

Order Amending Schedule I to the Hazardous Products Act (bisphenol A)

Statutory authority

Hazardous Products Act

Sponsoring department

Department of Health

REGULATORY IMPACT ANALYSIS STATEMENT

(This statement is not part of the Order.)

Executive summary

Issue: Polycarbonate baby bottles that contain 4,4' - isopropylidenediphenol (bisphenol A) have the potential to cause harmful effects in newborns and infants up to the age of 18 months. Migration of small amounts of bisphenol A into hot and boiling water or liquids that have been placed in polycarbonate baby bottles may contribute to newborns' and infants' oral exposure to bisphenol A. Recent research has identified uncertainty surrounding the potential for bisphenol A to cause neurological and behavioural effects at early stages of development in rodents. Given that toxicokinetic and metabolism data indicate potential sensitivity to newborns and infants, it is considered appropriate to apply a precautionary approach when characterizing risk. For this reason proactive measures by the Government of Canada are needed now in order to protect the health and safety of newborns and infants.

On October 18, 2008, a notice containing a summary of the final Government of Canada screening assessment report for bisphenol A and the proposed risk management approach were published in the *Canada Gazette*, Part I. The screening assessment concluded that bisphenol A is or 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 risk management approach document outlined actions as part of a Government of Canada-wide initiative to control this substance. In addition to a proposed prohibition of polycarbonate baby bottles that contain bisphenol A, measures were proposed to reduce migration targets in canned infant formula and regulations are being considered to minimize the risks from releases of bisphenol A to the environment.

Description: A prohibition of polycarbonate baby bottles that contain bisphenol A under Part I of Schedule I to the *Hazardous Products Act* is the most effective measure for ensuring these products are no longer advertised, sold and imported into Canada. The *Hazardous Products Act* provides the authority to prohibit or restrict products which are, or are likely to be a danger to health or safety.

Cost-benefit statement: The benefits of the proposal, a reduction in newborns' and infants' potential adverse health effects due to exposure to bisphenol A, outweigh the costs of implementation. Industry has already commenced the voluntary removal of polycarbonate baby bottles from the market and replaced them with alternatives; therefore the impact of the prohibition is expected to be limited. Economic burden on consumers is also limited as alternatives to polycarbonate baby bottles that contain bisphenol A are similar in cost.

Business and consumer impacts: It is expected that the proposed prohibition will have a minor overall impact on industry, while consumers will have the benefit of purchasing and using safer baby bottles at little or no additional cost, but which do not present an undue risk

to their newborns and infants.

Domestic and international coordination and cooperation: The prohibition is not anticipated to pose any adverse trade impacts. While Canada is the first country in the world to introduce a prohibition for these products, the United States is considering similar action.

Issue

Under the Government of Canada's Chemicals Management Plan, which was announced in December 2006, 4,4' - isopropylidenediphenol (bisphenol A) was identified as a high priority for assessment of human health risk because it was considered to present the greatest potential for human exposure and had been classified as a high hazard by other agencies on the basis of reproductive toxicity. The European Chemicals Bureau has classified bisphenol A as a Category 3 reproductive toxicant; that is a substance which causes concern for human fertility based on sufficient evidence of reproductive toxicity in experimental animals. A critical effect for characterization of risk to human health is reproductive and developmental toxicity.

On April 19, 2008, the Government of Canada published a draft screening assessment for bisphenol A. A notice containing a summary of the final screening assessment report for bisphenol A and the proposed risk management approach were published in the *Canada Gazette*, Part I, on October 18, 2008. The final screening assessment confirmed that exposure levels for bisphenol A are below those that could cause health effects in the general population. However, the report concluded, applying a precautionary approach, that bisphenol A is or 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. This conclusion was based in part on the uncertainty around bisphenol A's potential to cause neurological effects in early stages of development. Neural development is a complex process which begins in early embryonic development and continues through different life stages.

Bisphenol A is used as a monomer in the production of polycarbonate, which is a clear hard plastic that is used to manufacture many products including baby bottles. Bisphenol A migrates from polycarbonate in the presence of hot or boiling liquid and remains in the liquid after it has cooled. Dietary intake via the migration of bisphenol A from polycarbonate baby bottles is considered a primary source of exposure to bisphenol A for newborns and infants. Specific exposure estimates in the screening assessment identified newborns and infants up to the age of 18 months as the most highly exposed subpopulation.

Various animal studies where bisphenol A was administered to rodents at low doses suggested that exposure during gestation and early postnatal life may affect neural development and some aspects of behaviour. However, the overall weight of evidence is considered limited, making it difficult to determine actual significance of findings to human health risk assessment.

The neurodevelopmental and behavioural dataset in rodents, though highly uncertain, is suggestive of potential effects at doses at the same order of magnitude as 1–2 orders of magnitude higher than estimated levels of exposure. These studies suggest a trend towards heightened susceptibility during early stages of development in rodents. Additionally, toxicokinetic and metabolism data indicate potential sensitivity to newborns and infants. The human body rapidly metabolizes and eliminates bisphenol A after exposure compared to rodents. However, newborns and infants up to 18 months of age are still considered to be more susceptible to the potential adverse effects of bisphenol A due to their potentially less effective metabolism and elimination of bisphenol A, increased intake per body weight, increased potential for exposure due to the use of baby bottles, and rapid rate of physical growth and development. Although bisphenol A exposure levels in newborns and infants is below that which could cause health effects based on animal studies, it is considered appropriate to apply a precautionary approach when characterizing risk to health of this susceptible subpopulation.

The U.S. Department of Health and Human Services National Toxicology Program (September 2008) publication concluded current exposures to bisphenol A are possibly high enough to cause harm to human reproduction or development. Although laboratory animals are exposed to much higher doses of bisphenol A than those to which humans are exposed, estimated exposures in infants and children are similar to levels of bisphenol A associated with several "low" dose laboratory animal findings of effects on the brain and behaviour, prostate and mammary gland development, and early onset of puberty in females.

A 2003 European Commission Joint Research Centre Risk Assessment report concluded that "further research is needed to resolve the uncertainties surrounding the potential for bisphenol A to produce adverse effects on development at low doses." More recently, the European Union in the draft Updated Risk

Assessment of bisphenol A (2008) reaffirmed that "overall, taking together the low confidence in the reliability of the developmental neurotoxicity studies and the lack of consistency in the results of behavioural testing, no conclusions can be drawn from these studies." As a result of these two reports, the European Union is not taking any risk reduction measures beyond those which are already being applied, but continues to assess new information and data as it becomes available.

Since the April 2008 announcement by the Government of Canada, proposed legislation to control this substance has been introduced at the state and federal levels in the United States. On March 5, 2009, the Washington State House of Representatives passed a bill prohibiting the sale of "any bottle, cup, or other container that contains bisphenol A if the container is designed or intended to be filled with any liquid, food or beverage primarily for consumption from that container by children three years of age or younger." On March 16, 2009, in the United States, a bill to ban the use of bisphenol A in food containers, and for other purposes was introduced for the second time in the House of Representatives.

Objectives

This initiative is intended to enhance the health and safety of newborns and infants up to the age of 18 months by reducing their risk of developing adverse health effects as a result of exposure to bisphenol A. This will be accomplished by eliminating one of their sources of exposure by using the *Hazardous Products Act* to prohibit the advertisement, sale or importation of polycarbonate baby bottles that contain bisphenol A.

Description

The *Hazardous Products Act* provides the authority to prohibit or restrict products which are, or are likely to be a danger to health or safety. Part I of Schedule I to the *Hazardous Products Act* will be amended to include polycarbonate baby bottles that contain bisphenol A, thus prohibiting the advertisement, sale and importation in Canada of these products.

In addition to the proposed prohibition of polycarbonate baby bottles that contain bisphenol A, there are other Government-wide initiatives taking place to control this substance. Health Canada actions for foods include developing stringent migration targets in canned infant formula, continuing to scrutinize pre-market submission of food packaging applications as well as supporting industry in the development and implementation of codes of practice and in the evaluation of replacement options for bisphenol A in infant formula can coatings. Environment Canada is also considering regulations to minimize the risks from releases of bisphenol A into the environment. Additionally, the Government of Canada is funding multiple research projects to help address key knowledge gaps. The implications of new research results for bisphenol A will continue to be assessed and further action will be taken if warranted.

A complete list of measures may be found in the risk management approach document for bisphenol A at the following Web site: www.ec.gc.ca/substances/ese/eng/challenge/batch2/batch2_80-05-7_rm_en.pdf.

Regulatory and non-regulatory options considered

Status quo

The continued advertisement, sale and importation of polycarbonate baby bottles that contain bisphenol A is not considered a viable option.

Following the April 2008 announcement of the Government of Canada, a market shift away from polycarbonate baby bottles occurred. Industry began to dispose of existing stock of these products and to promote alternatives. Additionally, consumer demand precipitated a shift in the market as public awareness was heightened to the potential health risks associated with exposure to bisphenol A.

However, the status quo would not preclude polycarbonate baby bottles from returning to the marketplace. Under this option there would continue to be no legal restrictions on the advertisement, sale or importation in Canada of polycarbonate baby bottles that contain bisphenol A. For this reason, it is considered that this option does not best protect newborns and infants up to the age of 18 months from this source of bisphenol A exposure.

Labelling

Mandatory labelling to identify the use of bisphenol A in polycarbonate baby bottles cannot achieve the level of protection considered necessary to protect newborns and infants up to the age of 18 months.

The main purpose of precautionary labelling on a consumer product is to bring an issue to the attention of the user, and to help them use the product safely. Mandatory labelling to identify an inherent health hazard from the reasonably foreseeable use of a product would allow the product to be sold without directly reducing the health risk.

It cannot be assumed that a label on a polycarbonate baby bottle identifying bisphenol A content would result in the necessary consistent formula preparation procedures in which water is boiled and then allowed to cool before being put into the baby bottle all of the time. It is therefore prudent to introduce measures that would provide greater health and safety protection to this susceptible subpopulation.

Regulatory option

Under this option, a regulatory limit would specify an allowable level of migratable bisphenol A from baby bottles and any components of the baby bottle that are intended to hold a liquid. Baby bottles or any components of the bottles that leached bisphenol A in a quantity equal to or greater than the specified allowable limit would be prohibited. This requirement would include baby bottles made from any type of material, not just polycarbonate.

However, it is not possible to determine a safe level of bisphenol A exposure for newborns and infants up to the age of 18 months as the dataset of neurodevelopmental and behavioural studies in rodents is not yet adequately developed. Therefore, restricting bisphenol A content to a specified level without having more definitive datasets on those two effects may not actually help to adequately reduce the levels of exposure to newborns and infants, and thus is not considered a viable option.

Prohibition

The prohibition of polycarbonate baby bottles that contain bisphenol A from advertisement, sale and importation in Canada provides the greatest protection to Canadian newborns and infants. This option eliminates one source of bisphenol A exposure to this susceptible group, thus reducing their overall exposure to this substance.

Benefits and costs

A *Technical and Socio-Economic Background Study of Specific Uses of Bisphenol A* was prepared for Health Canada by Cheminfo Services Inc. (January 19, 2009). The purpose of the study was to provide background technical and socio-economic information on specific products containing bisphenol A. Data was collected by means of interviews with manufacturers and industry associations, and literature review. The report includes a summary of the economic impact of regulating the sale of polycarbonate baby bottles, which is available upon request. Information from this report was used by Health Canada to estimate the costs of a proposed prohibition on the importation, sale and advertising of polycarbonate baby bottles that contain bisphenol A.

The full report on the *Analysis of Benefits and Costs of a Proposed Prohibition on the Importation, Sale and Advertising of Polycarbonate Baby Bottles that contain Bisphenol A* (March 2009) prepared by the Risk Management Bureau of Health Canada is available upon request.

Current state of polycarbonate baby bottles containing bisphenol A in Canada

As of 2009, polycarbonate baby bottles represent practically 0% of the Canadian baby bottle market. Major retailers halted their sales of polycarbonate baby bottles in mid-2008 in response to the Government of Canada's announcement of the intention to propose a prohibition of the importation, sale and advertising of polycarbonate baby bottles made with bisphenol A. Manufacturers responded by offering baby bottles made from alternative materials to Canadian consumers. ([see footnote 1](#))

Profile of industry

The Canadian baby bottle market is characterized by a significant amount of market concentration, with low overall employment and relatively flat sales growth. This industry accounts for a very small portion of the Canadian gross domestic product (GDP). There is a significant amount of concentration in this market with six major manufacturers of baby bottles serving the North American market, supplying an estimated 70–90% of the Canadian market. The remaining Canadian baby bottle sales are accounted for by several smaller manufacturers. Although these companies are referred to as manufacturers, to a large extent they contract out the manufacture of bottles to independent plastic or glass processors. Information suggests that polycarbonate baby bottles are not, and have not historically been, manufactured in Canada. One company contracts to an independent plastic processor to produce baby bottles in Canada, while the

remaining baby bottle companies import to Canada from other countries. ([see footnote 2](#))

Costs to industry

Information gathered by Cheminfo Services Inc. indicates that there is likely no polycarbonate baby bottle production in Canada, and that the manufacturer/importer switch to alternative baby bottles for the Canadian market was done with ease due to the large number of plastic processors capable of producing alternative plastic baby bottles. It is expected that profit margins for alternative baby bottles were maintained to a large extent. ([see footnote 3](#))

While it cannot be stated definitively that these bottles are no longer imported and sold in Canada, major retailers have stopped selling polycarbonate baby bottles. Available evidence indicates that this market ceased in 2008. ([see footnote 4](#))

Given that there is practically no longer a market for polycarbonate baby bottles in Canada, prohibiting the importation, sale and advertising of polycarbonate baby bottles that contain bisphenol A would have negligible (and potentially no) economic impacts on the Canadian industry. More specifically, "the market already imposed whatever economic impacts will be incurred by essentially requiring polycarbonate-free baby bottles." (Cheminfo Services Inc., 2009). Therefore, the proposed prohibition is not expected to put any undue financial burden on industry.

Information suggests that market shares for smaller firms increased in 2008 as major manufacturers adjusted to the changing Canadian demand for polycarbonate baby bottles. However, major companies likely regained their market shares as they completed the switch to alternative materials for the Canadian market. ([see footnote 5](#))

Costs to consumers

In mid-2008, it was widely reported that major Canadian retailers selling infant products would pull polycarbonate baby bottles containing bisphenol A from store shelves. Some of these major retailers also offered to buy back and/or exchange polycarbonate baby bottles already sold. The increased public awareness of issues surrounding use of polycarbonate baby bottles, as well as major retailer's voluntarily removal of these products from shelves, effectively diminished demand for these products to zero in Canada.

The costs borne by consumers are minimal, as major retailers have not been selling polycarbonate baby bottles containing bisphenol A since mid-2008. Alternatives have a broad range of prices, and consumers can buy bottles at lower or higher prices than charged for polycarbonate baby bottles. The estimated range of costs for one household replacing five polycarbonate baby bottles is approximately \$35 to \$65, incurred only by households that choose to replace already owned polycarbonate baby bottles.

For the consumer cost analysis, a conservative upper bound of baby bottles sales of 3.5 million is used. Growth of the baby bottle market is believed to be relatively low, approximately 1% per year, because the birth rate in North America has been relatively stable and is expected to remain stable. ([see footnote 6](#)) The price of alternative bottles was obtained from Cheminfo Services Inc. and from information collected by Health Canada's Consumer Product Safety Bureau. Cheminfo Services Inc. estimates that bottle price ranged from approximately \$7 to \$13 per 8–9 oz. bottle in 2008, depending on material.

Using the assumption that the proposed prohibition will result in some households replacing polycarbonate baby bottles that would otherwise have been reused for subsequent infants, Health Canada analysis indicates that there may be a relatively small spike in sales of 4.6% in 2009 and 1.3% in 2010 if the proposed prohibition is introduced.

As noted above, the estimated range of costs to replace five polycarbonate baby bottles is approximately \$35 to \$65 per household replacing polycarbonate baby bottles owned prior to the prohibition. The increased demand for replacement alternative baby bottles results in a total undiscounted cost of approximately \$1.62 million in 2009 and \$460,000 in 2010, with an estimated total present value of \$2 million. The total cost to consumers in the years following 2010 is estimated to be \$0, as replacement of polycarbonate baby bottles will likely occur in the years immediately following the prohibition.

There is uncertainty associated with the consumer demand for baby bottles as there are no published reports of the Canadian market. The present value of the costs to consumers in this analysis assumes a demand of 3.5 million baby bottles in 2008, which is likely higher than actual sales, but provides a conservative estimate of costs. Sensitivity analysis conducted using the range of demand of 1.4 to 4.2

million bottles results in a range of present value of costs to consumers of \$760,000 to \$2.46 million.

Costs to Government

Estimated annual costs for Health Canada’s Consumer Product Safety Bureau will include monitoring, sampling, testing and enforcement at \$87,500 in the year after the legislation is introduced. These costs would decline over time as non-compliant products are removed from the marketplace. For subsequent years, the estimated average cost is \$10,000 per year. The estimated total present value of the costs to Government of the prohibition is \$159,000 from 2009 to 2020.

The estimated present value of the costs to consumers and Government is \$2.2 million. Sensitivity analysis conducted using discount rates of 5% and 10% does not significantly alter the present value of costs (\$2.19 million and \$2.23 million).

Benefit to Canadians

The main sources of exposure for newborns and infants are from bisphenol A migrating from the lining of cans into liquid infant formula and migrating from polycarbonate baby bottles into the liquid inside following the addition of boiling water. The proposed prohibition will eliminate one source of bisphenol A exposure for the susceptible infant population.

Although quantitative data on which to assess the human health effects is currently lacking, animal studies suggest, though highly uncertain, the potential for bisphenol A to cause neurological and behavioural effects at early stages of development. Given that toxicokinetic and metabolism data indicate potential sensitivity to infants, it is considered appropriate to apply a precautionary approach when characterizing risk. [\(see footnote 7\)](#)

A prohibition of the importation, sale and advertising of polycarbonate baby bottles containing bisphenol A will halt the possible future return of polycarbonate baby bottles, remove polycarbonate baby bottles that are still in the market (believed to be a small number), ensure standard requirements of stakeholders including industry and retail, and fulfill the apparent public preference to have these bottles removed from the Canadian market.

Consumers have signalled their desire to have polycarbonate baby bottles removed from Canadian commerce by reducing their demand to zero in 2008. Acting now will minimize economic impacts, as opposed to a longer term strategy that may allow for the resurgence of the polycarbonate baby bottle market. The proposed prohibition halts any future sales of polycarbonate baby bottles and ensures consistent requirements for all stakeholders.

Distribution of impacts

Costs are borne mainly by households with infants, however these costs are expected to be minimal because there have not been sales of polycarbonate baby bottles containing bisphenol A since mid-2008. The impact on consumers of the prohibition will be the same across all regions and is not expected to impact employment or inflation.

Net benefits

The annualized value of the costs to Government and consumers is an estimated \$309,000, with a present value of \$2.2 million, and an estimated \$0 cost to industry. Given that bisphenol A is potentially harmful to the health of newborns and infants up to 18 months, it is concluded that the proposed prohibition of the importation, sale and advertising of polycarbonate baby bottles containing bisphenol A is a reasonable preventative measure, despite the costs incurred.

Accounting Statement

Incremental Costs and Benefits (thousands of \$)	Base Year: 2009	2015	Final Year: 2020	Present Value 2009–2020	Average Annual
A. Monetized					

Costs	(1,709)	(10)	(10)	(2,209)	(309)
<i>Industry</i>	0	0	0	0	0
<i>Consumer</i>	(1,622)	0	0	(2,050)	(287)
<i>Enforcement</i>	(87.5)	(10)	(10)	(159)	(22)
B. Unquantified					
Benefits	Bisphenol A is potentially harmful to the neurological and behavioural development of newborns and infants. It is therefore considered appropriate to apply a precautionary approach when characterizing risk. The proposed prohibition would eliminate the risk from this source altogether.				

Rationale

Health Canada is proposing to proceed with the prohibition of polycarbonate baby bottles that contain bisphenol A as it is considered the most effective option to reduce the exposure to bisphenol A to newborns and infants. Total benefits to this proposal outweigh the costs as industry has already reacted to the Government announcement by replacing polycarbonate baby bottles with alternative plastics.

Consultation

Two public comment periods took place during 2008.

- On April 19, 2008, a draft screening assessment report and risk management scope for bisphenol A were published in the *Canada Gazette*, Part I, for a 60-day public comment period. The risk management scope document contained a proposal that should the Government conclude that bisphenol A meet the criteria under section 64 of the *Canadian Environmental Protection Act, 1999* (CEPA 1999), the Government would move ahead to prohibit the importation, sale and advertising of polycarbonate baby bottles. The closing date of the comment period was June 18, 2008.
- On October 18, 2008, a notice containing a summary of the final screening assessment report for bisphenol A and the proposed risk management approach were published in the *Canada Gazette*, Part I. In the risk management approach, the Government proposed a ban on the importation, sale and advertising of polycarbonate baby bottles made with bisphenol A monomer. This proposal was subject to a 60-day public comment period with a closing date of December 17, 2008.

Results of April 2008 consultation

Twenty-one submissions were received which included three industry members, five industry associations, sixteen non-government organizations, four public health organizations and four individuals. However, three industry associations and one industry member did not comment specifically on the proposed prohibition, but only on the draft screening assessment.

Additionally, two petitions were received. One of the petitions, containing 951 signatures, requested a complete ban of bisphenol A. The other petition, with 28 signatures, supported the proposed ban of polycarbonate baby bottles that contain bisphenol A and also promoted breastfeeding as a way of limiting the exposure of infants to bisphenol A.

Of the comments received that were directly relevant to the proposed prohibition of polycarbonate baby bottles that contain bisphenol A, 23 stakeholders expressed clear support of the Government of Canada's intention including one industry member, 15 non-government organizations, 3 public health organizations and 4 individuals. Three stakeholders were opposed to the prohibition, including one industry member, one industry association and one public health organization.

The industry member and association who opposed the prohibition indicated consumer education to not fill polycarbonate baby bottles with boiling water was a less trade restrictive measure which would increase safety without imposing trade barriers.

It cannot be assumed that these products will be used as intended or advice will be followed all of the time. A prohibition of polycarbonate baby bottles that contain bisphenol A is the best mechanism to eliminate one of the sources of exposure to newborns and infants and consequently reduce their risk of developing any potential adverse health effects.

One public health organization was opposed to the prohibition, indicating the exposure to bisphenol A from polycarbonate baby bottles was low and should be considered only as minor exposure.

Human exposure to bisphenol A in Canada can result from dietary intake (e.g. migration from food packaging, migration from repeat-use polycarbonate containers), from environmental media (i.e. ambient air, indoor air, drinking water, soil and dust), from use of consumer products and other sources. Dietary intake is the primary source of exposure. The screening assessment identifies bisphenol A intake from polycarbonate baby bottles when boiling water is added to the bottles as higher than that of intake from infant formula. Additionally, intake from polycarbonate baby bottles is identified as being a higher source of bisphenol A exposure than the formula and environmental media sources combined. A prohibition of these products removes a primary source of bisphenol A exposure to newborns and infants.

One industry association recommended an internationally harmonized approach to managing bisphenol A. In developing this approach to reduce newborns' and infants' exposure to bisphenol A, both existing international risk management activities and the Canadian context were considered. Although Canada is the first country in the world to prohibit polycarbonate baby bottles that contain bisphenol A, other countries are also considering action with respect to this substance.

Of the 15 non-government organizations, 3 public health organizations and 4 individuals who supported the proposed prohibition, many commented that the risk management did not go far enough. Some declared the prohibition should be expanded to include more products and others stated the risk measures should be expanded to reduce exposures to pregnant women in order to protect the fetus.

The Government of Canada has identified newborns and infants up to the age of eighteen months as the most highly exposed subpopulation. The Government of Canada is conducting studies which involve biomonitoring of bisphenol A in pregnant women, newborns and infants. There is currently no data to suggest pregnant women have an increased exposure to bisphenol A.

Results of October 2008 consultation

Fifteen submissions were received which included four industry associations, eight non-government organizations, one government department and two individuals. One of the submissions represented nineteen non-government associations. Five of the submissions did not include comments regarding the proposed prohibition.

The results of the comments received that were directly relevant to the proposed prohibition of polycarbonate baby bottles that contain bisphenol A indicated clear support from nineteen non-government organizations. One individual and two industry associations were opposed.

Of those opposed, one stated there was not sufficient evidence to ban bisphenol A use. Available studies suggest a trend towards heightened susceptibility during stages of development in rodents. Although it is difficult to determine the actual significance of existing studies to human health, it is considered appropriate to apply a precautionary approach when characterizing the risk to newborns and infants.

One stated that polycarbonate baby bottles were safe when used as intended and one recommended advice to parents as the best mechanism to protect newborns and infants. It cannot be assumed that these products will be used as intended or advice will be followed all of the time. A prohibition of polycarbonate baby bottles that contain bisphenol A is the best mechanism to eliminate one of the sources of exposure to newborns and infants and consequently reduce their risk of developing any potential adverse health effects.

Complete responses to all comments received are available on the Chemical Substances Web site at www.chemicalsubstances.gc.ca.

Implementation, enforcement and service standards

Compliance and enforcement of the prohibition under the *Hazardous Products Act* of polycarbonate baby

bottles that contain bisphenol A will follow established departmental approaches and procedures, including sampling and testing of products and follow-up of both consumer and industry complaints. Non-compliant products will be subject to the actions available to Health Canada inspectors specified under the *Hazardous Products Act* and will depend on the seriousness of the violation. These actions range from negotiation with stakeholders, including traders, for the voluntary withdrawal of products from the market, to prosecution under the *Hazardous Products Act*. Health Canada will also maximize compliance with the prohibition through ongoing industry and retailer education.

Contact

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PROPOSED REGULATORY TEXT

Notice is hereby given that the Governor in Council, pursuant to section 6 ([see footnote a](#)) of the *Hazardous Products Act* ([see footnote b](#)), proposes to make the annexed *Order Amending Schedule I to the Hazardous Products Act (bisphenol A)*.

Interested persons may make representations concerning the proposed Order within 75 days after the date of publication of this notice. All such representations must cite the *Canada Gazette*, Part I, and the date of publication of this notice, and be addressed to Sheila Davidson, Project Officer, Chemistry and Flammability Division, Consumer Product Safety Bureau, Department of Health, Postal Locator: 3504D, 123 Slater Street, Ottawa, Ontario K1A 0K9 (fax: 613-952-9138; e-mail: sheila_davidson@hc-sc.gc.ca).

Ottawa, June 11, 2009

JURICA ČAPKUN
Acting Assistant Clerk of the Privy Council

ORDER AMENDING SCHEDULE I TO THE HAZARDOUS PRODUCTS ACT (BISPHENOL A)

AMENDMENT

1. Part I of Schedule I to the *Hazardous Products Act* ([see footnote 8](#)) is amended by adding the following after item 15:

16. Polycarbonate baby bottles that contain 4,4'- isopropylidenediphenol (bisphenol A).

COMING INTO FORCE

2. This Order comes into force on the day on which it is registered.

[26-1-o]

[Footnote 1](#)

Cheminfo Services Inc., *Technical and Socio-Economic Background Study of Specific Uses of Bisphenol A*, January 19, 2009.

[Footnote 2](#)

Ibid.

[Footnote 3](#)

Ibid.

[Footnote 4](#)

Ibid.

[Footnote 5](#)

Ibid.

[Footnote 6](#)

Ibid.

[Footnote 7](#)

Environment Canada and Health Canada, *Screening Assessment for The Challenge Phenol, 4,4' -(1-methylethylidene)bis- (Bisphenol A)*, *Chemical Abstracts Service Registry No. 80-05-7*, October 2008, www.ec.gc.ca/substances/ese/eng/challenge/batch2/batch2_80-05-7.cfm

[Footnote a](#)

S.C. 1996, c. 8, s. 26

[Footnote b](#)

R.S., c. H-3

[Footnote 8](#)

R.S., c. H-3

NOTICE:

The format of the electronic version of this issue of the *Canada Gazette* was modified in order to be compatible with extensible hypertext markup language (XHTML 1.0 Strict).

Date Modified: 2009-06-26