

**Report on Consultations for Proposed  
Bisphenol A (CAS RN 80-05-7)  
Industrial Effluent Regulations**

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## Introduction

This report is submitted by two of the five Environmental Non-Governmental Organization (ENGO) delegates selected by the Canadian Environmental Network (RCEN) to attend an Environment Canada (EC) public consultation on proposed regulations to limit concentrations of bisphenol A (BPA) in industrial effluent,<sup>1</sup> held on November 27, 2009. While this joint report has many elements that are similar to those reflected in the consolidated ENGO submission, some divergences are present. An attempt has been made to retain some of the original content while at the same time expressing our viewpoints. We welcome the Government of Canada's initiative to enact such regulations and thank EC for making our participation possible.

The report details our concerns and recommendations with respect to the regulatory proposal. Our main concerns are with the overall risk management approach to BPA<sup>2</sup>, the proposed 1.75 µg/l concentration limit of BPA in industrial effluent, and the proposed environmental monitoring system (EMS). Our major recommendations are to take an overall risk management approach that works toward reduction at source and eventual elimination of the use of this chemical; to adopt a concentration limit much lower than 1.75 µg/l; and not to include the requirement for an EMS in the regulations.

## Background

According to the consultation document, over 4 billion kilograms of BPA were produced globally in 2006, of which approximately half a million kilograms were imported into Canada. Although BPA is not manufactured in Canada, five companies reported using between 100,000 and 1,000,000 million kilograms in the same year.

Research has confirmed that low level exposures of BPA may lead to adverse changes in hormonal, developmental or reproductive capacity in humans and other organisms. Aquatic ecosystems are particularly vulnerable. It has been found that industrial processes may release BPA into aquatic environments.

The final screening assessment of BPA, published in October 2008,<sup>3</sup> found the substance toxic to both human health and the environment under the *Canadian Environmental Protection Act 1999* (CEPA). At the same time, the Ministers of Health and the Environment adopted an overall risk management strategy "using a life-cycle approach, to prevent or minimize its release into the environment."<sup>4</sup>

The proposed regulations under discussion at the November 27, 2009 meeting deal with the release of BPA to water in industrial effluent. Separate regulations and other

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<sup>1</sup> Consultation Document. <http://www.ec.gc.ca/ceparegistry/documents/participation/pba/tm-toe.cfm>

<sup>2</sup> Proposed Risk Management Approach for ... (Bisphenol A) CAS RN 80-05-7.  
[http://www.ec.gc.ca/substances/ese/eng/challenge/batch2/batch2\\_80-05-7\\_rm\\_en.pdf](http://www.ec.gc.ca/substances/ese/eng/challenge/batch2/batch2_80-05-7_rm_en.pdf)

<sup>3</sup> Screening Assessment for ... (Bisphenol A).  
[http://www.ec.gc.ca/substances/ese/eng/challenge/batch2/batch2\\_80-05-7\\_en.pdf](http://www.ec.gc.ca/substances/ese/eng/challenge/batch2/batch2_80-05-7_en.pdf)

<sup>4</sup> Proposed Risk Management Approach.

proposed measures for limiting human exposure to BPA from consumer products and minimizing the release of BPA from recycling and disposal of products containing BPA were not part of these consultations, and are not addressed in this document.

### **Risk Management Approach**

The overall risk management approach proposed for BPA is “a life-cycle approach, to prevent or minimize its release into the environment” (*Proposed Risk Management Approach*, 4). We believe that this overall approach is unsatisfactory for managing this highly toxic, high volume chemical. We want to see an overall approach that involves reduction at source and works toward elimination.

The proposed ecological risk management objective for BPA is “to achieve the lowest release of BPA to water that is technically and economically feasible” (*Proposed Risk Management Approach*, 13). Our major concerns with this approach are:

- We are concerned that this ecological risk management approach does not seek to reduce or eliminate the use of BPA at source. We do not believe that an end-of-pipe solution is sufficient to protect the environment from the potentially harmful effects of the industrial use of BPA.
- We are concerned that the risk management objective as stated is tied to technological and economic feasibility rather than to ecological criteria. If economic and technological feasibility are allowed to determine risk management activities, there is a risk that the regulation will not prevent the release of levels of BPA that are harmful to the environment.
- The risk management objective does not include the release of BPA to media other than water.

Our major recommendations are:

- Adopt a risk management approach that works toward reduction at source and elimination.
- The ecological risk management objective should be tied to ecological criteria.
- The ecological risk management objective should include release to all media to which BPA is released.

### **Proposed Regulations**

The major elements of the regulatory approach discussed at the consultation are:

- a limit on the release of BPA from industrial effluents to a maximum concentration of 1.75 µg/L
- a requirement for facilities to implement an environmental management system (EMS). The proposed regulation will apply to facilities that manufacture, process or use at least 100 kilograms of bisphenol A per year. (*Consultation Document*).

We have serious concerns with both elements of this regulatory approach, which are summarized in the following sections.

### **Concerns with Proposed Release Limit**

We feel that the proposed release limit of 1.75 µg/l of BPA in industrial effluent is significantly too high.

The level of release chosen, 1.75 µg/l, reflects the Lowest Observed Effect Concentration (LOEC) of 1.75 µg/l reported in the screening assessment for BPA. This figure was derived from a study that found reduced semen quality and delayed ovulation in brown trout.<sup>5</sup> This level was divided by ten to account for a paucity of data on other species, giving a Predicted No Effects Concentration (PNEC) of 0.175 µg/l. The screening assessment then assumed that effluent will be diluted by a factor of ten once it enters the environment, increasing the regulated level to 1.75 µg/l, the same level as that of the LOEC.

The LOEC of 1.75 µg/l is higher than what other countries have determined to be safe levels of BPA. Several studies cited in the European Risk Assessment of BPA observed effects in aquatic environments at much lower levels. A study on adult dogwhelks, a type of mollusk, reported superfeminization at considerably lower levels. “The authors concluded that the results show that prosobranchs are sensitive to endocrine disruption at the lowest concentrations of bisphenol-A tested (1 µg/l nominal).”<sup>6</sup>

A study on fathead minnows found effects at very low concentrations. “Effects on the different stages of male spermatozoa development were seen at lower concentrations, with a NOEC value for the proportion of spermatogonia and spermatozoa of 1 µg/l for the F0 generation and a LOEC of 1 µg/l for the F1 generation.”<sup>7</sup>

Studies on the effects of BPA on snails preclude the determination of any safe level of release. In studies on ramshorn snails, science comes up against the limits of detectability: a no observed effect concentration “could not be calculated because there were significant effects (compared to the control) at the lowest test concentration of 106 ng/l.”<sup>8</sup> Documented effects occurred at the lowest levels of concentration measured.

Most disturbingly, recent research on humans continues to find adverse effects at ever lower concentrations. A study by Benachor and Aziz in *Toxicology and Applied Pharmacology* found “that exposure of placental cells to low doses of BPA may cause detrimental effects, leading *in vivo* to adverse pregnancy outcomes such as preeclampsia,

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<sup>5</sup> [http://www.ec.gc.ca/substances/ese/eng/challenge/batch2/batch2\\_80-05-7\\_en.pdf](http://www.ec.gc.ca/substances/ese/eng/challenge/batch2/batch2_80-05-7_en.pdf): p. 28.

<sup>6</sup> [http://ecb.jrc.it/documents/Existing-Chemicals/RISK\\_ASSESSMENT/ADDENDUM/bisphenola\\_add\\_325.pdf](http://ecb.jrc.it/documents/Existing-Chemicals/RISK_ASSESSMENT/ADDENDUM/bisphenola_add_325.pdf), p. 80.

<sup>7</sup> Ibid, p. 96.

<sup>8</sup> Ibid. p. p. 67.

intrauterine growth restriction, prematurity and pregnancy loss.”<sup>9</sup> Their results showed that levels between 0.2 µg/l to 200 µg/l are cytotoxic.

We are also concerned that there has been insufficient research on how BPA interacts with other chemicals and endocrine disruptors present in the environment. The regulation should reflect the precautionary principle in light of possible interactions that could amplify the effects of BPA. More study in this area may reveal effects at even lower doses.

Furthermore, the dilution factor of ten may overestimate the capacity of some environments to cope with multiple sources of effluent. There ought to be acknowledgement in the regulation that industrial concentrations may result in a greater cumulative impact in some regions as compared to others. Already, some of the study areas reported on during the consultation had elevated levels of BPA. Increased use of BPA could exacerbate these issues. Moreover, there was nothing in the screening assessment to account for changes in precipitation patterns that are anticipated as a result of climate change. While a dilution factor of 10 may be appropriate at present in some environments, more careful study will be needed to ascertain the applicable factor for any given environment.

- Major concern: that a release level of 1.75 µg/l is not low enough to protect the environment.
- Major recommendation: that the release level be reduced as much as possible at this time, with a view to eventual phase out and elimination of this highly toxic and pervasive substance.

### **Who is covered by the regulation?**

We are concerned that the proposed regulation would apply only 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” (*Consultation Document*, p. 11).

We recommend that all users should be subject to the regulation, since any amount of industrial release could potentially have a harmful effect at a local level, especially recognizing that BPA can have harmful effects at levels measured in parts per trillion.

### **Substitutes**

The cost of adhering to the regulation may encourage many industries to develop substitutes for BPA. At present, few substitutes have been identified. Study is required to ensure that all proposed substitutes are safe. We recommend that government work with stakeholders and other jurisdictions to identify safe potential substitutes.

### **Monitoring**

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<sup>9</sup> *Toxicology and Applied Pharmacology*, Volume 241, Issue 3, 15 December 2009, Pages 322-328  
Nora Benachour and Aziz Aris.

There is a shortage of data on how much BPA is currently in our environment. We are concerned that testing and monitoring sites do not reflect the full range of the country's geography, but instead focus on the convenience of using monitoring locations already in existence for other reasons. A lack of monitoring in the Arctic and far North was especially noted at the consultation. It should be assumed with 4 billion kilograms annual production, nowhere on the planet is pristine and unpolluted. Baselines are important to establish for all regions. Longitudinal studies should be enhanced for all monitoring stations. Monitoring of groundwater is also important, especially in rural regions where it is a source of drinking water.

### **Environmental Management System**

The proposed regulations include the implementation of Environmental Management Systems (EMS) at a facility level. While we encourage industries to adopt management procedures that reduce their environmental impact, we feel the EMS approach is inappropriate to be included in the regulations. We recommend that the regulations instead focus on strategies that will tangibly reduce BPA at the source and in the environment.

The consultation document provided few details about how the EMS would work. There was no clarity about whether it would include external verification or penalties for non-compliance. There is a lack of experience with EMS for similar regulatory applications in Canada or abroad. If details of the EMS and its operation are enshrined in regulations, they will be very difficult to change if they prove unworkable or ineffective. As a result of these concerns, we do not support including an EMS within the regulation.

### **Reporting and Sampling**

The proposed regulations only require reporting of emissions that exceed 1.75 µg/l. We hold that *all data concerning BPA emissions should be reported*. This is important so that the government has accurate data on emissions and the ability to determine whether concentrations could be increasing or decreasing in specific areas. This information would also be very useful as an indicator of whether the regulations need strengthening.

It is important that *all BPA emissions data be publicly accessible*. Communities have a right to know about the levels of toxic chemicals in their environment. Public records make future research possible in that they can help identify environmental and health problems and track their origin. These records should be maintained for a minimum of 10 years, rather than five years, as the proposed regulations currently state.

The regulation as it currently stands does not provide enough guidance about sampling methods. Without such guidance, these methods may vary considerably between sites and within sites, leading to a lack of comparability of results within and across facilities. We recommend that a protocol that prescribes specific sampling methods, frequencies, acceptable analytical methods, and recording of data be made part of the regulations to ensure the validity and comparability of results.

## **Capture and Control Technology**

We do not have specific expertise on any of the proposed technologies for removing BPA from industrial effluent, but as with any new technology, it is important to adopt a precautionary approach. These technologies should be examined for their broad environmental effects before being implemented. Safe disposal technologies should also be required where capture involves removing BPA from effluent. For example, we would not want waste BPA to find its way into agricultural sludge. Otherwise, we will be no further ahead with respect to environmental protection.

## **Next Steps**

It is important that the ENGO community continues to be involved in the process of creating new regulations for BPA. For example, the upcoming analysis of social and economic factors, to be used in the development of the regulations, should be as open and transparent as possible, with an opportunity for public involvement and comment. The ENGO community should have the opportunity to continue to play a consultative role in developing these regulations.

According to the consultation document, the BPA regulation “may be used as part of a broader strategy to prevent and reduce industrial releases containing substances determined to be toxic.” It is therefore, all the more important that we get these regulations right, and that they set a model for environmental stewardship in how we deal with other chemicals yet to be regulated. Our concerns with the risk management approach for BPA carries through into opposition to using the same strategy for other toxic chemicals: *An end-of-pipe concentration limit for industrial effluent and an EMS are not sufficiently protective of the environment.*

BPA is among the best known chemicals to be regulated in the Challenge process, partly as a result of its widespread usage, but also because of recent media coverage. Under the spotlight of this scrutiny, errors made in the construction of these regulations will reflect poorly on all who have been involved in constructing them. We must adopt a precautionary perspective, and strive to build into these regulations the highest standards of sustainability.

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