

Summary of Public Comments Received on the Government of Canada's Proposed Risk Management Approach Document on Phenol, 4,4' -(1-methylethylidene)bis- (CAS RN 80-05-7)

The proposed risk management approach document for **Phenol, 4,4' -(1-methylethylidene)bis-** (referred to throughout this document as “bisphenol A”) was published as part of the Government of Canada's Chemicals Management Plan Challenge. Comments were provided by the American Chemistry Council, the Canadian Council of Grocery Distributors, Medical Device Technology Industry (MEDEC), North American Metal Packaging Alliance (NAMPA), Plastics Europe (European producers of bisphenol A and polycarbonate), a consolidated submission representing 19 environmental non-governmental organizations, Canadian Environmental Law Association & Chemical Sensitivities Manitoba, Crooked Creek Conservancy Society of Athabasca, Environmental Working Group, Learning Disabilities Association of Canada, STORM Coalition, Toxic Free Canada (formerly Labour Environmental Alliance Society), and two private citizens. The proposed Risk Management Approach was published in October, 2008; however, the responses below represent the status of the risk management activities as of the date of publication of this summary table (October, 2010).

A summary of comments and responses is included below, organized by topic:

- Basis of risk management
- Precaution
- Risk management timelines
- Extent of risk management actions
- Vulnerable populations
- Additional research
- Alternatives
- Labelling
- Cosmetics
- Food packaging
- Medical devices
- Environment
- Releases
- Socio-economic impacts
- Other jurisdictions

TOPIC	COMMENT	RESPONSE
Basis of risk management	The proposed risk management objectives are not supported by the scientific evidence. The Government should complete its research, evaluate the findings and then take action when and where necessary.	The proposed risk management objectives are based on the conclusions in the Final Screening Assessment Report. The Government agrees that there are areas where more information is needed. The proposed Risk Management Approach outlined some information gathering initiatives which are planned or underway.
Precaution	The Government of Canada has applied the precautionary principle without an appropriate scientific basis as required by CEPA 1999.	The Government of Canada's approach is based on the best available science, and is the result of extensive consultation with stakeholders and industry and thorough reviews of scientific research and evaluation.
Risk management timelines	The proposed risk management approach is vague and non-committal with no timelines. It lacks immediate actions that will reduce exposures of Canadians or the environment in the near future.	<p>The proposed Risk Management Approach outlined the Government's plan to prohibit the importation, sale and advertising of polycarbonate baby bottles that contain bisphenol A by fall 2010. The prohibition of polycarbonate baby bottles that contain bisphenol A came into force on March 11, 2010. Parents and caregivers can find out how to immediately reduce exposure to bisphenol A when using polycarbonate baby bottles by visiting the following website: http://www.chemicalsubstanceschimiques.gc.ca/challenge-defi/batch-lot-2/bisphenol-a/index-eng.php .</p> <p>The ALARA (As Low As Reasonably Achievable) approach has been adopted and is currently being used to reduce the exposure to bisphenol A from canned infant formula and other canned foods. Some actions require consultation before timelines can be established.</p> <p>The Government published a proposed Pollution Prevention Planning Notice (P2 Planning Notice) in the <i>Canada Gazette</i>, Part I, on October 16th, 2010, which aims to reduce releases of bisphenol A from industrial facilities.</p>

Extent of risk management actions	No actions are proposed for other bisphenol A-containing products (e.g. polycarbonate reusable water bottles, polycarbonate food containers, sippy cups and polycarbonate water pipes).	The Screening Assessment Report indicated that the exposure from all sources of bisphenol A to the general population is low and that most uses of products containing bisphenol A pose little risk to Canadians. Therefore, at this time, there are no immediate plans to take actions related to health concerns beyond those specified in the proposed Risk Management Approach. However, the Government continues to review new research and monitoring information and take further action if necessary, to protect the health and safety of Canadians and their environment.
	Risk management should focus on elimination and replacement of bisphenol A and not on the minimization of release and exposure.	<p>A complete prohibition is not justified at this time because the Screening Assessment Report indicated that the exposure from all sources of bisphenol A to the general population is low and that most uses of products containing bisphenol A pose little risk to Canadians.</p> <p>The proposed Risk Management Approach to prevent or minimize releases of bisphenol A into the environment is consistent with the Government's Toxic Substances Management Policy for a life-cycle approach to the risk management of substances that do not meet the criteria for virtual elimination.</p>
Vulnerable populations	<p>No actions are proposed for the pregnant women/foetus or nursing infant.</p> <p>An advisory for pregnant women and young children on dental work, canned food and polycarbonate food and drink containers should be developed and made more accessible than just on the web.</p>	<p>The final Screening Assessment Report confirmed current exposure levels for the general population, including pregnant women or nursing infants, are below those that could cause health effects. However, due to the uncertainty raised in some studies relating to the potential effects of low levels of bisphenol A in experimental animals, the Government is taking action to enhance the protection of newborns and infants. For this reason, risk management is focused on decreasing exposures to infants by prohibiting polycarbonate baby bottles that contain bisphenol A and by working with industry to reduce the amount of bisphenol A in infant formula can linings.</p> <p>The Government has developed advice for pregnant and breastfeeding women in relation to canned food and polycarbonate food and drink containers. The Government has also made information available to</p>

		<p>parents and caregivers on how to reduce exposure to bisphenol A when using polycarbonate baby bottles.</p> <p>This information can be found at www.chemicalsubstanceschimiques.gc.ca.</p> <p>Paper copies of this information may also be requested by mail, telephone, fax or e-mail. Contact information is below.</p> <p>Mail: Chemical Substances Website c/o Health Canada A.L. 4905B Ottawa (ON) K1A 0K9 Telephone: 613-954-9807 Fax: 613-952-8857 E-mail: info@chemicalsubstanceschimiques.gc.ca</p>
	Data should be collected on the use, release, presence and impact of bisphenol A in aboriginal communities.	Aboriginal communities and newborns and infants in particular, are expected to have similar exposures to other communities. Nonetheless, the Government is working with Aboriginal communities to explore the possibility of undertaking biomonitoring surveys of 91 chemicals of interest, including bisphenol A.
	No actions are proposed to protect workers in an occupational setting. Government should amend the <i>Canada Occupational Health and Safety Regulations</i> under the <i>Canada Labour Code</i> to provide occupational exposure limits for bisphenol A and encourage provincial authorities to adopt them.	The scope of Screening Assessment Reports under CEPA 1999 are focused on the potential risks to the general Canadian public. In terms of risk management, the focus is on protecting the health of the Canadian general population. However the detailed scientific information within the Screening Assessment Reports are shared with officials at the federal and provincial levels responsible for occupational health and safety, including the Chief Medical Officers of Health, and they may subsequently consider additional action with respect to protecting workers.

Additional research	It is important that the second stage of the Maternal-Infant Research on Environmental Chemicals (MIREC) study be funded.	Further information on bisphenol A and exposures of pregnant women will be collected through several research projects, including the MIREC Study. The MIREC study will provide a national profile of exposures to environmental contaminants during pregnancy and breastfeeding. Funding has been secured through the Chemicals Management Plan for the second stage of the MIREC study which is to follow a sub-set of the MIREC infants until they are 6 months of age. This part of the study will examine the association, if any, of environmental chemicals with key biological systems that underlie the normal development of children (e.g., sensory functions; heart rate variability; sexual development and growth).
	The government should investigate the sources of bisphenol A in household dust.	Research on levels of substances in dust, including bisphenol A, is occurring as part of the Government of Canada's house dust study. Based on preliminary data from the study (included in the final risk assessment), the exposure from house dust appears to be low.

Alternatives	<p>Safer alternatives should be identified and assessed. Government should support research to identify them. Data on the safety of known alternatives should be presented.</p> <p>The alternative materials for baby bottles have not been assessed so the risks are unknown.</p>	<p>Where available and relevant to the Canadian context, reliable information on the availability and cost of alternatives to bisphenol A were included in the Risk Management Approach document.</p> <p>The Government has initiated consultations with industry and has committed to evaluating alternatives to bisphenol A for infant formula can linings on a priority basis.</p> <p>There are a number of alternative options to polycarbonate baby bottles, including: baby bottles or baby bottle liners (flexible plastic inserts) made of polyethylene (PE) or polypropylene (PP) or other plastics not made with bisphenol A monomer, and glass baby bottles.</p> <p>Specific bisphenol A substitutes have not undergone a screening risk assessment to determine whether they would meet the criteria under section 64 of CEPA 1999. However, Health Canada has recently published information indicating that the trace levels of bisphenol A that may be contained in non-polycarbonate baby bottles do not represent a health concern and that Health Canada has no current concerns with respect to the safety of baby bottles or bottle liners made from non-polycarbonate plastic.</p>
Labelling	<p>All products containing bisphenol A should be labelled.</p>	<p>The Government uses labelling as a risk management measure to inform consumers of potential risks or to provide them with tools to protect and improve their health (e.g., nutrition labelling). Since the Screening Assessment Report concluded that exposure to bisphenol A from all sources does not pose a risk to the general population, mandatory labelling of cans and other products is not being considered at this time. While the Government's assessment recognized that bisphenol A may be released to some extent from individual products during use, it concluded that most consumer products do not present a significant source of human exposure to bisphenol A.</p>

	The Government of Canada should provide adequate time to consult on and implement changes to packaging and/or products.	The Government considers all relevant social, economic and technical matters when developing risk management instruments. Stakeholders will be engaged and consulted during the development of the risk management instrument(s).
Cosmetics	Bisphenol A should be added to the Cosmetic Ingredient Hotlist.	<p>Cosmetics were not expected to contribute significantly to the overall exposure to the general population, however due to the health concerns identified in the Screening Assessment Report, bisphenol A was added to the Cosmetics Ingredient Hotlist.</p> <p>The Cosmetic Ingredient Hotlist is an administrative tool to help manufacturers satisfy the cosmetic safety provisions of section 16 of the <i>Food and Drugs Act</i>. Compliance with the provisions of section 16 are monitored, in part, through the mandatory notification provisions of section 30 of the <i>Cosmetic Regulations</i> of the <i>Food and Drugs Act</i>, which requires that all manufacturers and importers provide a list of the cosmetic's ingredients to Health Canada.</p>
Food packaging	Leaching studies are needed for polycarbonate tableware and food packaging as well as inks on food packaging and recycled paper.	<p>While bisphenol A may be found in food packaging materials this does not necessarily mean that bisphenol A migrates into food at levels that cause health concern. However, the Government will continue to monitor the levels of bisphenol A in the Canadian food supply by adding it to the list of chemicals to be monitored regularly as part of the Canadian Total Diet Study (TDS), and by performing a number of targeted surveys. Fast foods and prepared sandwiches purchased at different cafeterias or fast-food outlets will be captured in the TDS. This data will be accounted for in regular exposure estimate updates. The results of the BPA targeted surveys for food commodities can be found at:</p> <p>http://www.hc-sc.gc.ca/fn-an/securit/packag-emball/bpa/index-eng.php.</p> <p>The TDS data on BPA will be published as it becomes available.</p>

	Potential exposures from several packaged products were not discussed in relation to minimizing levels in infant formula.	The ALARA (As Low As Reasonably Achievable) principle will be used to minimize the levels of bisphenol A in infant formula and a code of practice is being developed by industry to apply this principle.
	It is recommend that migration levels should be zero in food packaging for infants.	The Government will work with the food packaging industry towards having the levels of bisphenol A As Low As Reasonably Achievable in canned infant formula. This will include the setting of stringent migration targets for bisphenol A in infant formula cans.
	The Government should remove reference to potential actions on canned foods in general because this is not supported by the assessment or the Government's Qs and As.	The levels of bisphenol A in foods packaged in cans are low, and, based on the weight of scientific evidence available to date, do not pose a risk to the health of the average consumer. However, data on bisphenol A occurrence in food sources from a variety of canned foods for all age groups is still being collected. This will help determine whether the option of establishing migration targets for bisphenol A in other canned foods is warranted. The Government is currently moving ahead with actions on canned infant formula, which includes working with the food packaging industry towards having the levels of bisphenol A As Low As Reasonably Achievable and setting stringent migration targets for bisphenol A in infant formula cans.
	Action on infant food packaging should be mandatory.	For infant formulas, the article B25.046. (2) (j) of the <i>Food and Drug Regulations</i> requires the manufacturer of infant formula to include in its notification the description of the type of packaging to be used, so the safety of its packaging material can be assessed. The Government conducts safety evaluations of packaging materials to be sold with food with the objective to make sure these containers do not pose a health risk to consumers. The Government will continue to take measures to protect infants by setting stringent migration targets for bisphenol A in infant formula cans. The Government will also continue to work with industry to develop a 'Code of Practice' to reduce levels of bisphenol A in infant formula can linings to the lowest possible levels and to support efforts to develop alternative can coatings which are bisphenol A-free.

	The Government should recommend that people use infant formula (whether powdered or liquid) in plastic containers as these products are likely lower in bisphenol A.	Health Canada has concluded that the current dietary exposure to BPA through food packaging uses is not expected to pose a health risk to the general population, including newborns and infants. While the Government of Canada is working with industry to both reduce the level of BPA in infant formula can linings and is facilitating the assessment of alternatives, the current packaging type for infant formula is one which provides an important safety function of providing sterility to the infant formula without chemical interactions or corrosion happening at the food-packaging interface. Given this, from a food safety perspective, it would not be considered appropriate to recommend that consumers only buy infant formula in plastic containers.
Medical devices	Bisphenol A should be prohibited from new medical devices and existing devices should be replaced with devices which do not contain Bisphenol A.	The Government plans to gather information from manufacturers of some medical devices that are made from raw materials containing or derived from bisphenol A. However, no risk management activities for bisphenol A are currently suggested for medical devices.
	The survey of medical devices should not be mentioned in the Risk Management Approach as it is unrelated to the findings of the assessment.	No risk management activities for bisphenol A are suggested for medical devices. Information on the survey was included under the heading “other information gathering, monitoring and research”.
Environment	The proposed Risk Management Approach is almost entirely lacking in measures to protect the environment.	On October 16 th , 2010, a proposed Pollution Prevention Planning Notice (P2 Planning Notice) was published in the <i>Canada Gazette</i> , Part I that requires any facility using over 100 kg/year and releasing bisphenol A to the environment to develop a pollution prevention plan to ensure that levels of BPA in effluent are below a level that could cause harm. When developing the P2 Plan, facilities are required to consider: <ul style="list-style-type: none"> • the objective of a 1.75 µg/L limit for bisphenol A in industrial effluents, • working towards preventing or further reducing releases to the lowest level that is technically and economically feasible, • establishing a sampling program to monitor effluent concentrations,

		<ul style="list-style-type: none"> • using pollution prevention as a means of reducing releases of bisphenol A, and • the toxicity of any potential alternatives. <p>Facilities subject to the P2 Planning Notice must also prepare and submit to Environment Canada Declarations of Preparation and Implementation, as well as regular intermediate progress reports containing information on bisphenol A use quantities, processes in place to control releases and measured concentrations of bisphenol A in effluents.</p> <p>The Government also continues monitoring work for bisphenol A in surface water, wastewater (effluent and biosolids), and landfill leachate to evaluate the effectiveness of risk management measures.</p>
	The Government should develop measures to broadly reduce uses and releases at the source, rather than manage levels in waste streams.	The P2 Planning Notice places an emphasis on the reduction at the source (industrial effluents) rather than managing the release of bisphenol A at wastewater treatment systems.
	The proposed Risk Management Approach will not eliminate bisphenol A in waste streams and soil.	The Screening Assessment Report determined that, based on the available information, bisphenol A did not meet the criteria requiring virtual elimination from the environment. Although bisphenol A is bioavailable and can accumulate to some extent in organisms, it did not meet the criteria for bioaccumulation potential as defined in the <i>Persistence and Bioaccumulation Regulations</i> under CEPA 1999. In addition, the risk assessment found that current levels are unlikely to result in harm to terrestrial organisms with exposure via soil, but there is a potential risk to aquatic organisms from wastewater effluents containing bisphenol A. On October 16 th , 2010, a proposed Pollution Prevention Planning Notice (P2 Planning Notice) was published in the <i>Canada Gazette</i> , Part I that would require any facility using over 100 kg/year and releasing bisphenol A to the environment to develop a pollution prevention plan to examine their operations relation to releases of bisphenol A. The P2 Planning Notice will minimize risks associated with industrial releases of bisphenol A in the aquatic environment and private or public wastewater systems.

	Incineration is not considered to be adequate to address disposal of products containing bisphenol A.	The Government is working closely with its provincial, territorial and municipal counterparts to minimize the quantities of bisphenol A released to the Canadian environment from the disposal or recycling of products containing bisphenol A. This approach will take into consideration that the federal, provincial and territorial governments and municipalities have jurisdiction to regulate waste management in Canada.
	Data indicate a higher risk for marine fish around wastewater treatment plants. Information on this and the <i>Fisheries Act</i> should be included in the Risk Management Approach.	As indicated in the proposed Risk Management Approach, monitoring of bisphenol A is underway for wastewater effluents and wastewater biosolids, as well as for receiving waters downstream of wastewater treatment plants and in fish and wildlife. Data collected during the monitoring program will be used during the performance measurement and evaluation part of the regulatory cycle and guide further decision making accordingly. Potential implications of the <i>Fisheries Act</i> (and any other relevant legislation) are considered during development of the proposed risk management measures.
	The Government should modify the environmental objective to prevent releases of bisphenol A into the Canadian environment at levels that could cause adverse population impacts to wildlife species. The Government should also modify the corresponding risk management objective to preventing adverse population impacts on fish and wildlife to the extent technologically and economically feasible.	<p>The environmental objective and the environmental risk management objective consider the potential for continued or increasing exposure of biota to the substance, along with evidence of potential long-term adverse effects relevant to concentration ranges currently measured in the environment.</p> <p>The objective for industrial effluents identified in the P2 Planning Notice is directly linked to the Predicted No Effects Concentration (PNEC) published in the final Screening Assessment Report for bisphenol A, forming a linkage between the objectives of environmental risk management and current understanding of the concentration of bisphenol A in surface water capable of causing harm.</p>
	Rather than an effluent limitation regulation, a more appropriate step would be to issue a water	Environment Canada's National Guidelines and Standards Office is currently developing a Federal Environmental Quality Guideline

	quality guideline for the protection of aquatic life.	<p>(FWQG) for bisphenol A in water. This guideline will identify environmental concentrations that represent slight, moderate and high risk of adverse effects on biota such as fish and wildlife.</p> <p>Based on the information gathered to inform risk management, the measure proposed to address releases of bisphenol A in industrial effluents is a P2 Planning Notice. Regulatory action will be considered only if the P2 Planning Notice does not result in sufficient reductions in industrial releases.</p>
	The Government should not rely on treatment plants to remove bisphenol A because there is variation in treatment plants across Canada. The Government should require the development of sewer use bylaws to make facilities discharging to municipal sewage treatment plants prepare pollution prevention strategies.	In accordance with the proposed regulatory framework for wastewater to manage pollutants at their source, the proposed P2 Planning Notice requires implicated industrial facilities to develop a plan to examine their operations in order to prevent or reduce releases to wastewater systems.
	There should be a strategy for collection and disposal of bisphenol A products including industrial disposal.	The Government is working with provinces and territories on how to best approach the collection and disposal of bisphenol A products to minimize the quantities released to the environment.
	Implement best-practices management in facilities where bisphenol A is used.	The proposed P2 Planning Notice requires facilities to consider the use of pollution prevention activities to achieve reductions in release of bisphenol A in their effluents. Implementation of pollution prevention activities would be considered “best practices” in this situation.
Releases	National Pollutant Release Inventory (NPRI) data do not capture daily variations in releases which may impact local communities.	When risk management instruments are developed to target releases to the environment, the collection of information on daily variations in releases will be considered where appropriate.
	NPRI reporting thresholds should be lowered for bisphenol A and pollution prevention activities should be reported. Facilities should report the location and recipient of off site disposal.	Companies that meet reporting requirements for the NPRI are already required to report their pollution prevention activities. Those companies that dispose off-site are also required to submit the name and address of each receiving facility and the quantity sent to each

		<p>facility.</p> <p>Since the publication of the Risk Management Approach, industry has taken significant steps to reduce the use and release of BPA, such that imports for industrial use have decreased by more than 75% and very few facilities still have effluent containing BPA. Increased reporting of bisphenol A through NPRI is not being considered since submission of data to Environment Canada on bisphenol A including quantities used, measured concentrations in industrial effluent and pollution prevention activities is required under the proposed P2 Planning Notice. The P2 Planning Notice would apply to facilities using over 100 kg/year, which is lower than the current NPRI threshold for bisphenol A of 10,000 kg/year.</p>
	Facilities should monitor releases for bisphenol A according to a standardized methodology.	<p>The proposed P2 Planning Notice requires industrial facilities to consider the following elements during the monitoring of bisphenol A in their effluent:</p> <ul style="list-style-type: none"> • The sampling should be representative of regular or typical operating conditions related to the manufacturing or use of bisphenol A. • Samples should be undiluted, unfiltered and representative of the industrial facility's effluent. • Samples should be collected and analysed at a minimum of 4 times per year using a composite sampling method. <p>Analysis of the samples should be performed in accordance with generally accepted standards of good scientific practice at the time of the analysis by a laboratory that is accredited by a Canadian accrediting body under the International Organization for Standardization standard ISO/IEC 17025.</p>
	The Government should monitor levels in wastewater effluent, biosolids, water, air, fish, landfill and sewage treatment plants.	<p>Environmental monitoring of bisphenol A was initiated in 2008 for surface water, wastewater (effluent and biosolids) and landfill leachate. This monitoring will be used to determine ambient levels of bisphenol A in the environment and assess the efficacy of risk management actions.</p>

Socio-economic impacts	The social and economic impacts of the proposed risk management action should be considered in more detail.	Economic and social impacts were considered during the development of risk management instruments.
	The proposed health risk management objective has already been achieved through voluntary action so further Government action is not efficient or effective. Pursuant to the <i>Cabinet Directive on Streamlining Regulation</i> , the Government should “advance the efficiency and effectiveness of regulation by ascertaining that the benefits of regulation justify the costs, by focusing human and financial resources where they can do the most good, and by demonstrating tangible results to Canadians.”	The Regulatory Impact Analysis Statement for the prohibition of polycarbonate baby bottles containing bisphenol A, published in the <i>Canada Gazette</i> , Part II, volume 144, number 7, demonstrates that the benefits of the prohibition of polycarbonate baby bottles containing bisphenol A justify the cost. The efficiency and effectiveness of future government actions will also be assessed in accordance with the <i>Cabinet Directive on Streamlining Regulation</i> , using the best available information.
	The proposed risk management actions would lead to a restriction on the free trade of goods which is unsupported based on Health Canada’s characterization of the assessment as “in general, most Canadians are exposed to very low levels of bisphenol A , therefore it does not pose a health risk”.	In general, most Canadians are exposed to low levels of bisphenol A; therefore it does not pose a health risk. The Government’s focus now is on the health of newborns and infants under 18 months. Scientific evidence indicates that exposure levels are below those that cause health effects in experimental animals. However, due to the uncertainty raised in some studies relating to the potential effects of low levels of bisphenol A, the Government is taking action to enhance the protection of infants and young children.
Other jurisdictions	The <i>Cabinet Directive on Streamlining Regulation</i> states that the federal government will make decisions based on the best available knowledge and science in Canada and worldwide. Other agencies and governmental bodies have concluded that there is no need for risk management actions. The reputation of bisphenol A-based products will be unjustifiably affected by Canadian risk management actions on products despite the fact that the assessment has not identified any health risk.	The Government recognizes that other jurisdictions have conducted health and environmental risk assessments on some of the substances being assessed under CEPA 1999 and these assessments are considered in the process. However, our conclusions may differ due to the requirements of Canadian legislation and/or due to use patterns and sources of exposure and releases specific to Canadian circumstances.

	<p>The Government is urged to take an internationally harmonized approach to managing internationally used chemicals such as bisphenol A.</p>	<p>The Government will continue to work closely with our international partners on the risk assessment and risk management of bisphenol A. The Government continues to support development of a North-American approach to the reduction of bisphenol A in food products by actively collaborating with the U.S. FDA, other regulatory agencies, and industry. The Government is also hosting the expert meeting of the World Health Organization to review the toxicological and health aspects of bisphenol A from November 1-5 2010 in Ottawa.</p>
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