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LIST OF ACRONYMS

CEPA 1999	Canadian Environmental Protection Act, 1999		
BPA	Bisphenol A		
PNEC	Predicted No-Effects Concentration		
μg	Micrograms = 10 ⁻⁶ grams		
L	Litre		

1. Introduction

1.1. Purpose and Scope of the Consultation

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

As proposed in the Risk Management Approach for bisphenol A, published in October 2008², the Government of Canada indicated it would consider developing regulations establishing maximum bisphenol A concentrations in industrial effluents and require the implementation of an environmental management system to ensure best management practices are adopted at facilities where bisphenol A is used. These proposed risk management actions are intended to achieve the lowest level of release of bisphenol A from industrial facilities to water that is technically and economically feasible.

The intent of this consultation paper is to encourage discussion and to give interested and affected parties an opportunity to provide input into the bisphenol A regulatory proposal for industrial effluent. This consultation focuses on the environmental and economic issues associated with the proposed industrial effluent regulations. Please note that there may be other initiatives developed to address emissions from other sources. Health concerns associated with use of bisphenol A are currently being managed by Health Canada.

The consultation paper aims to:

- Inform interested stakeholders of the regulatory proposal;
- Provide an opportunity for interested stakeholders to contribute to the development of the proposed risk management instrument; and
- Ensure that Environment Canada addresses any questions or concerns from interested stakeholders on the proposed risk management of bisphenol A in industrial effluent.

1.2. Consultations with Interested and Affected Parties

The Government of Canada is committed to providing interested and affected parties with the opportunity to take part in consultations at all stages of the regulatory development process. All interested parties may comment on the regulatory proposal in writing by mail, fax or e-mail to the addresses provided in Section 7 of this document.

 $^{^{1}\} http://www.chemicalsubstanceschimiques.gc.ca/challenge-defi/batch-lot-2/index-eng.php$

² http://www.ec.gc.ca/substances/ese/eng/challenge/batch2/batch2_80-05-7_rm_en.pdf

It is expected that potential interested and affected parties may include: non-government organizations, provincial, territorial and federal government departments, industries and companies belonging to the following sectors: adhesive and sealant; chemical manufacturing and distribution; polymer manufacturing; paints and coatings; packaging; resin and synthetic rubber manufacturing; concrete product manufacturing; plastics and plasticizer manufacturing and distribution; rubber manufacturing; automotive, aircraft and transportation sector; metals, metallurgical, metal plating sector; mining and mineral products; petroleum, oil well treatment and drilling; pulp and paper; textiles; and other commercial manufacturing.

1.3. Objectives

The general objective of the current consultation is to invite stakeholders to provide their comments on the regulatory proposal for bisphenol A and contribute to the development of recommendations based on a common understanding of the environmental benefits to be achieved through the proposed risk management instrument. The specific objectives are to:

- Identify interested and affected stakeholders;
- Discuss feasibility and timelines for the implementation of proposed regulations;
- Assess the economic impact associated with the regulatory proposal;
- Solicit comments on the proposed maximum allowable concentration of bisphenol A release from industrial effluent;
- Identify sampling and testing methodologies (e.g. detection limits, precision and accuracy) to evaluating and monitoring bisphenol A releases from industrial effluents;
- Solicit comments on the proposed requirement to develop an Environmental Management System; and,
- Identify technologies, that are economically feasible, to control, mitigate or eliminate the release of bisphenol A to water (e.g. control and capture technologies, chemical alternatives, better handling practices).

2. Background

2.1. Final Screening Assessment Report

A notice summarizing the scientific considerations of the final screening-level risk assessment report was published by the Government of Canada in the *Canada Gazette*, Part I, on October 18, 2008. ³ The approach taken in this ecological screening assessment was to examine available scientific information and develop conclusions based on a weight-of-evidence approach and using a

³ http://www.ec.gc.ca/substances/ese/eng/challenge/batch2/batch2_80-05-7_en.pdf

precautionary approach, as required under section 76.1 of the *Canadian Environmental Protection Act*, 1999 (CEPA 1999). The final screening assessment report 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 also 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. Therefore it was concluded that bisphenol A met the criteria in paragraph 64 (a) and 64 (c) of CEPA 1999.

Bisphenol A is acutely toxic to aquatic organisms and has been shown to adversely affect growth and development in both aquatic and terrestrial species. There is evidence that low-level exposure to bisphenol A, particularly at sensitive life cycle stages, may lead to permanent alterations in hormonal, developmental or reproductive capacity.

In laboratory testing, these effects have occurred within the range of concentrations measured in Canada, indicating that there is potential for adverse effects in populations, particularly those close to point sources.

Releases of bisphenol A may occur during production, processing, use or disposal of the substance or products containing it. 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, epoxy resins and other industrial uses of bisphenol A are the most likely sources of release to the environment. However, there are potentially many other sources of releases into the Canadian environment including unintentional releases from handling and transportation.

2.2. Proposed Risk Management Approach

A proposed Risk Management Approach for bisphenol A was also published on October 18, 2008. ⁴ It identified potential risk management actions to address both environmental and human health risks associated with bisphenol A.

Bisphenol A has shown high toxicity to aquatic organisms, with acute toxicity values falling below 13 mg/L and chronic values below 2 mg/L. The empirical and modelled data demonstrate that bisphenol A can be considered highly hazardous to the aquatic environment⁵.

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

⁴ http://www.ec.gc.ca/substances/ese/eng/challenge/batch2/batch2_80-05-7_rm_en.pdf

⁵ http://www.ec.gc.ca/substances/ese/eng/challenge/batch2/batch2_80-05-7_en.pdf

objective for industrial effluent is to achieve the lowest level of release of bisphenol A to water that is technically and economically feasible. In order to achieve this objective, the Government of Canada intends to develop regulations that would limit the release of bisphenol A in industrial effluent to a maximum concentration of 1.75 μ g/L. This level was calculated using a factor of 10 times the Predicted No-Effects Concentration (PNEC) as identified in the final Screening Assessment Report. The PNEC accounts for a dilution factor of bisphenol A released directly to surface water or to municipal wastewater treatment facilities.

The proposed regulation would require the implementation of an environmental management system to ensure best management practices are adopted at facilities where bisphenol A is used and to ensure that levels in the effluent are below the maximum concentration specified.

The Risk Management Approach document also recognized that releases of bisphenol A to water and wastewater can result from the disposal or recycling of products containing bisphenol A. Options outside of the current proposal will be explored to work towards the risk management objective for bisphenol A from these sources.

2.3. Environmental Monitoring

As part of the Government's monitoring initiative, environmental monitoring of bisphenol A is being conducted 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. The above monitoring was initiated in 2008 and continued in 2009.

3. Industrial Use of Bisphenol A

3.1. Current Uses and Industrial Sectors

Bisphenol A is a high volume chemical, with global production at 4 billion kilograms (kg) in 2006. In the United States, production quantities increased from 736 million kg in 1995 to an estimated production of 1 billion kg in 2007. Quantities in the Canadian market in 2006 may be lower than those for the U.S, as no bisphenol A was manufactured in Canada at quantities equal to or greater than a reporting threshold of 100 kg. However, 25 companies reported importing an approximate total of 500 000 kg of bisphenol A into Canada and 5 companies

reported using 100 000 to 1 000 000 kg of bisphenol A in Canada either alone, in a product, in a mixture or in a manufactured item.⁶

The type of mixture, product or manufactured item reported for 2006 in response to a notice issued by the Minister of Environment to 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 polycarbonate is used in the manufacture of compact discs, food and beverage contact containers (e.g., baby bottles, repeat use water bottles, pitchers, water carboys, tableware and storage containers), water pipes, medical devices, and in glazing applications and film. Polycarbonate blends find application in the electric and electronics industry (e.g., alarm devices, mobile phone housings, computer parts, household electric equipment, lamp fittings, power plugs) and the automotive industry (e.g., car headlight and rear light reflectors and coverings, bumpers, radiator and ventilation grills, safety glazing, inside lights, motorcycle windshields and protective helmets) (NTP 2007; EFSA 2006).

3.2. Characterization of Industrial Effluents

The manufacture of products that contain biphenol A may result in a release of bisphenol A to the environment. In Canada, significant releases of bisphenol A have been measured from both industrial effluents and municipal wastewater treatment facilities. Industrial releases may occur both directly to water and via municipal wastewater collection systems.⁷

The release of bisphenol A to surface water can result in a direct exposure to aquatic organisms. Bisphenol A that is released to municipal wastewater systems is combined with inputs from other industrial sources and domestic wastewater to form influent to municipal wastewater treatment systems. As indicated in the final Screening Risk Assessment report, quantities of bisphenol A exceeding harmful effect levels have been measured in effluents at Canadian wastewater treatment facilities.

⁶ http://www.ec.gc.ca/substances/ese/eng/challenge/batch2/batch2_80-05-7_en.pdf

⁷ http://www.ec.gc.ca/substances/ese/eng/challenge/batch2/batch2_80-05-7_en.pdf

3.3. Reducing Bisphenol A in Industrial Effluents

3.3.1. Substitution

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

3.3.2. Control and Capture Technology

No information on potential control and capture technology for bisphenol A was brought forward in the Voluntary Challenge Questionnaire submissions. However, literature searches have identified a few methods that may be used to reduce the release of bisphenol A from industrial effluent. All of the techniques identified below can remove over 90% of bisphenol A from wastewater. The start up costs as well as running costs depends on many factors including the amount of effluent, the cost of material as well as the space available for the setup.

<u>Ultrafiltration and Reverse Osmosis</u>

Ultrafiltration and reverse osmosis use filters to remove the bisphenol A from industrial effluent water by forcing it through a semi-permeable membrane⁸. Suspended solids and solutes of high molecular weight are retained on the filter, while water and low molecular weight solutes pass through the membrane.⁹ Ultrafilters are currently used by chemical and pharmaceutical manufacturing, food and beverage processing, and waste water treatment. Unfortunately, these types of methods require large start up costs and may not be economically feasible to small and medium size facilities.

Titanium dioxide catalysis

Titanium dioxide (TiO₂) is the naturally occurring oxide of titanium. TiO₂ can be used as a photocatalyst under ultraviolet light to degrade bisphenol A. This technology requires about 8g of TiO₂ for a 250mL sample of bisphenol A at a concentration of 50mg/L¹⁰. This would mean a cost of 1.78\$/L¹¹ of water processed when using pure TiO₂. However, since this is a catalytic reaction, it may be possible to reuse the TiO₂, which would diminish the cost. There would also be a start up cost to set up to install the photodegradation UV lamp and the waiting bath for the reaction to take place.

⁸ Bing-zhi, D., Lin, W., & Nai-yun, G. (2008). *The removal of bisphenol A by ultrafiltration*. Desalination, 221(1-3), 312-317

⁹ *Industrial Applications*, GEA filtration web accessed 1, 10, 2009, http://www.geafiltration.com/applications/industrial applications.asp

¹⁰ Hsien, K. -., Tsai, W. -., & Su, T. -. (2009). Preparation of diatomite-TiO₂ composite for photodegradation of bisphenol-A in water. Journal of Sol-Gel Science and Technology, 51(1), 63-69 ¹¹ *Titanium(IV) Oxide* 98.0 - 100.5% *TiO*₂, Fisher scientific, Web accessed 1, 10, 2009, https://ecat.fishersci.ca/(0w5xssrordj3di552501xz55)/Coupon.aspx?cid=41247

Bacteria and Bioreactor

The use of bacteria for the degradation of bisphenol A is a potential control technology. This method could be coupled with existing activate charcoal filters to reduce the concentration of bisphenol A release to water¹². Experimentally, bioreactors have been found to remove up to 90% of bisphenol A from water at a flow rate of 6000L/h.¹³

4. Existing Risk Management Tools and Actions

4.1. Information Gathering Activities

Canada

NPRI: 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).

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).

4.2. Existing Risk Management Activities

Ontario

The Ontario Ministry of Environment has established a provisional water quality objective 14 of 5 μ g/L for Bisphenol A. The water quality objectives are used to provide guidance when making water quality management decisions (Ontario Ministry of the Environment and Energy, 1994).

¹² Yamanaka, H., Moriyoshi, K., Ohmoto, T., Ohe, T., & Sakai, K. (2008). Efficient microbial degradation of bisphenol A in the presence of activated carbon. Journal of Bioscience and Bioengineering, 105(2), 157-160. Retrieved from www.scopus.com DOI: http://dx.doi.org/10.1263/jbb.105.157

¹³ Wintgens, T. Et all, Endocrine disrupter removal from wastewater using membrane bioreactor and nanofiltration technology, Desalination, I46 (2002) 387-391

¹⁴ http://www.ene.gov.on.ca/envision/gp/3303e.pdf

Europe

A 2003 European Union Risk Assessment Report prepared in part by U.K. Environment Agency identified a need to limit the risk of exposure in the environment from thermal paper recycling and the use of bisphenol A as an additive in PVC production. The report noted that the use of bisphenol A in manufacturing of PVC resin was voluntarily phased out of PVC production in all European Council Vinyl Manufacturers (ECVM) member companies by the end of 2001 (European Union Risk Assessment Report, 2003).

5. Proposed Regulations Concerning Industrial Effluents

5.1. Regulatory Framework

This regulatory proposal may be used as part of a broader strategy to prevent and reduce industrial releases containing substances determined to be "toxic" under section 64 of CEPA 1999. Common elements of this framework could include industrial release limits as well as requirements to develop and implement an environmental management system, specific to these release limits.

5.2. Elements of the Proposed Regulations

5.2.1. Application and Exemptions

The proposed regulations would apply to all facilities that manufacture, process or use (alone, or as part of an industrial chemical) at least 100 kg of bisphenol A per year. An industrial chemical formulation may be defined, for the purposes of this consultation, as an intermediate or ingredient used in a process to manufacture an intermediate or finished product.

The proposed regulations would not apply to facilities using bisphenol A in a laboratory for analysis, research or as an analytical standard.

5.2.2. Environmental Management System

The proposed regulations would require facilities to implement an environmental management system (EMS). An EMS is a set of management processes and procedures that allows an organization to analyze, control and reduce the environmental impact of its activities, products and services. An EMS is based on the methodology known as Plan-Do-Check-Act (PDCA). PDCA can be briefly described as follows:

Plan: establish the objectives and processes necessary to deliver results in accordance with the facilities environmental policy

Do: implement the processes

Check: monitor and measure processes against the environmental policy,

objectives, targets, legal and other requirements, and record the

results

Act: take action to continually improve the performance of the EMS

The level of detail and complexity of an EMS, the extent of documentation and the resources devoted to it depend on a number of factors, such as the scope of the system, the size of the facility and the nature of its activities, products or services.

For the purposes of fulfilling the risk management objective for bisphenol A, facilities owners or operators would be required to implement and maintain an EMS with the overall objective to manage, reduce or eliminate the release of bisphenol A from industrial effluent. The EMS would be required to contain the following:

- Procedures to achieve the protection of the environment against the adverse effects that may result from the release of bisphenol A to water:
- Measures for monitoring the effectiveness of the procedures and modifying them in the event that they do not protect the environment;
- Verification of compliance with the applicable laws with respect to the protection of the environment;
- Procedures to monitor, measure, sample and analyze industrial effluent releases and to keep documents, records and other relevant information as part of the EMS; and,
- Objective and impartial verification that the EMS includes the above requirements.¹⁵

Under the proposed regulations, the EMS would need to be accessible at each facility to which the regulations would apply and be made available to an Environment Canada enforcement officer upon the officer's request.

5.2.2.1. Proposed Sampling and Analysis Requirements

Under the proposed regulations, sampling and analytical testing should be performed in accordance with generally accepted standards of good scientific practice.

Sampling should be performed using a documented and validated method by a person trained to perform release sampling for the bisphenol A. The samples

¹⁵ ISO 14001:2004(E) Environmental Management Systems – Requirements with Guidance for Use

should be undiluted and representative of the facility industrial effluent and representative of normal operating conditions related to bisphenol A manufacturing, process or use. Facilities will be required to develop effective sampling schedules, methods and identify sampling parameters (e.g sampling points and frequencies). Facilities may be required to keep documents, records and other relevant information be made available to an Environment Canada enforcement officer upon the officer's request.

Analysis of the samples should be performed in accordance with generally accepted standards of good scientific practice at the time of the analysis by a laboratory that is accredited by a Canadian accrediting body under the International Organization for Standardization standard ISO/IEC 17025: 2005 entitled *General requirements for the competence of testing and calibration laboratories*, as amended from time to time.

5.2.3. Release Limit

The proposed regulations would limit the release of bisphenol A from industrial effluents to a maximum concentration of 1.75 μ g/L. This proposed limit would apply to the source of the discharge of wastewater from an on-site treatment facility, or the discharge from a facility, other than wastewater from the treatment of intake water, including process water, wash-down water and cooling water, whether the discharge is released into the municipal (wastewater) system or directly to water. The proposed limit would apply to industrial effluents from an identifiable discharge point of a facility beyond which the operator of the facility no longer exercises control over the quality of the effluent.

5.2.4. Reporting of Releases

Where a release of bisphenol A exceeding the proposed release limit occurs, information on the release would need to be provided to the Regional Director, Environmental Enforcement Division, Enforcement Branch for the region in which the release occurs and contain the following items:

- Name, civic address, civic address of the facility (if different), phone number and e-mail address (if any) of the person submitting the report;
- The date, time, location and duration of release;
- The estimated quantity and / or concentration of bisphenol A released;
- Description of the circumstances leading to the release, including identification of its cause, if known, and any corrective action taken;
- Description of the corrective and preventative actions taken and review their effectiveness; and
- The identification of all persons and agencies notified as a result of the release or likely release.

5.2.5. Record-keeping

Under the proposed regulations, the owner or operator of a facility would be required to retain all relevant records for a period of at least five years beginning on the date of their creation and be made available to the Minister of Environment or enforcement officer upon request.

5.2.6. Coming into Force

The proposed regulations will be published in the *Canada Gazette*, Part I, no later than October 17, 2010 followed by a 60 day public comment period.

It is anticipated that the final regulations will be published in the *Canada Gazette*, Part II, no later than April 2012.

It is proposed that the regulations will come into force on the day that they are registered.

6. Performance Measurement of Proposed Regulations

The number of releases above the regulatory limit reported each year and the results of environmental monitoring would be used as indicators to assess the performance of the proposed regulations in achieving the environmental objective.

7. Next Steps

Following the consultation, there will be a 30 day comment period. All comments received during the comment period will be taken into consideration while drafting the proposed regulation. Please submit comments prior to December 27^{th} , 2009 since Environment Canada will be moving forward with the development of the content of the proposed regulation for bisphenol A after this date. Environment Canada welcomes the distribution of this consultation document to any interested and affected parties. A copy of this consultation paper will be available on the CEPA 1999 Environmental Registry www.ec.gc.ca/ceparegistry.

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. Comments and information submissions on this regulatory proposal should be submitted to the addresses provided below:

Mail	E-mail
Director	Products.Produits@ec.gc.ca
Products Division	
Environment Canada	Please type "Consultation on Bisphenol
Place Vincent Massey, 18th Floor	A Release Limit Regulations" in the
351 St-Joseph Blvd.	subject line of your message.
Gatineau QC K1A 0H3	
Fax	
Director	
Products Division	
Environment Canada	
Place Vincent Massey, 18 th Floor	
351 St-Joseph Blvd.	
Gatineau QC K1A 0H3	
(819) 953-3132 or	
1-888-391-3695	

8. References

- [EFSA] European Food Safety Authority. 2006. Opinion of the scientific panel on food additives, flavourings, processing aids and materials in contact with food on a request from the Commission related to 2,2-bis(4-hydroxyphenyl)propane (Bisphenol A) Question number EFSA-Q-2005-100. The EFSA Journal, 428:1-75. Available from: http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178620770164.htm
- European Union Risk Assessment Report. 2003. 4,4'-Isopropylidenediphenol (Bisphenol-A) Cas No: 80-05-7 Einecs No: 201-245-8 Risk Assessment http://ecb.jrc.ec.europa.eu/DOCUMENTS/Existing-Chemicals/RISK_ASSESSMENT/REPORT/bisphenolareport325.pdf
- Health Canada and Environment Canada. 2008. Proposed Risk Management Approach for Phenol, 4,4'-(1-Methylethylidene) Bis (Bisphenol A).
 http://www.ec.gc.ca/substances/ese/eng/challenge/batch2/batch2 80-05-7 rm en.pdf
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ANNEX

Questions to open forum discussion

1. Current use

- How is bisphenol A used by your organization? (e.g. paint, coating, sealant, adhesive, metal, paper plastics, etc.)
- What are the trends for bisphenol A use (has consumption increased, decreased, remained the same...)?
- Are there bisphenol substitutes available?
- Do you know if you use a product containing BPA? If so, who is your supplier?
- If available, please provide the MSDS for your product containing BPA.

2. Release limit

- Do you consider the proposed concentration limit of 1.75 μg/L of bisphenol A achievable? If not, please explain why and what changes would be needed to achieve this level?
- Do you consider concentration limit of 1.75 μg/L of bisphenol A sufficient to protect the environment? If not, what concentration would be sufficient and why?

3. Capture and release technology

- How is industry currently managing the industrial effluent releases of bisphenol A to water?
- Which process, technology or methods would be most appropriate to control the release of bisphenol A to water and how prevalent are they used by industry?
- Are the costs of implementing, maintaining or developing capture and release technologies economically feasible? Please explain.

4. Sampling and analysis methods

- What effluent sampling and test analysis methodology does your company use for bisphenol A?
- What sampling frequency and equipment would be required to obtain representative data of bisphenol A of effluent discharge?
- Does your facility currently sample industrial effluents? If so, was bisphenol A tested for?
- What are the costs associated with sampling and testing for bisphenol A?

5. Environmental Management System

- Are the proposed requirements for an EMS achievable? Please explain.
- How prevalent is an EMS used to manage substance by industry?
- Is the requirement for an EMS sufficient to manage, prevent or reduce the release of bisphenol A? Please explain.
- If your facility does not have an environmental management system, what methodology is used to ensure that the environmental requirements to which your organization are currently subject to are being met?
- What costs would be associated with maintaining or updating your current environmental management system to include actions to prevent or reduce the release of bisphenol A to water?

6. Compliance

- How long would it take your company to comply with the proposed maximum concentration limit and the proposed environmental management system requirements?
- What are the estimated costs associated with compliance?
- How would this regulatory proposal affect your company? (Market share, increase cost, loss of market, etc.)