regulatory actions that are to be taken on Bisphenol A.

Recommendation: Furthermore, these reports should also identify what legislation will apply and provide rational for this approach. The management process should include a forum to discuss these proposals.

Other management tools to track Bisphenol A in Canada

Reducing reporting thresholds for Bisphenol A

The government should ensure that Bisphenol A is reduced and eliminated over time in Canada. Tracking use and release of these substances should be part of the strategy. The government's proposal to update the Domestic Substances List, which includes Bisphenol A is one important element in these efforts. Future discussions on the update of the DSL are expected to be undertaken. The government should take this opportunity to expand the requirements of reporting of releases of Bisphenol A under the National Pollutants Release Inventory. Although current data included in the assessment report suggest that Bisphenol A levels have declined, the trend of release is unclear for these substances. It is entirely appropriate to reduce the thresholds for reporting from facilities who release Bisphenol A to demonstrate the level of release in Canada.

Recommendation: The reporting threshold for Bisphenol A under the National Pollutants Release Inventory should be reduced to obtain a better understanding of the sources of Bisphenol A from industry. Furthermore, improved reporting will provide more insight on trends for Bisphenol A from Canadian facilities.

Requiring action plans for reduction through pollution prevention planning

The government's proposed management regime on Bisphenol A does very little to promote safer alternatives to Bisphenol A. The government should seize this opportunity offered through the industry challenge to promote and develop safer alternatives that would contribute to the reduction of levels in use, release and generation of these harmful toxic substances. The draft assessment report does not offer information on the availability or cost of safer alternatives to Bisphenol A in the wide range of applications, including the use in food can linings. It has been demonstrated in various jurisdictions (such as Japan) and companies have identified alternatives to the applications of Bisphenol A in can linings. This information should be more extensively presented in the follow-up management document. CELA supports the inclusion of preliminary information on safer alternatives in the assessment reports. This information could be collected in the voluntary questionnaire or through the government's own research efforts. Such an approach would also be valuable in that it would be more consistent with a precautionary approach. This type of information would also facilitate management discussions that could shift the focus on the use of Bisphenol A and highlight the availability of the safer alternatives.

There are various opportunities and tools under CEPA that have yet to be utilized to the full extent in the promotion of reduction and elimination. This would include the development of Pollution Prevention Plans in order to promote reduction at source for Bisphenol A. The need for Pollution Prevention Plans from facilities using or releasing Bisphenol A would contribute to a better understanding of a facilities' contribution of Bisphenol A to the environment, in particular, to the presence of Bisphenol A in waste water and a better understanding where technical improvements for efficiencies can be undertaken. These tools should be incorporated in the management regime.

Recommendation: The government should require pollution prevention planning for all facilities using and releasing Bisphenol A to the environment to promote the reduction and elimination of Bisphenol A.

We are pleased to have the opportunity to provide these comments and would be pleased to provide further information if that would be of assistance.

Yours very truly,

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