

**Consolidated Environmental Non-Governmental Organization Report
on Consultations for Proposed Bisphenol A (Chemical Abstracts Service
Registry Number 80-05-7) Industrial Effluent Regulations**

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Introduction

This document is a joint report by the Environmental Non-Governmental Organization (ENGO) delegation to consultations for proposed regulations to limit Bisphenol A in industrial effluent. Bisphenol A was among a group of 17 chemicals (Batch 2) subject to new assessments through the Challenge initiative of the Canadian government's Chemical Management Plan. Environment and Health Canada published their final screening assessment of Bisphenol A in October 2008.¹ This assessment identified Bisphenol A as a high priority because of the high potential for exposure to individuals in Canada and on the basis of its reproductive toxicity. Environment Canada identified that it is inherently toxic to aquatic organisms, and that it "meets the criteria for persistence, but does not meet the criteria for bioaccumulation, as defined by the *Persistence and Bioaccumulation Regulations*."² Bisphenol A was subsequently added to the list of toxic substances under Section 1 of the Canadian Environmental Protection Act.³ The Ministers of Health and Environment did not propose virtual elimination for Bisphenol A, but adopted a risk management strategy "using a life-cycle approach, to prevent or minimize its release into the environment."⁴ The proposed regulations deal with the environmental release of Bisphenol A from industrial processes. Separate regulations that the government has proposed for limiting human exposure from consumer products were not part of these consultations, and are not addressed in this document, except in so far as these regulations are related.

The proposed industrial effluent regulations were published in November 2009.⁵ A one-day multi-stakeholder consultation was held in Toronto on November 27. Environment Canada asked the Canadian Environmental Network (RCEN) to select five delegates for the consultation through its delegate selection process.⁶ Delegates were chosen for their expertise and experience on Bisphenol A and the environment by a peer committee and attended the November 27 consultation. This document brings together their comments and recommendations.⁷ RCEN and the delegates would like to thank Environment Canada for making their participation possible.

¹ http://www.ec.gc.ca/substances/ese/eng/challenge/batch2/batch2_80-05-7_en.pdf

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

³ <http://www.gazette.gc.ca/rp-pr/p1/2009/2009-05-16/html/reg2-eng.html>

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

⁵ <http://www.ec.gc.ca/ceparegistry/documents/participation/pba/tm-toc.cfm>

⁶ More information about the delegate selection process can be found at: http://www.cen-ree.org/eng/consultations/delegate_selection.html

⁷ Josh Brandon, (Resource Conservation Manitoba, MB), Sheila Cole, (EHANS, NS), Gabrielle Kretschmar, (New Brunswick Partners in Agriculture, NB) signed on to this report, while Sandra Madray, (Chemical Sensitivities Manitoba, MB) and Mary Richardson, (Crooked Creek Conservancy Society of Athabasca, AB) delivered their comments in separate submissions.

Our major concerns with the consultation document were:

- We disagreed the Risk Management Approach and with the proposed 1.75 µg/l concentration limit of bisphenol A in industrial effluent.
- We do not support the proposed Environmental Management System.

Background

Bisphenol A is an organic compound widely used in the production of plastics and plastic additives. According to the consultation document, over 4 billion kilograms were produced globally in 2006, of which approximately half a million kilograms is imported into Canada. Although it is not manufactured in this country, five companies reported using between up to a million kilograms in products.

Bisphenol A has been common in industrial applications for over half a century, despite warnings of its toxicity since the 1930s.⁸ Research has since confirmed that that low level exposures of Bisphenol A 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 production processes may release Bisphenol A into water environments. Delegates welcome the Government of Canada's initiative to enact regulations that seek to ensure that unsafe releases are prevented.

Bisphenol A is found in a wide range of products including food liners, baby bottles, and other containers. It is present in a broad range of products including from dental sealants to credit card receipts. It is likely that some usages remain undocumented as new uses for the chemical continue to be developed. It is one of the most ubiquitous chemicals used in products in common daily usage. This pervasiveness underlines for us the importance of creating regulations that ensure human and environmental exposures are kept to safe levels.

Delegates do not believe that the proposed regulations will meet the goal of preventing unsafe levels of bisphenol A in the environment.

Risk Management Approach

The proposed objective for the risk management of industrial effluent is “to achieve the lowest level of release of bisphenol A that is technologically and economically feasible.” The Government of Canada intends to achieve this risk management objective by a regulation that will limit releases from industry to 1.75 µg/l in industrial effluent. Secondly, the regulation would require the implementation of an environmental management system to ensure best management practices. The proposed regulation will apply to facilities that process or use at least 100 kilograms of bisphenol A as an ingredient or as part of an industrial chemical.

⁸ Colborn, T., Dianne Dumanoski and John Peterson Myers, 1996. *Our Stolen Future*, New York; Dutton, p. 46.

Concerns with proposed Risk Management Approach and Objective

We believe that this approach is not satisfactory for managing this ubiquitous and highly toxic chemical, for several reasons. We are concerned that the risk management objective as stated is tied to technological and economic feasibility rather than to scientific and ecological criteria. If economic and technological feasibility are allowed to determine the objective, there is a risk that the regulation will not prevent the release of levels of bisphenol A that pose hazards to human health or the environment. We do not believe that economic criteria should be the primary basis for assessing environmental regulations. Subsequent assessment of the effectiveness of the regulation should be subject to advances in science.

We are also concerned that the risk management approach does not seek to reduce bisphenol A at source. We do not believe that this end-of-pipe objective is sufficient to protect the environment from the effects of industrial use of bisphenol A. Furthermore, there was also no discussion of what would happen to bisphenol A collected in filtration processes from industrial effluent. The risk management approach focuses exclusively on water, and does not consider other media into which bisphenol A will eventually be disposed.

Joint Recommendations

- We recommend that scientific and ecological criteria guide the objective, not technological and economic feasibility.
- The regulations should include measures to reduce bisphenol A at source.
- Considerations should be made of all media into which bisphenol A is disposed.
- All delegate members felt that release limit of 1.75 µg/l in industrial effluent is too high.

Release Levels of Bisphenol A and Effect Concentrations

We have concluded that 1.75 µg/l is not a safe level to protect the environment. We strongly urge that the level be reduced as much as possible, with a view to eventual phase out and elimination of this highly toxic and pervasive substance.

The level of release chosen, 1.75 µg/l, reflects Canada's Screening Assessment's Lowest Observed Effect Concentration (LOEC) of 1.75 µg/l. This figure was derived from a study that found reduced semen quality and delayed ovulation in brown trout.⁹ 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 assumes that effluent will be diluted by a factor of ten once it enters the environment, increasing the regulated level 1.75 µg/l, coincidentally, the same level as the LOEC.

⁹ http://www.ec.gc.ca/substances/ese/eng/challenge/batch2/batch2_80-05-7_en.pdf: p. 28.

The LOEC of 1.75 µg/l is higher than what other countries have determined to be unsafe levels of bisphenol A. Several studies cited in the European Risk Assessment of bisphenol A 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).”¹⁰

A study on fathead minnow 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.”¹¹

Studies on the effects of bisphenol A 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.”¹² 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, intrauterine growth restriction, prematurity and pregnancy loss.”¹³ 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 bisphenol A interacts with other artificial chemicals and endocrine disrupters present in the environment. The regulation should reflect the precautionary principle in light of possible interactions that could amplify the effect of bisphenol A. More study in this area may reveal effects at even lower doses.

The dilution factor of ten may over estimate the capacity of some environments to cope with multiple sources of effluent. There ought to be acknowledgement in the regulation that industrial concentration will result in a greater cumulative impact in some regions than others. Already, some of the study areas reported on during the consultation had elevated levels of bisphenol A. Increased use of bisphenol A 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.

¹⁰ http://ecb.jrc.it/documents/Existing-Chemicals/RISK_ASSESSMENT/ADDENDUM/bisphenola_add_325.pdf, p. 80.

¹¹ Ibid, p. 96.

¹² Ibid. p. p. 67.

¹³ *Toxicology and Applied Pharmacology*, Volume 241, Issue 3, 15 December 2009, Pages 322-328
Nora Benachour and Aziz Aris.

These results warrant a re-examination of the government's proposed effluent limit of 1.75 µg/l. As an interim measure in a longer-term elimination strategy, a significantly lower target of bisphenol A in industrial effluent should be set. This target should be subject to periodic review as the science develops.

Who is covered by the regulation?

The proposed regulation 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. (*Consultation Document*, p. 11).

The regulation covers only a subset of industrial users responsible for bisphenol A emissions into the environment. ENGO delegates have concerns with the 100 kilogram threshold for reporting. All users should be subject to the regulation, since even 100 kilograms can have a deleterious impact on a local level, especially recognizing that bisphenol A can have negative effects at levels measured in parts per trillion. All uses should be reported.

The ENGO delegation also felt that definitions of who constitutes an industrial user were unclear. The regulation applies to industries that use intermediate ingredients that contain bisphenol A, but not necessarily to industries that use intermediate products that contain bisphenol A. This distinction is not well defined within the regulation, and generated considerable confusion during the consultation as to who is covered. The regulation should ensure that companies are not able to externalize previously internalized processes to escape regulation, for example, by creating shell subsidiaries that transform intermediate ingredients into intermediate products. In any case, the criterion for regulation should be not how processed the bisphenol A is within a product, but rather its potential for release. An assembly plant using parts that contain bisphenol A should be subject to the regulation as much as the parts factory itself, if there is a possibility of emissions into the environment from it. We recommend better clarification of the definition of industrial user.

Substitutes

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

Monitoring

There is a shortage of data on how much bisphenol A is currently in our environment. ENGO delegates were concerned that testing and monitoring sites did not reflect the full

range of the country's geography, but instead focused 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. 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.

It is likely that government needs more information about who is currently releasing bisphenol A. The National Pollution Release Inventory (NPRI) does not seem to be providing a complete picture of total emissions of bisphenol A. This is partly a problem with its high reporting threshold. Also some releases to air were reported in the 2006 NPRI data, but no releases to water were reported. Mandatory notices should be used to gather this information. As well, there should be more specific data collection from specific industrial sectors such as agriculture where contamination may be diffuse, but widespread. In particular, the use of plastics in agriculture, as well as the use of sludge containing bisphenol A needs further study. Without better reporting of current bisphenol A emissions, we will not be able to determine the effectiveness of the regulations.

Environmental Management System

The proposed regulations include the implementation of Environmental Management Systems (EMS) as a facility level. While the ENGO delegation encourages 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 bisphenol A in the environment.

The consultation document provided few details about how the EMS would work. There was no clarity about if it would include external verification. There is a lack of experience with EMS for similar regulatory applications in Canada or abroad. As a result of these inconsistencies, we do not support including EMS within the regulation.

Reporting and sampling

The proposed regulations only require reporting of emissions that exceed 1.75 µg/l. The ENGO delegates hold that all emissions should be reported. This is important so that the government has accurate data on emissions and also to ensure that concentrations do not build up in any one area. This takes into account future possible strengthening of the regulations.

It is important that records be publicly accessible. Communities within the watershed have a right to know about the levels of toxic chemicals in their environment. Public records ensure that future research can identify environmental and health problems and

track their origin. These records should be maintained for at minimum 10 years, rather than kept for five as the proposed regulations currently state.

The regulation as it currently stands does not provide enough guidance about sampling methods to determine if and when levels are reported. Without such guidance, these records will vary considerably from site to site and possibly within a site from time to time. There must be a protocol that prescribes specific sampling methods to ensure their validity and comparability.

Capture and Control Technology

ENGO delegates did not have specific expertise on any of these proposed technologies, but as with any new technology, it is important to adopt a precautionary approach. These technologies should be analyzed for their broad environmental effects before being implemented. Safe disposal technologies should also be assured where capture involves removing bisphenol A from effluent. Otherwise, we will be no further ahead with respect to environmental protection.

Next Steps

It is important that the ENGO community continue to be involved in the process of creating new regulations for bisphenol A. The upcoming proposed social and economic analysis of the regulations should be conducted with an awareness of broad principles of sustainability, not the narrow economic interests of a few stakeholders. The ENGO community can continue to play a role in implementing and improving regulations on industrial effluent.

According to the consultation document, the bisphenol A 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 the hundreds of other chemicals yet to be regulated. Our concerns with the risk management approach for bisphenol A 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.

Bisphenol A is among the best known chemicals on to be regulated with 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 of us who have been involved in constructing them. Instead, we must adopt a precautionary perspective, and strive to build into these regulations the highest standards of sustainability.

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