**Summary of Public Comments Received on the Government of Canada's Draft Screening Assessment Report and Risk Management Scope on Bisphenol A (CAS RN 80-05-7)**

Comments on the draft screening assessment report and risk management scope on bisphenol A, a substance included in Batch 2 of the substances to be addressed as part of the Chemicals Management Plan Challenge under the *Canadian Environmental Protection Act, 1999* (CEPA 1999), were provided by the American Chemistry Council, Bayer Inc., the Canadian Environmental Law Association, the Canadian Council of Grocery Distributors, the Central South West Reproductive Health Working Group, Chemical Sensitivities Manitoba, the Crooked Creek Conservancy Society of Athabasca, Dow Chemical Canada Inc., the Institut national de la santé publique du Québec, the International Formula Council, the Joint ENGO Submission, the Learning Disabilities Association of Canada, MEDEC (Canada's Medical Device Technology Companies), the North American Metal Packaging Alliance, Inc., Philips Electronics Ltd., Toronto Public Health and four individuals during the 60-day public comment period that took place from April 18, 2008 to June 18, 2008.

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

- Human exposure
- Effects on human health
- Pregnant women and fetuses
- Food
- Consumer products
- Medical devices
- Releases to the environment
- Effects on wildlife
- Persistence and bioaccumulation
- Validity of evidence
- Weight of evidence and precautionary principle
- Challenge Advisory Panel
- Peer review
- International
- Substitution and alternatives
- Labelling
- Data collection
- Modelling
- Monitoring and research
- Economic considerations
- Communication
- Typographical errors

| TOPIC | COMMENT | RESPONSE |
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| Human Exposure | Non-oral dosing is inappropriate due to lack of utility and route dependency in the metabolism and pharmacokinetic for adults and should not be used for human health risk assessment. | The predominant exposure to bisphenol A in humans is through the oral route. However, some minor exposure may occur through environmental media or consumer products. Bisphenol A has been detected in parts per billion concentrations in the urine samples of about 92% of a U.S. cohort, which suggests that human exposure to bisphenol A may possibly be continuous and through multiple sources and non-oral routes. |
| | The draft screening assessment should not rely on the study by Taylor et al. (2008) to support the use of studies employing non-oral (subcutaneous) dose routes and to reach conclusions regarding potential exposure to the fetus and neonate. The commenter considered this publication to be inadequate and unreliable. | The draft screening assessment acknowledges the effect of route of exposure on circulating bisphenol A levels. However, Taylor et al. (2008) found no effect of route of exposure on the pharmacokinetics of bisphenol A in neonatal female mice following oral or subcutaneous exposure, indicating that first-pass metabolism did not play a significant role in neonates. Studies using exposures given by non-oral routes may |

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| | | mimic continuous exposure and, in the case of bisphenol A, where many data gaps remain, it is suggested that non-oral studies conducted in neonatal animals provide useful information for hazard identification and risk characterization of potentially vulnerable phases of development where xenobiotic metabolism is low. Moreover, Taylor et al. (2008) study was not used for hazard characterization in the draft screening assessment. |
| | Several studies have indicated that the human metabolic elimination pathways for bisphenol A are more rapid than those for rodents. This could possibly indicate that actual human exposure is greater than what many studies have indicated. Also, a few studies are indicating that different routes of exposure can result in different health outcomes. The metabolism of acute bisphenol A exposure, as compared to low-dosage bisphenol A, differs in laboratory animals. Data from laboratory animals with chronic low-level exposure to bisphenol A would be more pertinent to real life bisphenol A exposures for humans. | It is acknowledged that, despite some available information, data gaps exist regarding the metabolism of bisphenol A following acute or chronic exposure using different routes of exposure. The Government of Canada has identified the effects of repeat low-dose exposures as a research need. |
| | The screening assessment does not describe bisphenol A exposure(s) from polycarbonate-containing products of all kinds or indicate whether significant bisphenol A is released from the polymer matrix or degradation of the polymeric structure of these products.<br><br>Furthermore, the government should conduct a "first-priority, high-level health risk assessment" across all age groups of Canadians covering all potential bisphenol A domains. | The screening assessment does not identify all exposures as posing a risk; however, the most vulnerable populations and their source(s) of exposure were identified.<br><br>Within the scope of a screening assessment, an overall evaluation was carried out and this resulted in the identification of the exposure pathways noted in the draft screening assessment. |
| | Exposure estimates assuming regular use of boiling water in baby bottles are very conservative. | Exposure estimates were provided for two formula preparation scenarios: i) as per directions typically specified (i.e., water be boiled for sterilization purposes and then be cooled before adding to the bottle) and ii) a plausible high-temperature use (boiling water added directly to the bottle). For each scenario, average concentrations (not maximum ones) were used. |
| | Uncertainties identified in the draft screening assessment regarding the estimation of human exposure (based on multi-media approach) are not well-founded, as extensive data exist regarding the estimates of aggregate human exposure through urinary or biomonitoring data. | The biomonitoring studies did not include a key segment of the population—infants. Biomonitoring data for the general population of Canada (including pregnant women and children younger than 6 years old) would decrease the uncertainty in the exposure assessment and has been identified as a research need. |

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| | While recognizing that a major exposure source for bisphenol A is through our dietary intake, other sources of exposure such as transdermal and inhalation also require adequate evaluation. | Exposure to bisphenol A via the inhalation route was taken into consideration in the assessment. Specifically, concentrations of bisphenol A in indoor and ambient air were used in characterizing exposure from environmental media. Additionally, exposure via inhalation and dermal routes was quantified for users of an epoxy adhesive containing residual bisphenol A. Exposures via the dermal and inhalation route were demonstrated to be very low. |
| | It was suggested that a cautionary note be extended to adults who have bioaccumulated this chemical over the span of a lifetime in order to err on the side of safety for everyone. | The exposure assessment 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. Furthermore, in humans, bisphenol A is quickly metabolized to an inactive form and rapidly excreted in urine. There is inadequate evidence to indicate that bisphenol A bioaccumulates over a lifespan. |
| | A governmental organization with expertise in public health submitted results of an in-house study that indicated that, under normal use conditions, infant exposure to bisphenol A due to the migration of bisphenol A from polycarbonate baby bottles is low in relation to exposure through infant formula and constitutes only a minor source of exposure. | The results from the study submitted on the migration of bisphenol A from reusable polycarbonate baby bottles filled with milk and apple juice under a scenario of normal use conditions (refrigeration followed by heating using a microwave) has been incorporated into the final screening assessment. |
| | While the assessment includes an extensive list of uses for bisphenol A in the production of some polyesters, polyurethanes and polyvinyl chloride, it does not include levels of bisphenol A that might remain in these polymers. | It is acknowledged that there is incomplete information regarding residual levels of bisphenol A for some materials manufactured from bisphenol A. With respect to the human health assessment, much of the analysis for bisphenol A has been focused on migration from materials that could result in dietary intake, a key source of exposure to the general population. Health Canada has identified this as a data gap and targeted research in this area is ongoing. |
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| Effects on Human Health | The assessment of risk should not be based on behavioural effects whose health impacts are difficult to interpret. | Health Canada scientists focused on effects that scientists considered to be suggestive of the possibility that effects in human development may also occur. Even though there are some unknowns about the developmental neurotoxicity effects of bisphenol A, Health Canada considers that there is enough information to indicate that actions should be taken to minimize exposure to the highly exposed subpopulation, newborns and infants. |
| | The screening assessment should clarify that a case has not been demonstrated to link breast and prostate cancer or obesity and bisphenol A, consistent with the conclusions presented on the Health Canada website. | While there have been no such studies involving humans, bisphenol A was not found to cause cancer in adult experimental animals. Only limited evidence in animal studies suggests a possible role for bisphenol A exposure in early life and adult onset cancer of the breast and prostate. |

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| | | However, Health Canada has identified this area as well as any link to obesity as research needs. |
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| Pregnant Women and Fetuses | The risk management scope document had not proposed adequate and necessary steps to protect pregnant women or developing fetuses. | The Government of Canada agrees that infants, pregnant women and fetuses are potentially vulnerable groups. As the screening assessment report describes, limited studies in laboratory animals have shown differences in toxicokinetics and the metabolism of bisphenol A for these vulnerable groups. Our estimate of exposure showed that infants are much more likely to be exposed to bisphenol A. For this reason, our risk management is focused on decreasing exposures to infants by proposing to ban polycarbonate baby bottles and by working with industry to reduce the amount of bisphenol A in infant formula can linings. |
| | More research is needed on sources of exposure to bisphenol A by pregnant women and fetuses. | The Government of Canada is conducting several research studies on chemicals and human health, which include biomonitoring of bisphenol A in the general population, including pregnant women, newborns and infants. These studies will provide additional information for more refined estimates of exposure for the various Canadian subpopulations. |
| | The Government should develop practical advice for pregnant/breastfeeding women on how to reduce exposures. | The Government of Canada has developed advice for pregnant and breastfeeding women. This information is available here.<br><br>Communication materials for parents and caregivers on how to reduce exposure to bisphenol A when using polycarbonate baby bottles are available here. |
| | The studies used in the screening assessment to estimate fetal or neonate plasma levels of free bisphenol A had methodological problems. | Limited data is available regarding the concentration of free bisphenol A in maternal or fetal blood/serum.<br><br>Studies cited in the draft screening assessment (reported using common analytical techniques) provided evidence that bisphenol A can be present in human blood/serum in parts per billion (ppb) levels. This is in agreement with other studies that showed that, in addition to plasma, bisphenol A may be present in other biological fluids including urine, breastmilk, colostrum and adipose tissue in ppb concentrations. |
| | The suggestion that fetuses and neonates may be more sensitive to bisphenol A due to reduced clearance is not adequately supported by the scientific evidence presented. Pregnant women and fetuses should not be viewed as unable to metabolize bisphenol A as proposed in the draft screening assessment. | Information is limited about the effects of bisphenol A in pregnant or developing animals. Available data suggests that the activity of major xenobiotic metabolizing UDP-glucuronyltransferase (UDPGT) enzymes is low in pregnant animals, fetuses and neonates. Some studies have suggested the induction of UDPGT enzymes in pregnant animals following exposure to xenobiotics; however, no bisphenol A-specific |

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| | | data was found for pregnant animals. In the human fetus/neonate, UDPGT enzyme activity does not reach the adult level until several months after birth. In the absence of a full understanding of the toxicokinetics of bisphenol A in developing animals, and of the reduced activity of xenobiotic metabolic enzymes in the feto-maternal unit, pregnant animals and neonates may be considered sensitive to bisphenol A. |
| | It was suggested that sulfotransferase enzymes are relatively high in fetuses and neonates and are likely an effective means of metabolizing bisphenol A in humans. | Studies have shown that glucuronidation is the major pathway of bisphenol A metabolism in adult mammals, including humans, and it has been suggested that sulfotransferase (SULT) enzymes may play a minor role in metabolism of bisphenol A. Sulfotransferase enzymes are considered functional at birth in humans and rodents and it has been suggested that these enzymes may play a role in xenobiotic metabolism. However, the available data showed that SULT enzymes may be substrate-specific. A few in vitro studies have shown that SULT enzymes may have the ability to metabolize bisphenol A in cell cultures. However, to date, no data have been made available to Health Canada to support the suggestion that sulfotransferases play a primary role in the metabolism of bisphenol A in human neonates. |
| | The commenter supports the aggregate work summarized under Table 20 (Aggregate estimate of exposure for breastfed infants aged 0 to 7 months) for bisphenol A. This table should also include estimates for exposure for vulnerable populations such as pregnant women and their developing foetuses and account for the degree of magnification across the placenta. | If a pregnant woman follows a regular diet (i.e., similar to the average citizen), exposure to bisphenol A is not expected to be any different.<br><br>The Government of Canada has developed advice for pregnant and breastfeeding women. This information is available here. |
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| Food | All uses of bisphenol A in food and drink packaging should be prohibited. | The government has proposed adopting a precautionary approach for bisphenol A in food packaging for products destined to newborns and infants and will be adopting the ALARA (as low as reasonably achievable) principle to minimize exposure of these vulnerable populations to bisphenol A. The government will develop stringent migration targets for bisphenol A in infant formula cans and will explore the option of establishing stringent migration targets for bisphenol A in canned foods in general. The government will continue to scrutinize pre-market submissions for infant formulas to enable the lowest levels of bisphenol A in the food packaging for these products. For existing food packaging, the government is engaging industry in the development and implementation of codes of practice to reduce levels of bisphenol A in |

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| | | infant formulas as much as is reasonably achievable. The government will also support manufacturers in the evaluation of replacement options for bisphenol A in infant formula can coatings. The government is proposing to ban polycarbonate baby bottles made with bisphenol A. |
| | Manufacturers of can linings should be obligated to prove that these linings are safe before they go on the market. | Division 25 of the *Food and Drug Regulations* requires manufacturers of infant formulas to include in their notifications the description of the type of packaging to be used so that the safety of its packaging material can be assessed. In addition, food packaging materials must meet the requirement of Division 23 of the *Food and Drug Regulations*, which prohibit the sale of foods in packages that may yield to their contents any harmful substances that may be injurious to the health of consumers of the food. Health Canada conducts safety evaluations of packaging materials to be sold with food with the objective of ensuring these containers do not pose a health risk to consumers. |
| | Given the essential role that metal packaging plays in assuring an economical, nutritious and wholesome food supply, and the current lack of any viable alternative to epoxy linings derived from bisphenol A, any "stringent migration targets" that would limit or preclude use of epoxy linings in canned food in general would have profound economic and public health consequences. | The assessment 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, including canned foods, pose little risk to the general population. However, the government has proposed adopting a precautionary approach for bisphenol A in food packaging for products destined for newborns and infants and will be adopting the ALARA (as low as reasonably achievable) principle to minimize exposure of these vulnerable populations to bisphenol A.<br><br>The government will develop stringent migration targets for bisphenol A in infant formula cans and will explore the option of establishing stringent migration targets for bisphenol A in canned foods in general. The availability of alternatives, potential public health impacts and economic factors will all be considered as the government explores this option. |
| | The migration of bisphenol A in inks used in food packaging into food must be considered toward reducing this dietary source of bisphenol A.<br><br>A study of bisphenol A levels in paper food containers found between 190 and 26 000 nanograms per gram in eight of the 12 food containers made from recycled paper, including sandwich and fried chicken packaging. The highest levels of bisphenol A—26 000 nanograms per gram in a sandwich box—were considered to be equal to | While bisphenol A may be found in food packaging materials, this does not necessarily mean that bisphenol A migrates into food. 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 2009 cycle of the Canadian Total Diet Study (TDS). Fast foods and prepared sandwiches purchased at different cafeterias or fast-food outlets will be captured in the TDS. This occurrence data will be accounted for in regular exposure estimate updates. |

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| | bisphenol A levels found in polycarbonate plastic food packaging. Upon further examination, the researchers found microscopic traces of ink and copy paper among the fibres of items made from recycled pulp, which could explain the source of the contamination | |
| | The health risk for all ages from use of polycarbonate microwave food cooking utensils manufactured or used within Canada was not sufficiently addressed. | Due to limited data on migration from polycarbonate tableware and storage containers, the lack of information on availability of these products on the Canadian market, and use patterns by the general population, exposure estimates cannot be derived. Based upon available information under normal use conditions, exposure from this source is expected to be limited. |
| | Data from the draft assessment document indicated that some foods have significantly higher residual bisphenol A levels than others. There is a very noticeable wide range of measured bisphenol A for some foods. Without further statistical details for these commonly used foods, interpretation of the data is difficult.<br><br>For the tested foods that have a wide range of bisphenol A concentrations, if the ranges were subdivided into smaller ranges and the number of cans indicated for each subcategory, the geometric mean value would be more meaningful, particularly for vulnerable populations. | The Government of Canada agrees that existing data is limited in scope, and it has been used with these limitations taken into consideration. We are currently generating additional bisphenol A occurrence data in food, which will allow for more robust and thorough exposure assessments for vulnerable populations. |
| | A significant percentage of human exposure to bisphenol A is from its release from epoxy-lined food and drink cans and the use of polycarbonate bottles. It is not clear why bisphenol A migrates from the matrix of the molecule, particularly as some documents suggest that it is tightly held within the matrix of the molecule. Apart from temperature and possibly pH, other contributing factors to bisphenol A migration were not identified. | The focus of the screening assessment is on risk characterization from potential exposures. The Government of Canada agrees that more research is needed on the underlying process of migration of bisphenol A from polymers. We are engaging industry with regards to conducting studies looking at manufacturing processes that influence bisphenol A migration from can linings. |
| | Due to much of the sampling to date having been done utilizing gas chromatography with mass spectrometry (GC/MS), an approach that is prone to interferences from other substances that are naturally present in food products, the reliability of the residue data reporting bisphenol A in foods are often significantly overstated. High-performance liquid chromatography with tandem MS (HPLC/MS/MS) is a more reliable approach, but has | Health Canada recognizes the importance of identifying uncertainties in the exposure assessment. The limit of the studies reporting the concentration of bisphenol A in canned foods using GC/MS have been documented within the literature. Methods such as the ones that were described in this comment have been used in a limited capacity for the reason also described. The draft screening assessment has been based on the state of the science and currently available information in order to provide a timely assessment. |

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| | seldom been used for monitoring bisphenol A levels in food because of the high cost of equipment and operation.<br><br>In any case, these data call into question the general presumption utilized in most bisphenol A studies of metal packaged foods that all of the reported bisphenol A is from excess monomer migrating from the epoxy lining. Bisphenol A exposure estimates would be more reliable if the residue data utilized to develop such estimates are collected with more robust and defensible analytical technologies and protocols. | The Government of Canada has developed a sensitive, efficient and reproducible method for the determination of bisphenol A in food samples to more accurately assess potential human exposure (Cao et al 2008; Cao and Corriveau 2008). |
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| Consumer Products | Bisphenol A should be prohibited in consumer products. | The screening assessment showed that exposure to bisphenol A is low among the Canadian population. Most uses of products containing bisphenol A pose little risk. For these reasons, the Government of Canada is focusing its risk management actions to protect health on infants, the most vulnerable group. |
| | Given the levels of bisphenol A found in house dust, a particular emphasis should be placed on reducing the use of the chemical in household products that may contribute to this exposure source. | More research is needed to understand if and how consumer products contribute to house dust. Research on levels of substances, including bisphenol A in dust, is occurring as part of the Government of Canada's house dust study. Based on data available so far, the exposure from house dust seems to be very low compared to other sources. |
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| Medical Devices | It was suggested that medical devices be exempt from risk management activities. Medical devices routinely undergo risk assessment, including science-based scrutiny regarding their safety and effectiveness prior to market access and the review of such risk assessment throughout the entire product life cycle. | No risk management activities for bisphenol A are suggested for medical devices. However, the government plans to gather information from manufacturers of all currently licensed Class II, III and IV medical devices that come into contact with the patient or patient fluids that are manufactured from raw materials containing or derived from bisphenol A. |
| | Risks from dental sealants should be examined more closely. | Health Canada continues to monitor the safety of all medical devices, including dental sealants. There is no evidence in the current scientific literature that dental sealants are a significant source of exposure. While it is correct that most, but not all, dental sealants are manufactured from a chemical derived from bisphenol A, it is known that the bisphenol A-derived polymer that forms the core of a dental sealant is stable and not easily broken down in the mouth. Any exposure to bisphenol A from dental restorative materials or sealants has been shown to be extremely low and transient. |
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| Releases to the Environment | Risk management should address bisphenol A in dust, water and agricultural soil. | Risk management actions to protect the environment will focus on releases of bisphenol A into wastewater and from landfills.<br><br>Bisphenol A in dust, water and agricultural soil were not shown to be major sources of human exposure.<br><br>The Government is proposing introducing maximal bisphenol A concentrations at the effluent and measures to ensure the proper handling and disposal of bisphenol A in industrial manufacturing facilities using bisphenol A; working with provincial 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 and monitoring levels of bisphenol A nationally in specific media including wastewater effluent and wastewater sludge; landfill leachate; wildlife; and receiving waters downstream of wastewater treatment plants. |
| | Releases of bisphenol A to the environment have been overstated. The assessment does not correctly represent industrial processes and makes unvalidated assumptions. | The screening assessment reports concentrations measured in Canadian industrial wastewaters and in waste products from sewage treatment plants that may receive industrial inputs (see Table 9a of the assessment). Bisphenol A is present in industrial wastewaters originating from chemical and chemical products facilities, commercial laundries, textile products and clothing industries, fabricated metal products industries, paper and allied products industries, plastic products industries and a variety of miscellaneous industries, confirming that there are many potential sources of bisphenol A in the Canadian environment. In addition, the substance has been detected in sewage treatment plant sludge and in sewage treatment plant final effluents being discharged to receiving waters.<br><br>While most bisphenol A appears to be effectively retained within the polymer matrix of materials, there is also evidence for some release from end products. For example, the ability of bisphenol A to migrate from food contact materials into food is well documented (see Human Health section of screening assessment) and has led to the establishment of specific migration limits for the substance (ECB 2003). This clearly demonstrates that some portion of the bisphenol A present in finished goods is available for release, both during product use and at disposal. |
| | The mobility of bisphenol A in soil and the potential to contaminate groundwater are overstated in the | Biodegradation is more likely to impact quantities available for transport rather than the potential of the substance to move through soil and/or |

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| | assessment, as the impact of biodegradation on migration in soil are not considered. | groundwater. This point was clarified in the assessment. |
| | Bisphenol A can be effectively treated in well-operated wastewater treatment facilities with primary and secondary treatment. | Lee and Peart (2000) reported a range of < 1 to 99% in overall reduction rates of bisphenol A in Canadian sewage treatment plants, with a median reduction value of 68%, indicating that reduction efficiencies for the substance vary widely among Canadian sewage treatment plans and that removal efficiencies may be very low at some facilities. For this reason, the screening assessment must adopt a conservative approach when representing the potential for risk from wastewater treatment plant effluents in Canada. |
| | Other mechanisms, namely indirect photolysis, may also contribute to the removal of bisphenol A from the environment. | Photolysis and phototransformation of bisphenol A are discussed in the Environmental Fate section of the screening assessment, and these processes are recognized as contributing to overall loss of the substance from the environment. Additional sentences were added to the paragraph describing environmental fate processes in water, to emphasize the potential contribution of photodegradation in this medium. |
| | While the screening assessment correctly concludes that biodegradation is the dominant loss process for bisphenol A released into water, it is more correct to state that biodegradation is expected to be the dominant loss process for bisphenol A released to the environment as a whole. | The Environmental Persistence section of the screening assessment was clarified to state that aerobic biodegradation is likely to be the dominant loss process for bisphenol A in most aquatic and terrestrial environments. |
| | It was suggested that the government require pollution prevention planning for all facilities using and releasing Bisphenol A to the environment. | The Government is proposing introducing maximal bisphenol A concentrations at the effluent and measures to ensure the proper handling and disposal of bisphenol A in industrial manufacturing facilities using bisphenol A.<br><br>As recommended by the Government of Canada's Cabinet Directive on Streamlining Regulation, and by criteria identified in the Treasury Board document entitled Assessing, Selecting, and Implementing Instruments for Government Action, the proposed risk management actions outlined in the risk management approach document were selected using a consistent approach and took into consideration information on alternative chemicals and substitutes, as well as other information received through the Challenge and other information available at the time. |
| | The risk management approach should provide assurance that bisphenol A-containing products will be disposed of safely through mandatory measures. | The development of an approach for the management of products or materials containing bisphenol A requiring disposal or recycling will be explored taking into consideration that the federal, provincial and |

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| | | territorial governments have authority to regulate waste management in Canada in accordance with their constitutional powers and law-making authorities. |
| | 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. 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. | The Government of Canada recognizes that other potentially toxic substances may be present or formed during processing, use and disposal of products that contain bisphenol A. However, the screening assessment focuses on lines of evidence that relate directly to bisphenol A, in order to conclude on whether the subject substance meets the "toxic" criteria under section 64 of CEPA 1999. |
| | The assessment does not investigate the quality of the leachate and the potential level of exposure and impact to the environment or human health. | Bisphenol A has been detected in leachate from other parts of the world (e.g., Norway, Japan); however, no Canadian data are available. ECB (2003) provides discussion on the presence of bisphenol A in leachate. Many uncertainties exist as to the nature and extent of contamination, as well as the implications for environmental exposure. Further research is needed and this has been flagged in the Uncertainties section of the screening assessment. |
| | The screening assessment fails to consider the findings of a comprehensive statistical analysis of concentrations of bisphenol A in various environmental media in North America and Europe. This analysis should be the basis for defining ecological exposures.<br><br>Most of the exposure scenarios used in the characterization of ecological risk are unrealistic and overly conservative. Most exposure assessments were calculated using maximum reported concentrations, rather than reasonable worst case or 95th percentiles. | While not comprehensively reported, the broader international database of environmental concentrations and its statistical evaluation of North American and European data provided by the commenter have been considered. It is standard practice to use Canadian data for our assessments if considered relevant and available. It is also the practice to utilize conservative approaches to estimate exposures to ensure that the environment is protected. The available Canadian database respecting bisphenol A concentrations in effluent and the environment is considered sufficient and current, and is deemed appropriate to represent Canadian conditions, albeit high-end exposure conditions that are protective of the environment. The broader international database of environmental concentrations and its statistical evaluation provided by the commenter has been considered, although not reported in the screening assessment. The existing PECs utilizing the Canadian data are considered representative to estimate conservative level exposures protective of Canadian conditions. |
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| Effects on Wildlife | Other valid toxicity studies are available for assessing the effects of bisphenol A on aquatic organisms and these studies are appropriate for use in hazard and risk | The Government of Canada acknowledges the receipt of information regarding additional scientific studies on bisphenol A. As screening assessments do not represent exhaustive or critical reviews of all |

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| | assessment. | available data, only those studies deemed to influence the ultimate conclusions of the assessment have been added to the assessment report. |
| | With regard to the ecological effects assessment, clarification was requested on use of the terms "acutely toxic" and "highly hazardous." | Numerical endpoint values associated with these terms (i.e., $(L(E)C_{50}$ values at or approaching 1 mg/L and/or chronic NOEC equal to or less than 0.1 mg/L) were added in to relevant section of screening assessment. |
| | Several terrestrial toxicity studies of acceptable data quality were not included in the screening assessment. | Due to the paucity of data relating to toxicity in non-mammalian terrestrial species, these studies will be included in the assessment as part of the weight of evidence. However, all studies are unpublished; therefore, they must be cited to a secondary reference and the data cannot be used in the determination of a PNEC value for the terrestrial compartment. |
| | Measurement endpoints used in the quantitative characterization of ecological risk should be directly linked to population-level effects. | The Government of Canada considers that all effects that can influence the survival, development and reproduction of individual organisms have the potential to act on populations. These include responses such as reduced semen quality, delayed ovulation and alterations to neurodevelopment and behaviour; for this reason, these effects were included in the evaluation of potential risk to the environment. |
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| Persistence and Bioaccumulation | The weight-of-evidence evaluation concerning the persistence of bisphenol A is incomplete and the interpretations are not supported by the weight of the scientific evidence.<br><br>Many of the studies used to evaluate the potential for biodegradation under anaerobic conditions are inappropriate. | While studies conducted using well-established and reliable testing methods such as the OECD Test Guidelines have determined that bisphenol A does not always meet ready biodegradation criteria (e.g., NITE 1977), the weight of scientific evidence suggests that bisphenol A can be expected to biodegrade under aerobic conditions in water and soils. It is recognized that significant biodegradation may still occur in cases where the pass criteria for ready biodegradation testing were not met.<br><br>Government scientists reviewed data (both empirical and modelled) on the potential for biodegradation under anaerobic conditions and have determined that the studies cited in the screening assessment are of acceptable quality and provide information that is both appropriate and relevant to the consideration of potential biodegradation under environmental conditions of low oxygen.<br>For example, microorganisms identified in studies (e.g., *Pseudomonas* sp. and *Pseudomonas putida* in Kang and Kondo 2002) are known to be a diverse and versatile group of facultative anaerobes that have demonstrated the ability to degrade phenolic compounds. Additionally, studies conducted using sediment collected from industrial sites, tidal estuaries, the marine environment and aquifers are deemed relevant, as |

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| | | are those that examine anaerobic degradation in agricultural soils, as all these conditions can be expected to exist in Canada. The results carry implications for Canadian environmental sites where oxygen is absent (anaerobic), or has become depleted (anoxic) through natural processes such as algal blooms or anthropogenic activities (contaminated sites). Applying a weight-of-evidence approach and precaution, the screening assessment determined that the evidence is sufficient to conclude that bisphenol A has the potential to remain stable and to not degrade or to degrade only slowly under conditions of low or no oxygen. |
| | Studies of the aerobic biodegradation of bisphenol A in soils have not been included in the assessment. | Additional data relating to aerobic biodegradation in soils were added to the screening assessment. |
| | Relevant information concerning the anaerobic biodegradation of bisphenol A in sediments and groundwater was overlooked in the screening assessment. | Details regarding a recent degradation study by Sarmah and Northcott (2008) were added to the screening assessment. |
| | Bisphenol A does not meet the definition of a bioaccumulative chemical. Statements that specify that bisphenol A is bioavailable and can accumulate in tissues are overstated and not supported by the weight of evidence. Such statements of bioavailability and accumulation of bisphenol A are based on a poorly described field study by Takahashi et al (2003). Further, it is unclear and unlikely that the concentrations in periphyton and water were at steady state or equilibrium. The commenter suggests that the value of 650 most likely reflects adsorption of bisphenol A (i.e., a $K_{oc}$ value) rather than a true bioaccumulation factor.<br><br>The capacity that organisms have to metabolize bisphenol A has been underestimated. | The Government of Canada agrees that bisphenol A does not meet the definition of bioaccumulation defined under the *Persistence and Bioaccumulation Regulations* of CEPA 1999, and notes that data generally point to low bioaccumulation potential. The Government of Canada also agrees that metabolism plays an important role in determining final tissue levels of bisphenol A. The limitations of Takahashi et al. (2003) study are also noted; however, various other studies identified in the screening assessment (e.g., relating to bioconcentration and levels in biota) support evidence that bisphenol A is bioavailable and can accumulate in tissues of biota to some degree. Although there may be some uncertainty respecting potential uptake versus adsorption in the periphyton species, the study by Takahashi et al. (2003) demonstrates accumulation and concentration of bisphenol A at a lower trophic level, thereby providing a potential pathway for its uptake and potential accumulation in higher trophic levels.<br><br>Modifications were made to the screening assessment to increase clarity with respect to the potential for accumulation in biota and the importance of metabolic transformation. |
| | A comment noted that "consistent with low measured BCF values," the available data should suggest low concentrations of bisphenol A are present in biota. | The Government of Canada agrees that data on bisphenol A point to low bioaccumulation potential and low biota concentrations. Presentation of data in the screening assessment does not conflict with this comment. |
| | Provided a community of competent microorganisms is present in the environment, acclimation to bisphenol A should not be rate-limiting to biodegradation and | Lag phases of between 3 and 8 days have been reported for microorganisms in natural waters (e.g., Dorn et al. 1987; Klečka et al. 2001, and a study by Turner and Watkinson (1986) cited in ECB (2003) |

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| | therefore the screening assessment is incorrect to conclude that a slower rate of biodegradation is expected to occur in non-acclimated waters. | estimated a lag phase of 13 to 17 days for municipal wastewater treatment plant microorganisms. During this lag period, biodegradation of bisphenol A is absent or much reduced, implying that a period of adaptation or acclimation is required. Therefore, overall loss of bisphenol A from an aquatic system is influenced by prior exposure of microorganisms to the substance and will be slower if microorganisms must first undergo a period of acclimation. |
| | Conclusions concerning persistence and the formation of "sinks" in the environment are overstated and highly speculative. While bisphenol A has some tendency to adsorb to sediments ($k_{oc}$ = 750 L/kg) as noted by Cousins et al. (2002), bisphenol A released to the environment will have a greater tendency to partition into the water phase. | Cousins et al. (2002) describe bisphenol A as a moderately hydrophobic substance that will partition to organic phases such as soils and sediments, although an appreciable fraction of the compound will be present in the dissolved phase. Measured sediment concentrations from Canada and other parts of the world (e.g., see ECB 2003, 2008) indicate that sediment may meet the US EPA definition of an environmental sink for bisphenol A—that is, "a place in the environment where a compound or material collects." Deposition areas of bisphenol A represent regions of increased exposure potential for organisms residing in or travelling through the vicinity of the deposit. Increasing production and use of bisphenol A, along with evidence for environmental persistence of the substance in sediment, point to an increased risk of exposure to aquatic species. |
| | In the quantitative evaluation of potential risk to wildlife species, a commenter questioned the use of an estimated BAF value when calculating the estimated concentration of bisphenol A in a prey fish ($C_i$ in the characterization of ecological risk) when empirical data for bioaccumulation are available. | While measured values are available for bioconcentration factors (BCF) in fish (see Table 6a of the screening assessment), there are no measured data for fish bioaccumulation factors (BAF).<br><br>A bioconcentration factor (BCF) represents the ratio of the steady-state concentration of a substance in an organism due to uptake via contact with water to the concentration of the substance in the test water, while a bioaccumulation factor (BAF) incorporates consideration of uptake from all routes of exposure, including food. Thus, a BAF for fish was required for the calculation of $C_i$ and this value was estimated using the method described in the screening assessment. |
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| Validity of Evidence | The validity of studies used in the screening assessments should be determined by subjecting studies to a critical review using internationally accepted practices. | The Government of Canada is leading the development of risk assessment methodology for succinct and focused assessments to better address public and scientific concerns in more efficient manner. While the Government of Canada may rely on assessments from other international agencies as basis for prioritization and the principal focus of screening assessments, this is in cases where these substances have already undergone rigorous assessment by other regulatory agencies. For |

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| | | substances where no other regulatory bodies have conducted a rigorous assessment, the Government of Canada will develop methodology to efficiently address the issues surrounding the substance (for example, developing models to determine the exposure of Canadians to a particular substance). Scientific studies used to assess the risks to human health and the environment are subjected to rigorous, internationally accepted criteria including such requirements as following the Organisation for Economic Co-operation and Development (OECD) Test Guidelines or other internationally accepted study protocols. Government of Canada scientists also use their expert scientific judgement and experience in taking into consideration the contribution a particular study to the determination of "toxic" or "not toxic."<br><br>The quality of studies used to determine critical empirical values for persistence, bioaccumulation and inherent toxicity in their screening assessments are evaluated using an approach generally analogous to that of Klimisch (Klimisch et al. 1997). This involves the use of modified robust study summary forms based on the OECD templates) and a scoring system to quantitatively evaluate reliability of the studies. Robust study summaries for critical studies are generally included in an appendix to the assessment. |
| | The draft screening assessment relies on unvalidated low-dose studies with design and statistical limitations that do not support a finding of potential neurodevelopmental effects that constitute or may constitute a danger in Canada to human life or health.<br><br>Furthermore, an in-depth review of the reproductive and neurotoxicity studies could have revealed further weaknesses. | The draft screening assessment considered data available in the scientific literature and focused on effects that were considered most relevant for human health. The limitations and inconsistencies associated with the mentioned datasets were recognized and acknowledged in the draft screening assessment; however, the key studies identified in the developmental neurotoxicity dataset were conducted by the National Toxicology Program - Center for the Evaluation of Risks to Human Reproduction (NTP-CERHR) expert panel (a science-based interagency program in the United States). These studies were rigorously designed, relevant and considered of high utility by the expert panel; therefore, they were included in hazard identification and risk characterization. Scientists within and external to the Government of Canada having the required expertise were consulted for peer review and had significant input on the validation of the scientific evidence included in the draft screening assessment. An in-depth review of the developmental neurotoxicity dataset was done by Health Canada and, collectively, the |

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| | | studies suggest alterations in sexual dimorphism resulting from bisphenol A exposure.<br><br>Although the data that is currently available does not permit a comprehensive understanding of the developmental neurotoxicity effects of prenatal and perinatal bisphenol A exposure, the critical studies selected in the dose range of 10 to 100 µg/kg-bw per day are well-performed and robust studies based on oral route of administration, appropriate design and analysis, adequate sample sizes and the inclusion of appropriate positive controls. |
| | It is not scientifically defensible to give so much credibility to the "low dose" studies in the absence of a plausible explanation of the claimed non-monotonic dose-response relationship between the effects reported at low doses and the effects observed in numerous well-conducted studies at higher bisphenol A exposure levels. | Irrespective of uncertainty over how to interpret a non-monotonic dose-response relationship, the experimental data suggest alternations in sexual dimorphism associated with bisphenol A exposure. Health Canada recognizes the importance of establishing the dose-response relationship; however, at this time it is complex and poorly understood for bisphenol A. The issue of the non-monotonic dose response relationship was not directly addressed with respect to the developmental neurotoxicity dataset as a broad range of doses were not assessed. Further assessment of dose-response relationships is identified as a research need in the screening assessment. |
| | A concern was expressed that the validity and objectivity of studies conducted by the Environmental Working Group and reported by the Chapel Hill Expert Panel are questionable. | The Environmental Working Group data were used because they were the most recent data available for canned foods and were comparable to other data published in the scientific literature. Considering the limitations of these data, Health Canada has committed to generating additional occurrence data of bisphenol A in food sources from a variety of canned and bottled foods for all age groups (including liquid and powdered infant formulas and infant and baby foods). These data will be used to regularly update Canadian exposure estimates.<br><br>The Chapel Hill report and associated manuscripts were produced by panels of experts from various disciplines in toxicology. These manuscripts were subsequently peer-reviewed under the normal manuscript submission guidelines for *Reproductive Toxicology.* As such, the Chapel Hill report is a credible consensus statement regarding the potential health effects of bisphenol A. |
| | The screening assessment overlooked relevant information on several physical and chemical properties. The commenter provided a list of preferred properties for bisphenol A. | The screening assessment does not aim to include all valid data, but rather provides values that are considered representative of the physical and chemical properties of the substance. Most of the experimental values reported in the screening assessment agree well with "preferred" |

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| | | values provided by the commenter. |
| | The validity of the studies used in the assessment of aquatic and terrestrial toxicity has not been determined, as the studies were not subjected to a critical review for study quality following internationally accepted practices. | While it is recognized that some toxicity values reported in the screening assessment were derived from studies that examined non-traditional endpoints, all studies cited in the assessment were critically reviewed and evaluated for data quality. Only studies deemed to be of satisfactory reliability and acceptable quality were used in the assessment and both traditional and non-traditional endpoints from acceptable studies were used in the weight of evidence. |
| | The relevance of maximum concentrations reported in the literature were not critically evaluated. | Maximum concentrations were considered in the context of the larger database during the preparation of the draft screening assessment. Canadian studies presented in the screening assessment are considered appropriate to represent Canadian conditions and to enable conservative-level assessment. |
| | Bisphenol A should be added to the Priority Substances List for further evaluation.<br><br>Furthermore, the government should develop a mechanism to review the screening assessments when new information becomes available. | Although there are uncertainties in the assessment of risks from Bisphenol A, the government believes that, based on existing information, there is concern for health and the environment that warrants action at this time. To address the uncertainties and data gaps, the government is undertaking an aggressive research agenda and will continue to monitor the scientific literature, to determine whether additional action will be warranted in the future.<br><br>All substances that have undergone assessment remain subject to additional, future assessment if new, substantive information is identified that indicates that a further evaluation is warranted. All incoming information is reviewed and, if further assessment is indeed needed, it will be conducted in keeping with other existing assessment priorities. |
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| Weight of Evidence and Precautionary Principle | More information was requested on how the government applied weight of evidence. | A weight-of-evidence approach is used in assessments conducted under CEPA 1999. This approach accounts for and weighs multiple sources of information in the identification of critical values used in the assessment, and in evaluation of multiple lines of evidence in determining whether a substance may pose a risk. More details on the use of weight of evidence will be posted on the Chemical Substances website in the future.<br><br>In the case of bisphenol A, a more in-depth assessment was conducted entailing a detailed review of all relevant health-related data and full weight-of-evidence analysis for hazard characterization associated with developmental neurotoxicity. This included an evaluation of the quality and quantity of available scientific evidence, determination of the |

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| | | adequacy and/or limitations of studies, identification of critical toxicological endpoints and the nature of the dose-response curve. A generic weight-of-evidence framework was applied for consideration of data for purposes of a screening level assessment. A qualitative weighting of all relevant data, taking into account factors such as rigour, power, consistency and biological plausibility of observed effects, was applied. Importantly, the weight-of-evidence analysis for bisphenol A also considered the uncertainty and variability associated with the body of information.<br><br>Taking this into consideration, the weight of evidence associated with the developmental neurotoxicity dataset was considered to be limited, based on uncertainty and variability; however, collectively, the studies, considered of adequate utility, provide evidence that gestational and early postnatal exposure to bisphenol A may alter neural development and some aspects of behaviour in rodents. These conclusions, based on a weight-of-evidence assessment, justify the application of precaution to protect potentially vulnerable human subpopulations. |
| | The application of the precautionary principle is excessive and without an appropriate scientific basis. Application of the weight-of-the evidence approach and precautionary principle does not mean that any uncertainty requires action as a precaution. The precautionary principle should be applied when the weight of the evidence suggests that a potential threat to the environment and human health exists and when that threat is of serious or irreversible damage. Until both of these conditions are met, application of the precautionary principle to justify actions limiting trade is inappropriate. | A precautionary approach to decision making, as defined in *A Framework for the Application of Precaution in Science-Based Decision Making About Risk* (Government of Canada), emphasizes the need to take appropriate action, even in the absence of full scientific demonstration of cause and effect. The *Canadian Environmental Protection Act, 1999* (CEPA 1999) states that "where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation." It is important to note that precaution may be invoked when there is uncertainty about the extent to which the available evidence actually indicates that the substance is causing such harm. It is incumbent on the government to judge whether a substance has the potential to cause serious or irreversible damage to the environment and/or human health. This evidence is then summarized in the draft screening assessment report. |
| | Screening assessments are an oversimplification and do not make use of all the available information on the substance. | Screening assessments under the Challenge program focus on information that is critical to determining whether the substance meets the criteria for defining a chemical as "toxic" under section 64 of CEPA 1999. While not all data are presented, the broader database of Canadian and international data, as well as international assessments, were considered in the production of the screening assessment. The most |

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| | | salient data supporting the lines of evidence are presented. |
| | The conclusions concerning the weight of the evidence in the draft screening assessment should be based upon studies employing internationally approved test protocols conducted under good laboratory practice (GLP) principles. | The key studies used to inform the risk characterization were well-performed, robust studies deemed of high utility by the CERHR expert panel. The one study conducted under GLP and according to existing OECD guidelines that lacks the endpoints contested did not assess comparable developmental neurotoxicity and behavioural endpoints as covered by the studies conducted in academic institutions. As such, the single study conducted according to OECD guidelines would not capture the breadth of endpoints investigated by various additional and diverse studies. Thus, there is not sufficient evidence to set aside the observed changes in rodent behaviour following bisphenol A exposure. Collectively, considering the broad spectrum of endpoints assessed, the dataset is considerably consistent; loss of sexual dimorphism emerges as a consistent bisphenol A-related effect. |
| | Environment Canada's *Overview of the Ecological Assessment of Substances under the Canadian Environmental Protection Act, 1999* should be rewritten to explain the weight-of-evidence approach in more detail, including the criteria used in weighing the available evidence and how assessors "calculate" the weight of evidence. | A technical guidance module on the application of weight of evidence in ecological assessments entitled *Use of the Weight-of-Evidence Approach for the Ecological Assessment of Existing substances under CEPA 1999 – An Overview* is available on request from the Existing Substances Division of Environment Canada.<br><br>In considering the exposure potential of bisphenol A, the measured presence of the substance in all environmental media, as well as documented presence in Canada and in other parts of the world, was taken to indicate that 1) the substance is widely distributed in the environment, 2) the rate of entry and quantities entering the environment exceed the degradation rate, as otherwise the substance would not be so widely detected, particularly in media to which it is not directly released (e.g., sediment), and 3) the substance is stable in the environment and does not break down quickly. Along with evidence of increasing production and use, this points to the potential for increasing levels in the environment, with an associated increase in exposure potential to organisms.<br><br>In considering effects, while the experimental database based on standard toxicity endpoints is comparatively large, the presence of bisphenol A at low concentrations in different environmental media necessitates consideration of potential impacts from chronic, low-level exposure to the substance. It is recognized that the science pertaining to chronic low-level exposure of organisms to endocrine active substances (EACs) in the |

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| | | environment is still developing; however, the data on bisphenol A are considered sufficient to indicate a potential for risk. In addition, the measured presence of bisphenol A in biota confirms that the substance can be taken up by organisms and is therefore bioavailable to exert possible effects.<br><br>A conservative and quantitative evaluation of exposure and ecological effects was conducted for bisphenol A as part of the weight-of-evidence evaluation of its potential to cause harm. Predicted environmental concentrations (PECs) were determined based on an analysis of exposure pathways, and these exposure pathways were used to identify sensitive receptor organisms. A predicted no-effects concentration (PNEC) was determined for each exposure pathway. This analysis demonstrated the potential for risk to pelagic and soil organisms, as well as wildlife. |
| | While secondary supplemental endpoints may support an evaluation of possible mechanisms of action, they are not and should not be substituted for apical endpoints that are used to conduct risk assessments.<br><br>Valid data does not support a finding that there is strong evidence of low dose effects on secondary supplemental endpoints, effects after brief, low-dose exposures, effects in subsequent generations or effects using more than one mode of action. | While the Government of Canada recognizes the uncertainties associated with individual studies from which the endpoint values presented in Table 7c were derived, each study was critically evaluated and determined to be of acceptable quality and robustness for use in the assessment. Taken together, the number of similar studies with reported similar responses in a variety of species was considered a meaningful indicator in relation to this endpoint. Therefore, no single study was considered pivotal to the analysis of potential hormonal effects; rather, the weight of evidence taken from all studies considered together was used in the determination of potential risk |
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| Challenge Advisory Panel | Reports prepared by Challenge Advisory Panel members should describe how they reach their agreement in support of the conclusions reached by Health Canada and Environment Canada. | The panel is composed of independent experts from outside government who are mandated to respond to specific questions posed to them by Health Canada and Environment Canada on approaches taken in the assessment of Challenge substances, as well as the application of precaution and a weight-of-evidence approach. Before a panel meeting takes place, panel members are provided with draft screening assessments and other relevant documentation to increase their understanding of the question. During the course of a meeting, the panel members have a free and open debate and discussion, when they are also able to question government staff for further clarification on processes. The panel then agrees to a response, striving for consensus while also being respectful of minority viewpoints.<br><br>It was agreed early on in the process that a template report would best |

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| | | facilitate the reporting of panel advice to the public, and the current format was approved by the chair of the panel as an appropriate reflection of the panel's advice to the government.<br><br>More information on the Challenge Advisory Panel is available here.<br><br>The Challenge Advisory Panel is external to the Government of Canada; the deliberations and information provided are at the discretion of the panel. |
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| Peer Review | In order to improve the transparency and credibility of the screening assessment report, the peer review validation method needs to be clearly described, the reviewers/consultants identified and their validation report (with response comments) made available. The screening assessment document should indicate when a validation method is not used and provide a rationale for this action. | All assessments are subject to a comprehensive internal peer review by government scientists. Areas of uncertainty found during the assessment and internal review are identified for external scientific peer review. Technical expertise is the main criteria for identifying suitable individuals, who may come from academia, industry or consulting firms. All comments provided to the Government of Canada by peer reviewers are taken into consideration. Draft assessments are also subject to a 60-day public comment period. These comments are taken into consideration in finalizing the assessment report. |
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| International | Canada has not given serious consideration to the conclusions of risk assessments conducted in other regulatory jurisdictions. Canada should rely upon comprehensive risk assessments from other countries. | The Government of Canada recognizes that other jurisdictions have conducted risk assessments on some of the substances being assessed under CEPA 1999 and we do consider these assessments. However, our conclusions may differ due to the requirements of Canadian legislation and/or due to specific Canadian circumstances, such as use patterns and exposure. |
| | It was suggested that science-based, international risk management criteria be taken into consideration to ensure an internationally harmonized approach to managing this internationally used chemical. | In developing an approach to managing bisphenol A, both existing international risk management activities and the Canadian context were considered. |
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| Substitution and Alternatives | If new requirements are introduced for any of the chemical substances in the Challenge, the Government should provide sufficient notification time to allow industry to make the necessary product changes. | The release of a toxic conclusion in the final screening assessment report will be accompanied by the release of the risk management approach document indicating the proposed risk management actions. Industry and other interested stakeholders are invited to submit comments on the contents of the risk management approach during the 60-day comment period following the publication of this document. During the development of the risk management instrument(s), stakeholders will be engaged and consulted prior to and after the publication of the proposed |

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| | | instrument(s) in the *Canada Gazette*, Part I. It should be noted that the risk management process must take into account the relevant social, economic and technical matters. |
| | The government should work with stakeholders to identify alternatives to bisphenol A. Information on the availability or cost of alternatives to bisphenol A should be more extensively presented in the risk management approach document. | The Government of Canada welcomes input from stakeholders on alternatives to bisphenol A. Stakeholders and members of the public are requested to submit such information via the Challenge questionnaire or by email to DSL.surveyco@ec.gc.ca<br><br>Where available and relevant to the Canadian context, reliable information on the availability and cost of alternatives to bisphenol A will be included in the risk management approach document. |
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| Labelling | A hazard-labelling initiative should be developed for hazardous ingredients identified by the International Agency for Research on Cancer and other authoritative agencies, including the Government of Canada.<br><br>All consumer products with free bisphenol A should be appropriately labelled. | Labelling is one possible risk management tool that is considered for use under the Chemicals Management Plan. However, as the risk to the general public from bisphenol A in consumer products was found to be low, labelling is not being proposed at this time. The Government of Canada is instead proposing to protect the health of infants, the most vulnerable group, by taking a regulatory approach and prohibiting baby bottles made with bisphenol A. |
| | All food and drink cans that have internal epoxy linings should be appropriately labelled, indicating the presence of bisphenol A and its potential to be a reproductive toxicant. | The government uses labelling as a risk management measure to inform consumers or subsets of consumers of the potential risks of food constituents (e.g., allergen labelling), or to provide them with tools to protect and improve their health (e.g., nutrition labelling). Since the screening assessment concluded that exposure to bisphenol A from all food sources (including canned foods) does not pose a risk to the general population, labelling is not being considered at this time. |
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| Data collection | Surveys under section 71 of CEPA 1999 should request data for more than one year. | Information from the 2006 calendar year collected in May 2007 is deemed sufficient to assess risk and enable a preliminary scoping of risk management options. More targeted information requests can be issued if necessary and additional information may also be obtained through the Domestic Substances List Inventory Update. |
| | Surveys under section 71 of CEPA 1999 should request data on breakdown products, including information on the by-products released from waste disposal. | The Government of Canada agrees that this type of information would be useful. However, it is felt that this information is most likely to be obtained through technical studies. Breakdown products are considered during the assessment phase, as appropriate, based on available information. |
| | Data should be collected on the use, release, presence and impact of bisphenol A on the Aboriginal community. | The Government of Canada is working with Aboriginal communities to explore the possibility of undertaking biomonitoring surveys of |

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| | | chemicals of interest, including bisphenol A. |
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| Modelling | Computer models were used to generate information on environmental fate and effects. For substances with extensive empirical data available, modeling approaches are both unnecessary and unwarranted. Valid empirical data should always be used in place of model predictions.<br><br>Given the extensive empirical data available for bisphenol A, it is not appropriate to use quantitative structure-activity relationship (QSAR) modelling, which should only be used in the absence of substantial and robust empirical data. | Environment Canada assessment guidance specifies that QSARs should be used routinely as part of a weight-of-evidence approach, as these may serve to offer support to experimental data and raise flags where QSAR estimates conflict with limited experimental data.<br><br>The Government of Canada agrees that, in most cases, empirical data will be weighted more heavily than modelled data. However, even when there is empirical data, computer models should be used to generate information on environmental fates and effects. It is likely that reliable model results would receive more weight than empirical data that is of questionable quality or relevance. |
| | The screening assessment fails to specify preferred values to be used in multimedia modeling. | Values for the EQC (equilibrium criterion) were added to Table 4. |
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| Monitoring and Research | The Minister should consider establishing a long-term national biomonitoring program for widely used chemicals to better identify exposure sources in Canada, identify populations with higher exposures and track exposure trends over time, particularly to monitor progress on interventions. | As part of the Chemicals Management Plan, Health Canada initiated, in 2007, a national biomonitoring survey in partnership with Statistics Canada's Canadian Health Measures Survey (CHMS). Budget 2008 provided funding to continue the CHMS and explore ways of measuring environmental chemicals in children below six years of age. The continuation of this survey will allow for the monitoring of a wide range of environmental chemicals in nationally representative samples of Canadians. This will enable us to track exposure trends and monitor progress on interventions where appropriate. The second cycle of the CHMS, expected to be launched in 2009, is currently in the planning stages. |
| | The Minister of Health should assure funding to support the proposed continuation the Maternal-Infant Research on Environmental Chemicals (MIREC) study to the infant development (ID) phase that would follow the children born to the participating mothers from birth to least two years of age. The MIREC-ID study would considerably increase the value of the MIREC study by helping to better understand the ways in which environmental chemicals impact the health of Canadian children and how impacts can be mitigated. | The Maternal-Infant Research on Environmental Chemicals (MIREC) study is also a key deliverable under the Chemicals Management Plan. This study will provide a national profile of exposures to environmental contaminants during pregnancy and breastfeeding. The Government of Canada recognizes the need to generate additional information on pregnant women and children's exposure to environment chemicals. The co-investigators of the MIREC study are currently exploring funding opportunities for the continuation of the MIREC study to be able to follow the infants' development. Health Canada has been approached by the study co-investigators and will be considering their proposal. |
| | Several commenters suggested that further research is | The Government of Canada agrees that more research is needed. We are |

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| | needed in the following areas: chronic low-level exposure to bisphenol A in animals; determination of all possible sources of exposure and pathways, especially for vulnerable populations; bisphenol A content of breast milk, the kinetics of bisphenol A elimination in young children and on fetal exposure during pregnancy; and the use of polycarbonate water pipes.<br><br>One commenter suggested that many of the research needs that the Government of Canada identified have either already been addressed or will be addressed shortly. | working with the research communities both inside and outside government to address current gaps in knowledge. While the studies that are currently available may begin to address some of the uncertainties, there remain many critical endpoints that require further exploration. New data will be considered as it becomes available. |
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| Economic Considerations | The listing and regulation of bisphenol A as a "toxic" substance will have significant economic impacts and entail substantial disruption. | The designation of CEPA 1999 "toxic" is a result of the screening assessment, which considers only risks to health and the environment. The risk management process, including potential regulation, includes consideration of economic impacts. |
| | Risk management measures should not include a ban on the use of polycarbonate for manufacture of baby bottles. Rather than imposing trade restrictions based on inconclusive science, we suggest that bisphenol A be subject to further study and that the government investigate alternative risk management options that are available to it. | Risk management options under CEPA 1999 and other acts were considered. The government proposes to ban polycarbonate baby bottles made with bisphenol A. |
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| Communication | The Government of Canada should recognize the need for clear risk communications and develop a protocol to pro-actively address and respond to situations and issues that may arise in the future delivery of the Chemicals Management Plan and related programs to avoid or at least minimize risk uncertainties in the marketplace as a result of inadequate risk communications. | The Government of Canada recognizes the importance of risk communications and initiates risk communications activities as appropriate, focusing on substances where there are identified risks to human health and/or the environment. |
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| Typographical errors | A commenter noted that the units for the effect level reported by Duft et al. (2003) in Table 7c should be µg/kg rather than µg/L. | The units for this study were incorrectly reported as µg/L and should be µg/kg. The screening assessment report was modified accordingly. |
| | Test results for the Great Pond Snail in Table 7c (Segner et al. 2003) have been incorrectly reported. | These data were incorrectly attributed to bisphenol A and were removed from Table 7c. |

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| | The screening assessment states that modelled predictions for aquatic toxicity should not be presented; however, a table of modelled data (Table 7b) is included in the assessment. | The sentence referring to modelled predictions for aquatic toxicity not being presented was removed. |

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