Government of Canada / Gouvernement du Canada

PROPOSED RISK MANAGEMENT APPROACH

for

Phenol, 4,4'-(1-methylethylidene) bis
(Bisphenol A)

Chemical Abstract Service Registry Number (CAS RN):
80-05-7

Environment Canada
Health Canada

October, 2008

Canada

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This proposed risk management approach document builds on the previously released risk management scope document for Phenol, 4,4'-(1-methylethylidene) bis and outlines the proposed control actions for this substance. Stakeholders are invited to submit comments on the content of this proposed risk management approach or provide other information that would help to inform decision making. Following this consultation period, the Government of Canada will initiate the development of the specific risk management instrument(s) where necessary. Comments received on the proposed risk management approach will be taken into consideration in developing the instrument(s). Consultation will also take place as instrument(s) are developed.

1. ISSUE

1.1 Categorization and the Challenge to Industry and Other Interested Stakeholders

The *Canadian Environmental Protection Act, 1999* (CEPA 1999) (Canada 1999) requires the Minister of the Environment and the Minister of Health (the Ministers) to categorize substances on the *Domestic Substances List* (DSL). Categorization involves identifying those substances on the DSL that a) are considered to be persistent (P) and/or bioaccumulative (B), based on the criteria set out in the *Persistence and Bioaccumulation Regulations,* and "inherently toxic" (iT) to humans or other organisms, or b) present, to individuals in Canada, the greatest potential for exposure (GPE). In addition, the Act requires the Ministers to conduct screening assessments of substances that meet the categorization criteria. The assessment further determines whether the substance meets the definition of "toxic" set out in section 64 of CEPA 1999.

In December 2006, the Challenge identified 193 chemical substances through categorization which became high priorities for assessment due to their hazardous properties and their potential to pose risks to human health and the environment. In February 2007, the Ministers began publishing, for industry and stakeholder comment, profiles of batches containing 15 to 30 high-priority substances. New batches are released for comment every three months.

In addition, the information–gathering provisions under section 71 of CEPA 1999 are being used under the Challenge to gather specific information where it is required. The information that is collected through the Challenge will be used to make informed decisions and appropriately manage any risks that may be associated with these substances.

The substance phenol, 4,4'-(1-methylethylidene) bis, Chemical Abstract Service Registry Number (CAS RN)[1] 80-05-7, referred to throughout this document by "bisphenol A", was included in Batch 2 of the Challenge under the Chemicals Management Plan.

[1] CAS RN: Chemical Abstracts Service Registry Number. The Chemical Abstracts Service information is the property of the American Chemical Society and any use or redistribution, except as required in supporting regulatory requirements and/or for reports to the Government of Canada when the information and the reports are required by law or administrative policy, is not permitted without the prior, written permission of the American Chemical Society.

1.2 Final Screening Assessment Report Conclusion for Bisphenol A

A notice summarizing the scientific considerations of the final screening assessment report was published by Environment Canada and Health Canada in the *Canada Gazette*, Part I, for bisphenol A on October 18, 2008, under subsection 77(6) of CEPA 1999. The final screening assessment report concluded that bisphenol A may be entering the environment in a quantity or concentration or under conditions that constitute or may constitute a danger in Canada to human life or health. The final screening assessment report also concluded that bisphenol A is entering or may be entering the environment in a quantity or concentration or under conditions that have or may have an immediate or long-term harmful effect on the environment or its biological diversity. It is therefore concluded that bisphenol A meets the criteria in paragraphs 64(a) and 64(c) of CEPA 1999.

The final screening assessment report also concluded that bisphenol A meets the criteria for persistence, but does not meet the criteria for bioaccumulation, as defined by the *Persistence and Bioaccumulation Regulations* made under CEPA 1999.

There are no known natural sources of bisphenol A and potential releases to the environment are restricted to those associated with human activities.

For further information on the final screening assessment report conclusion for bisphenol A, refer to the final screening assessment report, available at http://www.chemicalsubstanceschimiques.gc.ca/challenge-defi/batch-lot_2_e.html.

1.3 Proposed Measure

Following a screening assessment of a substance under section 74 of CEPA 1999, a substance may be found to meet the criteria under section 64 of CEPA 1999. The Ministers can propose to take no further action with respect to the substance, add the substance to the Priority Substances List (PSL) for further assessment, or recommend the addition of the substance to the List of Toxic Substances in Schedule 1 of CEPA 1999. Under certain circumstances, the Ministers must make a specific proposal either to recommend addition to the List of Toxic Substances or to recommend the implementation of virtual elimination (or both). In this case, the Ministers proposed to recommend the addition of bisphenol A to the List of Toxic Substances in Schedule 1 of CEPA 1999. As a result, the Ministers will develop a regulation or instrument respecting preventive or control actions to protect the health of Canadians and the environment from the potential effects of exposure to this substance.

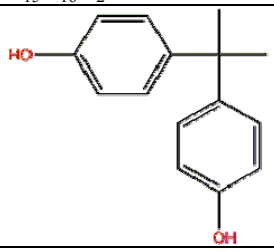
The final screening assessment report did not conclude that bisphenol A meets the conditions set out in subsection 77(4) of CEPA 1999. As a result, bisphenol A will not be subject to the virtual elimination provisions under CEPA 1999 and will be managed using a life-cycle approach, to prevent or minimize its release into the environment.

2. BACKGROUND

2.1 Substance Information

Table 1 presents other names, trade names, the chemical formula, the chemical structure, and the molecular mass for bisphenol A.

Table 1: Identity of bisphenol A

Chemical Abstracts Service Registry Number (CAS RN)	80-05-7
Name on Domestic Substances List (DSL)	*Phenol, 4,4' -(1-methylethylidene)bis-*
National Chemical Inventories (NCI) names[2]	*Phenol, 4,4'-(1-methylethylidene)bis- (TSCA, PICCS, ASIA-PAC)* *4,4'-isopropylidenediphenol (EINECS, PICCS)* *2,2-Bis(4'-hydroxyphenyl) propane (ENCS)* *Phenol, 4,4'-(1-methylethylidene)bis- (AICS, PICCS)* *4,4'-(1-Methylethylidene)bisphenol (ECL)* *4,4'-Bisphenol A (ECL)* *Phenol, 4,4'-(1-methylethylidene)bis- (SWISS)* *Bisphenol A (SWISS, PICCS)* *p,p'-isopropylidene diphenol (PICCS)* *Diphenol methylethylidene (PICCS)* *bis[phenol], 4,4'-(1-methylethylidene)- (PICCS)* *Bisphenol-a (PICCS)* *Bisphenol, 4,4'-(1-methylethylidene)- (PICCS)* *4,4-isopropylidene diphenyl (PICCS)* *4,4'-dihydroxyphenyl-2,2-propane (PICCS)* *2,2-di(4-hydroxyphenyl)propane (PICCS)* *2,2-di(4-hydroxyphenyl) propane (PICCS)* *2,2-bis-(4-hydroxy-phenyl)-propane (PICCS)*
Other names	*Bisphenol A, Diphenylolpropane, BPA*
Chemical group	Discrete organics
Chemical subgroup	Phenols
Chemical formula	$C_{15}H_{16}O_2$
Chemical structure	
Simplified Molecular Input Line Entry System (SMILES)	Oc(ccc(c1)C(c(ccc(O)c2)c2)(C)C)c1
Molecular mass	228.29 g/mol

[2] National Chemical Inventories (NCI). 2006: AICS (Australian Inventory of Chemical Substances); ASIA-PAC (Asia-Pacific Substances Lists); ECL (Korean Existing Chemicals List); EINECS (European Inventory of Existing Commercial Chemical Substances); ENCS (Japanese Existing and New Chemical Substances); PICCS (Philippine Inventory of Chemicals and Chemical Substances); SWISS (Inventory of Notified New Substances); and TSCA (Toxic Substances Control Act Chemical Substance Inventory).

3. WHY WE NEED ACTION

The screening assessment report concluded that bisphenol A be considered as a substance that may be entering the environment in a quantity or concentration or under conditions that constitute or may constitute a danger in Canada to human life or health. The basis of this conclusion is that the neurodevelopmental and behavioural dataset in rodents, though highly uncertain, is suggestive of potential effects at doses at the same order of magnitude to 1–2 orders of magnitude higher than exposures. Given that toxicokinetic and metabolism data indicate potential sensitivity to the pregnant woman/fetus and infant; and that animal studies suggest a trend towards heightened susceptibility during stages of development in rodents, it is considered appropriate to apply a precautionary approach when characterizing risk.

The screening assessment report also states that bisphenol A is entering or may be entering the environment in a quantity or concentration or under conditions that have or may have an immediate or long-term effect on the environment or its biological diversity.

Additionally, the screening assessment report states that bisphenol A meets the criteria for persistence but does not meet the criteria for bioaccumulation as defined by the *Persistence and Bioaccumulation Regulations* made under CEPA 1999.

4. CURRENT USES AND INDUSTRIAL SECTORS

Based on a survey conducted under section 71 of CEPA 1999, no bisphenol A was manufactured in Canada in 2006 at quantities greater than or equal to 100 kg. However, 25 companies reported importing approximately 0.5 million kg of bisphenol A in Canada and 5 companies reported using 0.1 to 1 million kg of bisphenol A in Canada either alone, in a product, in a mixture or in a manufactured item.

The type of mixture, product or manufactured item reported for 2006 in response to a survey of Canadian industry under section 71 of CEPA 1999 included resins, curing agents, epoxy curing agents, hardeners, plastic resin formulations, monomer, paperboard packaging, metal cans, phenolic resins, industrial coatings, plasticizers, adhesives, two-part epoxy adhesives, chain oil, brake fluid, heat transfer fluid and lubricant formulations. Information voluntarily submitted in 2007 in response to the Challenge questionnaire and other information submitted by industry include use in epoxy polymer flooring, as a laminating adhesive, in custom colour powder coating and as a curing agent for resurfacing concrete.

The literature indicates that bisphenol A is primarily used as a monomer in the manufacture of polycarbonates and as a precursor or a starting material for monomers of certain epoxy resins. Polycarbonate is used in compact disc manufacture, food and beverage contact containers, medical devices, and in glazing applications and film. Polycarbonate blends find application in the electric and electronics industry and the automotive industry. Epoxy resins are used in protective coatings, structural composites, electrical laminates, electrical applications and adhesives. Epoxy-phenolic resins are used as liners in metal cans for foods and beverages and as coatings on metal lids for glass jars and bottles. Epoxy resins are used in automotive electro-coating and in automotive and industrial primer and topcoat applications. Bisphenol A is also used in the production of phenolplast, phenolic and unsaturated polyester resins, thermal paper,

polyvinylchloride (PVC), alkoxylated bisphenol A and polyols/polyurethane. Bisphenol A may be used in the manufacture of modified polyamide, and tetrabromobisphenol A. Other products that may contain bisphenol A include protective window glazing, building materials, optical lenses and dyes.

5. PRESENCE IN THE CANADIAN ENVIRONMENT AND EXPOSURE SOURCES

5.1 Releases to the Environment

Releases of bisphenol A may occur during production, processing, use or disposal of the substance or products containing it. The National Pollutant Release Inventory (NPRI) indicates that where information was provided, on-site industrial releases of bisphenol A in Canada were solely to air. However, based on its physical and chemical properties and compartments to which it is released, the results of Level III fugacity modelling suggest that bisphenol A is expected to partition predominantly to soil or water.

The industrial sectors that did report emissions and disposals of bisphenol A to the NPRI included the manufacturers of motor vehicles, coatings, plastic products, resins, synthetic rubber and fiber and filaments, basic chemical manufacturing and foundries. Air releases reported to NPRI ranged from 0.04 to 8.77 tonnes annually, over the period of 1999 to 2006; although there is no temporal trend in emissions. The 2006 data indicated that only two companies released a total of 159 kg to air from a stack or point source. Off site disposals of bisphenol A reported to the NPRI ranged from 1.2 to 14 tonnes, with no temporal trend, over the same years, with 2.9 tonnes being reported for year 2006.

The NPRI reporting criteria for bisphenol A are 10 tonnes manufacture, process or otherwise used, with an equal to or greater than 1% by weight concentration, and ten full-time employees at that facility for a given calendar year. It is important to note that once a reporting facility meets all of the criteria noted above, they are obligated under CEPA 1999 to report all on-site releases (air, water, and land), on-site and off-site disposals, and transfers off-site for recycling. Based on information obtained from the NPRI, many facilities who reported for bisphenol A reported releases on site to air, but did not report any releases to water. This was mainly due to the fact that facilities who reported for this substance either do not have on-site releases of this substance to water or the quantity of releases to water were less than 1 kg (the current reporting system only allows reporting to this amount).

Based on its moderate water solubility and low vapour pressure, wastewaters and washing residue generated during production and processing of application materials such as polycarbonates and epoxy resins are the most likely sources of release of bisphenol A into the Canadian environment.

Release over the service life of end products may occur through volatilization or leaching. The majority of bisphenol A appears to be effectively retained within the polymer matrix of materials such as polycarbonates and therefore losses through leaching from the product surface are expected to be limited. As well, the low vapour pressure suggests bisphenol A will have little tendency to volatilize from products at normal environmental temperatures. Some losses could occur at elevated temperatures.

Bisphenol A may enter the environment through physical and chemical degradation of end products during disposal and recycling operations. Releases would be primarily to soil, and to a lesser extent, to water and air. Bisphenol A has been identified in groundwater samples collected in the vicinity of municipal landfills.

5.2 Exposure Sources

Currently, there is no indication that bisphenol A is naturally produced in the environment.

The following sources of exposure to humans were characterized in the screening assessment report: food packaging (migration of bisphenol A from epoxy resins which are used as an interior protective lining for food and beverage cans, including infant formula); repeat use containers (migration of bisphenol A from polycarbonate repeat-use containers such as baby bottles); breastmilk; environmental media (bisphenol A present in ambient air, indoor air, drinking water, soil and house dust); and consumer products (inhalation and dermal exposures during use of two-component epoxy adhesive).

Infants were the most highly exposed subpopulation. A common source of exposure, across all age categories, was food due to migration of bisphenol A from food packaging. Migration from polycarbonate repeat-use containers was also shown to contribute to exposure, particularly under test conditions in which boiling water was in contact with the container. For breastfed infants, very limited data indicate that breastmilk can be a source of exposure, although no data from Canadian women are available. Exposure via environmental media was low. Other potential sources of exposure (e.g., dental materials, two-component epoxy adhesives) were considered to contribute minimally to exposure. The exposure assessment did not identify other uses of bisphenol A (e.g., automotive, industrial, compact discs, optical lenses) as being significant contributors to human exposure.

Releases of bisphenol A to the environment may occur during the production, processing, use or disposal of the substance or products containing it. Unintentional release of fugitive dust from closed systems during handling and transportation of the substance may also occur. Elevated temperatures that occur during some processing operations could lead to possible emission of gaseous bisphenol A from manufacturing facilities or during heating of end products. Soil and groundwater exposure may also occur through weathering and breakdown of end products, particularly those with outdoor applications. Bisphenol A present in wastewater sludge could be released into the soil compartment through application of sludge biosolids to agricultural and pasture lands.

6. OVERVIEW OF EXISTING ACTIONS

6.1 Existing Canadian Risk Management

6.1.1 Water

The Ontario Ministry of Environment has established a provisional water quality objective of 5 µg/L. The water quality objectives are used to provide guidance when making water quality

management decisions. They are often a starting point in the development of site-specific acceptable wastewater limits (Ontario Ministry of the Environment and Energy, 1994).

Health Canada strongly recommends that consumers look for a mark or label indicating that products and materials that come into contact with drinking water be certified, by an accredited certification body, as meeting the health-based standards developed by NSF International (Health Canada, 2008). Products and materials certified as meeting NSF International/ANSI Standard 53 and/or 61, are tested for indirect additives, including bisphenol A, which can result from contact with drinking water. These standards indicate that the total allowable concentration of bisphenol A in resultant drinking water is 0.1 mg/L (Willhite et al., 2008). A recent survey performed by Health Canada found that NSF/ANSI Standard 61 has been adopted by all the provinces and the Northwest Territories in Canada.

6.1.2 Food

A provisional tolerable daily intake (PTDI) for bisphenol A of 25 µg/kg bw/day was established in 1996 by the Food Directorate of Health Canada; this TDI was reaffirmed for the general population in 2008.

Polycarbonate is on the list of acceptable polymers for use in food packaging in Canada (Health Canada, 2005).

The use of bisphenol A-based products in food packaging materials may be regulated under provisions of the *Food and Drug Regulations* which provide that no person shall sell any food in a package that may yield to its contents any substance that may be injurious to the health of a consumer of the food. Health Canada may conduct health safety evaluations of food packaging materials to assess if the packaging material constitutes a health risk to consumers.

6.1.3. Products intended for use in the workplace

The *Controlled Products Regulations* established under the *Hazardous Products Act* (HPA) stipulate that any supplier who imports or sells a chemical product that contains a listed substance in a concentration that is equal to or greater than the concentration denoted on the Ingredient Disclosure List (IDL) must supply a Material Safety Data Sheet disclosing that information. Bisphenol A is listed on the IDL with a concentration of 1% weight/weight. The IDL applies only to occupational settings with workplace chemicals and does not include consumer products available to the general public.

6.1.4. Releases

The National Pollutant Release Inventory (NPRI) was established in 1992 and legislated under CEPA 1999. The NPRI requires companies to report information on releases and on-site and off-site disposal of pollutants to the Government of Canada on an annual basis. Environment Canada makes the information available to Canadians in an annual public report, and maintains a detailed inventory that can be accessed and searched through an on-line database. Through this system, bisphenol A releases have been reported by industry annually (NPRI 2007).

6.2 Existing International Risk Management

6.2.1 United States

Emergency Planning and Community Right-to-know Act (EPCRA): Annual releases of bisphenol A must be reported if it is manufactured, imported or otherwise used at a level greater than one percent (US EPA, 2001). Release data are available through the toxic release inventory (TRI) (US EPA, 2006).

Food and Drug Act (FDA): Bisphenol A is listed as a potential component of indirect food additives including adhesives, resinous and polymeric coatings and polyestercarbonate resins. Indirect food additives that contain bisphenol A and that may be safely used with specified conditions included polycarbonate resins, polyethersulfone resins and several types of epoxy resins (US FDA, 2008).

6.2.2 Other National Legislation

In 2002, the European Scientific Committee on Food set a temporary tolerable daily intake of 10 µg/kg bw/day (SCF, 2002). A re-evaluation in 2006 by the European Scientific Panel on food additives, flavourings, processing aids and materials in contact with foods set a tolerable daily intake of 50 µg/kg bw/day based on newer data and this TDI was reconfirmed in a later scientific opinion in 2008 (EFSA, 2006, 2008). Under *The 2006 Plastic Materials and Articles in Contact with Food* (England) *Regulations*, the amount of bisphenol A permitted to migrate from food contact materials into food was set at 0.6 mg/kg (Food Standards Agency, 2007).

A 2002 draft environmental risk assessment by the Environment Agency for England and Wales and the UK Health and Safety Executive identified a need to limit the risk of exposure from thermal paper recycling and the use of bisphenol A as an inhibitor in PVC production. Bisphenol A use as an inhibitor was voluntarily phased out of PVC production in all European Council Vinyl Manufacturers (ECVM) member companies by 2001 (Risk & Policy Analysts Limited., 2003).

In 2007, a Japanese human health and ecological risk assessment concluded that the risks posed by bisphenol A were below the levels of concern; however, several voluntary risk reduction measures were examined. The substitution of polycarbonate tableware used for school lunches was estimated to have cost 370 million yen per year (approximately 3 million Canadian dollars) and to have potentially reduced daily bisphenol A intake by 0.2–0.3 µg/kg bw/day. The modification of the inner surface of drink cans to polyethylene terephthalate film lamination or epoxy resin paint was estimated to have minimal costs and to have potentially reduced daily bisphenol A intake by 0.1–0.2 µg/kg bw/day for average exposure individuals and 0.2–0.6 µg/kg bw/day for high exposure individuals (AIST, 2007)

Under the Food Sanitation Law in Japan, a migration limit in food-contact polycarbonate plastic is specified as 2.5 ppm (AIST, 2007)

Bisphenol A is listed in the EU Cosmetic Directive Annex. II, a list of substances which must not form part of the composition of cosmetic products.

7. CONSIDERATIONS

7.1 Alternative Chemicals or Substitutes

No information on potential substitutes for bisphenol A was brought forward in the voluntary Challenge Questionnaire submissions.

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.

The Government will support manufacturers in the evaluation of replacement options for bisphenol A in infant formula can coatings.

It is important to note that potential substitutes have not undergone an assessment to determine whether it would meet the criteria under section 64 of CEPA 1999.

7.2 Alternative Technologies and/or Techniques

Available information on alternative technologies and/or techniques will be considered as risk management measures are further developed.

7.3 Socio-economic Considerations

Socio-economic factors have been considered in the selection process for a regulation and/or instrument respecting preventive or control actions, and in the development of the risk management objective(s). Socio-economic factors will also be considered in the development of regulations, instrument(s) and/or tool(s) as identified in the *Cabinet Directive on Streamlining Regulation* (Treasury Board of Canada Secretariat 2007) and the guidance provided in the Treasury Board document *Assessing, Selecting, and Implementing Instruments for Government Action*.

Bisphenol A is not manufactured in Canada, however, Canadian firms reported import and use of bisphenol A in 2006, either alone, in a product, in a mixture or in a manufactured item.

Preliminary analysis suggests that the revenue of the plastic bottle manufacturing industry was in excess of $865 million in 2006, employing approximately 2800 persons in production, and almost 700 persons in non-manufacturing positions. A portion of this industry may manufacture repeat-use polycarbonate bottles, including baby bottles (Statistics Canada, 2008).

Several retailers have voluntarily removed polycarbonate plastic baby bottles containing bisphenol A from store shelves. Repeat-use polycarbonate bottles intended for other uses have also been removed by some retailers. Substitutes that exist for polycarbonate plastic baby bottles include bottles or bottle liners made of polyethylene (PE) or polypropylene (PP) or other plastics not made with bisphenol A monomer, and glass baby bottles. The retail price of baby bottles varies significantly; recent prices on one retailer's website indicate that the price of an 8-ounce

polypropylene plastic baby bottle varies from $1.29/bottle to $9.99/bottle, and the price of an 8-ounce glass baby bottle varies from $3.79/bottle to $14.99/bottle.

Baby formula (fresh, processed and bottled) manufacturing, and infants' formula manufacturing are included in the relatively large butter, cheese, and dry and condensed dairy products manufacturing industry. A portion of these sectors involve the use of infant formula cans which contain bisphenol A. Other industries on which the proposed risk management actions may have an economic impact include, but are not limited to: resin and synthetic rubber manufacturing, metal can manufacturing, and the fruit and vegetable canning, pickling and drying industry.

An economic analysis will be conducted as part of instrument development. Where information is available, this analysis will identify economic factors as they relate to bisphenol A use and manufacture in Canada, including employment, and regional dispersion of industries that use bisphenol A in the manufacturing process. The analysis will also, where possible, identify potential replacements, the relative cost of these replacements, and the effect on Canadian industries of potential alternatives. Finally, the benefits of pursuing regulatory action will be identified, with a valuation of benefits conducted where possible.

7.4 Children's Exposure

The Government of Canada considered, where available, risk assessment information relevant to children's exposure to this substance. As part of the Challenge, the Government asked industry and interested stakeholders to submit any information on the substance that may be used to inform risk assessment, risk management and product stewardship. In particular, stakeholders were asked through a questionnaire if any of the products containing the substance were intended for use by children.

The screening assessment stated that, based on limited studies in laboratory animals, the pregnant woman/fetus and infant are potentially vulnerable subpopulations due to potential differences in the toxicokinetics and metabolism of bisphenol A. Based on the exposure estimates in the screening assessment, infants were the most highly exposed subpopulation. This combination of both highest potential exposure and potential vulnerability led to the focus of risk management on decreasing exposures to newborns and infants under 18 months old (i.e., infant formula cans and some types of baby bottles).

8. PROPOSED OBJECTIVES

8.1 Environmental or Human Health Objective

An environmental or human health objective is a quantitative or qualitative statement of what should be achieved to address environmental or human health concerns identified during a risk assessment.

The proposed human health objective for bisphenol A is to minimize infant exposure to the greatest extent practicable.

The proposed environmental objective is to prevent or minimize releases of bisphenol A into the Canadian environment.

8.2 Risk Management Objective

A risk management objective is a target that is expected to be achieved for a given substance by the implementation of risk management regulations, instrument(s) and/or tool(s). In order to reduce exposure to infants from polycarbonate baby bottles and canned infant formula, the proposed health risk management objective for bisphenol A is to achieve the lowest level of release to infant formula and from polycarbonate baby bottles that is technically and economically feasible.

In order to prevent or minimize releases of bisphenol A to the environment, the proposed ecological risk management objective is to achieve the lowest level of release of bisphenol A to water that is technically and economically feasible.

9. PROPOSED RISK MANAGEMENT

9.1 Proposed Risk Management Regulations, Instrument(s) and/or Tool(s)

As required by the Government of Canada's *Cabinet Directive on Streamlining Regulation*,[3] and criteria identified in the Treasury Board document entitled *Assessing, Selecting, and Implementing Instruments for Government Action*, the proposed risk management regulations, instruments and/or tools were selected using a consistent approach, and took into consideration the information that has been received through the Challenge and other information available at the time.

In addition, the proposed risk management instruments will be developed in accordance with the principles of public participation as outlined in the *Guidelines for Effective Regulatory Consultations* developed under *the Cabinet Directive on Streamlining Regulation*

In order to achieve the health and ecological risk management objectives and to work towards achieving the human health and environmental objectives, the risk management being considered for bisphenol A is outlined below.

9.1.1 Polycarbonate baby bottles

The Government is proposing to ban the importation, sale and advertising of polycarbonate baby bottles made with bisphenol A monomer.

[3] Section 4.4 of the *Cabinet Directive on Streamlining Regulation* states that "Departments and agencies are to: identify the appropriate instrument or mix of instruments, including regulatory and non-regulatory measures, and justify their application before submitting a regulatory proposal".

9.1.2 Canned infant formula

The Government proposes to adopt a precautionary approach for bisphenol A in food packaging for products intended for newborns and infants and will be adopting the As Low As Reasonably Achievable (ALARA) 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.

The Government will continue to scrutinize pre-market submissions for infant formula to ensure 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, to as low as reasonably achievable, the levels of bisphenol A in infant formula. A meeting organized by the Government of Canada, with participation from the Centre for Food Safety and Applied Nutrition (CFSAN) of the United States Food and Drug Adminstration (US FDA), the North American Metal Packaging Alliance (NAMPA) and various North American infant formula manufacturers, resulted in support from all stakeholders to further develop the "Code of Practice" aimed at reducing levels of bisphenol A in canned infant formula to the lowest reasonably achievable levels.

9.1.3 Other canned food

The Government will explore the option of establishing stringent migration targets for bisphenol A in canned foods in general.

9.1.4 Management of Releases to the Environment

The Government of Canada will consider imposing regulations to minimize the risks from releases of bisphenol A into the environment. The regulatory proposal will be published in *Canada Gazette*, Part I, within approximately 24 months.

These regulations would be developed to prevent or minimize releases to the environment. They would:

- Establish maximal bisphenol A concentrations at the effluent, and
- Require the implementation of management system to ensure best management practices are adopted at facilities where bisphenol A is used.

The management system would include:

- procedures for ensuring the protection of the environment against the adverse effects that may result from the releases of the substance to the environment including measures for monitoring the efficiency of the procedures and modifying them in the event that they do not protect the environment,
- measures to monitor and ensure compliance with applicable laws with respect to the protection of the environment, and
- a verification protocol.

In accordance with Environment Canada's proposed regulatory framework for wastewater, this regulatory approach would be applied to manage pollutants at their source. For more information on the framework, please consult: www.ec.gc.ca/eu-ww.

Therefore, it is intended that this regulatory approach be applied to the following.

9.1.4.1 Industrial Users of Bisphenol A

The Government of Canada will explore with industrial users of bisphenol A on how this regulatory approach would be implemented at facilities releasing this substance to the environment or wastewater system.

9.1.4.2 Disposal or Recycling of Products or Materials containing Bisphenol A

The Government of Canada will work 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. Options will be explored for the implementation of the regulatory approach at facilities releasing this substance to the environment or wastewater system.

This approach will take into consideration that the federal, provincial and territorial governments and municipalities have jurisdiction to regulate waste management in Canada.

9.2 Other Information Gathering, Monitoring and Research

Information Gathering
Releases of bisphenol A will continue to be monitored under the National Pollutant Release Inventory.

A survey to gather information on all currently licensed Class II, III and IV medical devices that contain bisphenol A and that come into contact with the patient or patient fluids is planned. New Class II, III and IV medical device licence application forms as well as amendment application forms incorporating this information have also been posted on the Health Canada website.

Bisphenol A will be included in the Domestic Substance List inventory update initiative, to be launched in 2009.

Monitoring
Monitoring for bisphenol A will be conducted under a more comprehensive monitoring and surveillance strategy for substances in the Chemicals Management Plan. Monitoring has been identified as a key pillar in the Chemicals Management Plan which will serve the following functions: to collect and generate human exposure and environmental data to inform decision making; to provide an adaptive management framework to support intervention; and to measure the efficacy of preventive and mitigation actions.

Further information on bisphenol A and exposures of pregnant women will be collected through several research projects, including the Maternal-Infant Research on Environmental Chemicals (MIREC) Study and Plastics and Personal-care Product Use in Pregnancy. The MIREC study

will provide a national profile of exposures to environmental contaminants during pregnancy and breastfeeding.

The Canadian Health Measures Survey will measure levels of environmental chemicals in humans. Urine samples will be collected and analyzed for a number of different classes of substances, including bisphenol A. There will also be a questionnaire for each respondent to allow for the analysis of risk factors related to exposure to these environmental chemical substances.

Bisphenol A will be added to the list of chemicals to be monitored regularly as part of the 2009 cycle of the Canadian Total Diet Study (TDS) in order to refine exposure estimates to bisphenol A from all pre-packaged food sources, including canned foods.

Additionally, the Government will address data gaps for Canadian exposure estimates to bisphenol A by developing occurrence data from a variety of foods (including canned) for all age groups. Research plans include selected samplings of liquid and powdered infant formulas, as well as infant foods for infants and children aged 1–4 years.

Environmental monitoring of bisphenol A is planned nationally in the following media: wastewater effluent and wastewater sludge; landfill leachate; wildlife; fish; and receiving waters downstream of wastewater treatment plants. This monitoring will be used to inform the government on ambient levels of bisphenol A in the environment, to assess the efficacy of risk management actions and to help determine the fate of bisphenol A in waste streams.

Research
Further research on the mechanism of action of bisphenol A and potential fetal exposures to bisphenol A is being undertaken.

9.3 Implementation Plan

It is the intent of the Government to publish a proposed risk management measure in the *Canada Gazette*, Part I, by fall 2010.

10. CONSULTATION APPROACH

The risk management scope for bisphenol A, which summarized the proposed risk management under consideration at that time, was published on April 18, 2008, and is available at www.ec.gc.ca/TOXICS/EN/detail.cfm?par_substanceID=236&par_actn=s1. Industry and other interested stakeholders were invited to submit comments on the risk management scope during a 60-day comment period. Comments received on the risk management scope document were taken into consideration in the development of this proposed risk management approach document.
Consultation for the risk management approach will involve publication on October 18, 2008, and a 60-day public comment period.

The primary stakeholders include

- Food packaging (i.e., metal cans) industries
- Infant formula manufacturers
- Polycarbonate baby bottle manufacturers/importers
- Environmental non-governmental organizations
- Polycarbonate and epoxy resin producers
- Retailers

11. NEXT STEPS / PROPOSED TIMELINE

Actions	Date
Electronic consultation on proposed Risk Management Approach	October 18, 2008, to December 17, 2008
Response to comments on the Risk Management Approach	At time of publication of proposed instrument
Consultation on the draft instrument	Spring 2009
Publication of the proposed instrument	No later than October 2010
Formal public comment period on the proposed instrument	No later than fall 2010
Publication of the final instrument	No later than April 2012

Industry and other interested stakeholders are invited to submit comments on the content of this proposed risk management approach or to provide other information that would help to inform decision making. Please submit comments prior to December 17, 2008, since the Government of Canada will be moving forward with the risk management of bisphenol A after this date. Pursuant to section 313 of CEPA 1999, any person who provides information to the Minister of the Environment under CEPA 1999 may submit with the information a request that it be treated as confidential. During the development of the risk management regulations, instrument(s) and/or tool(s), there will be opportunity for consultation. Comments and information submissions on the proposed risk management approach should be submitted to the address provided below:

Existing Substances Division
Gatineau QC K1A 0H3
Tel: 1-888-228-0530 / 819-956-9313
Fax: 1-800-410-4314 / 819-953-4936
Email: Existing.Substances.Existantes@ec.gc.ca

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