

NGO comments on Final Assessment for 1,4-Dioxane: A Response to *Canada Gazette Part I, Vol. 144, No. 7* — March 31, 2010 – Batch 7 of the Industry Challenge of the Chemicals Management Plan

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Introduction

The Canadian Environmental Law Association (CELA) and Chemical Sensitivities Manitoba (CSM) are submitting the following comments in response to the *Canada Gazette*, Part I, Vol. 144, No. 9— March 31, 2010 release of the final screening level risk assessment report for one substance identified under the Chemicals Management Plan (CMP), Batch 7 of the Industry Challenge.

CELA (www.cela.ca) is a non-profit, public interest organization established in 1970 to use existing laws to protect the environment and to advocate for environmental law reform. It is also a legal aid clinic that provides legal services to citizens or citizens' groups who are otherwise unable to afford legal assistance. In addition, CELA also undertakes substantive environmental policy and legislation reform activities in the areas of access to justice, pollution and health, water sustainability and land use issues since its inception. Under its pollution and health program, CELA has been actively involved in matters that promote the prevention and elimination of toxic chemicals addressed in the *Canadian Environmental Protection Act*, including the categorization process and implementation of the CMP.

Chemical Sensitivities Manitoba (CSM), a volunteer organization, was founded in 1997 by four individuals who saw the need to address the affects of toxic chemicals on human health and the possible link between the onset of chemical sensitivities and chemical exposure and, in particular, chronic low-level exposure. CSM raises awareness of the presence of toxic chemicals in the home and the environment and strongly advocates for the safe substitution of these toxins.

Our respective organizations along with other Canadian environmental and health non-governmental organizations (NGOs) have submitted substantial comments on assessment results and proposed management options for substances in Batches 1 through 8, including the final assessments and draft risk management options for Batch 1 to 6.

For these batches, our organizations supported some of the proposed assessment results but, at the same time, have elaborated on the gaps and limitations on specific aspects of the risk assessment and the proposed management instruments for specific chemicals. Consequently, we have developed substantial recommendations to address these gaps and limitations.

For this submission, we have provided detailed commentary to the final screening of one substance in Batch 7 – 1,4-dioxane, a substance that has not been found to be toxic under *CEPA 1999* and, as a result, risk management measures for it have not been proposed. Our submission below outlines our continuing concerns regarding the government's decision not to conclude 1,4-dioxane as toxic under CEPA. Based on our commentary, we encourage your departments to reconsider the findings of the final results drawn from screening assessment and to conclude that this chemical meets the criteria for CEPA toxic.

The lack of comments for other substances in Batch 7 should not be misconstrued as a lack of concern, interest, or opposition to final decisions and proposals for management. On the contrary, we remain concerned about many decisions made by the government based on the assessment process in the CMP. However, the level of engagement possible for each chemical is consistently a challenge and the lack of evidence that the government decision process will

consider changes to a decision is significantly lacking. At present, even with the lack of data for many substances in the CMP Challenge Program, a conclusion of CEPA toxic has not been implemented for these substances – some of which are potential carcinogens. This is quite troubling as it has placed a significant burden on the public to raise concerns about the risks associated with these chemicals. As a result, we continue to submit comments on issues and gaps that are common for the first eight batches of chemicals released because there has been little progress made by government to improve its risk based approach by addressing these limitations. While there have been some responses to these issues and gaps, addressing them through regulatory measures aimed at eliminating chemicals of concern has been minimal.

In the following submission, we may not have addressed all aspects of the final screening for 1,4-dioxane but have commented on and reiterated specific issues outlined in the screening that are considered priority areas to our organizations. These comments are intended to provide the government with a broad understanding of the public interest expectations of the government to protect Canadians and their environment from this toxic chemical.

Through our participation in the implementation of all aspects of the Chemicals Management Plan to date, including the submission of comments on the risk assessment results for chemicals under the Industry Challenge, our organizations want to ensure that the government utilizes the full extent of its authority under *CEPA 1999* to promote and implement the elimination or phase out of the most toxic substances found in the Canadian market.

Since the beginning of the implementation efforts under CMP, our organizations have indicated our support for the application of the precautionary principle throughout the decision making process from assessment towards the development of management options for toxic chemicals. In this regard, we continue to question the government's decisions on selected chemicals. The government's decision to conclude a chemical does not meet the criteria under section 64 of CEPA, includes but is not limited to D6 (siloxane under Batch 2), various pigments under Batch 3, and now 1,4-dioxane (Batch 7). The evidence presented in these assessments was questioned but no obvious additional efforts by assessors were made to require submission of additional data (through monitoring, submission of experimental data to replace data derived from an analogue, or incorporation of occupational exposure data) from affected industry. It is our view that the government should increase its efforts significantly to require industry to supply relevant toxicity data to demonstrate the safety and use patterns of their chemicals. This information will improve the quality of assessments and inform the type of pollution prevention efforts that should be undertaken in Canada.

We will continue to reiterate the issues and gaps that continue to affect the quality of the decision making process including the assessment process with the hope that the government will seek greater accountability from those stakeholders that use, manufacture, import and sell chemicals in Canada. The commentary below identifies areas in the final screening report for 1,4-dioxane where the government should have taken additional efforts to address (i.e. require additional data) and strengthen its approach (i.e., consider cumulative impacts) before the conclusion of toxicity under CEPA for this chemical was made. These issues should have provided the evidence required for government to consider management measures for 1,4-dioxane.

General Comments on Information Gaps and Approach

Results from Categorization

Based on the categorization process, 1,4-dioxane was determined to be a high priority for assessment with respect to human health. However, this chemical did not meet the criteria for bioaccumulation potential or inherent toxicity to aquatic organisms but it did satisfy the persistence criteria as set out in the *Persistence and Bioaccumulation Regulations*.¹

Gaps in Screening Level Risk Assessments

Screening Level Risk Assessment Results

Based on the screening level risk assessment processes, it was concluded that 1,4-dioxane does not meet the criteria in section 64 of *CEPA 1999* – hence it is not CEPA toxic on the basis of the adequacy of the margins between conservative estimates of exposure to 1,4-dioxane and critical effect levels.

Potential carcinogen and lack of consideration of occupational exposure route

For the general population in Canada, it is expected that the principal routes of exposure to 1,4-dioxane are consumer products, food, drinking water, and air (ambient and indoor) and occupational exposure. Although the government gathered evidence that this substance is a potential human carcinogen (identified by the International Agency for Cancer Research, European Commission, US Environmental Protection Agency and US National Toxicology Program), there was no substantial discussion addressing occupational exposure to 1,4-dioxane included in the final screening document. The absence of addressing occupational exposure is considered a significant gap in the government's approach. It should be addressed regardless of the exposure route or if occupational exposure is considered a provincial matter. There has been no evidence to indicate that the provinces have conducted an assessment on this chemical. If this assessment had included occupational exposures, the resulting findings could have been beneficial to provinces' efforts to address chemicals of concern, particularly as they pertain to occupational health.

The human relevance of 1,4-dioxane is carcinogenicity and, in particular, liver tumour induction. This has been observed in all experimental animals tested following chronic oral administration and one should note that there are similar metabolic pathways for this substance in humans and experimental animals. Given this information, we do not support the government's conclusion in the screening assessment that 1,4-dioxane is not CEPA toxic. If the precautionary principle had been applied in the assessment of this chemical using the evidence of impacts to human health, the government should have concluded that 1,4-dioxane meets section 64 of CEPA and should be considered toxic. Application of the precautionary principle would include a further scrutiny of the use patterns and consideration of cumulative impacts from exposure to other chemicals with the same health impacts and the inclusion of evidence from occupational exposure. However, it appears that the government agreed with the conclusions from other agencies suggesting that 1,4-dioxane is not a likely a mutagen, despite the fact that potential modes of

¹ Environment Canada and Health Canada. Draft Screening Assessment for the Challenge: 1,4-Dioxane, Chemical Abstracts Service Registry Number 123-91-1. September 2009. Accessed at http://www.ec.gc.ca/substances/ese/eng/challenge/batch7/batch7_123-91-1.cfm.

action for 1,4-dioxane have not been fully elucidated and also, all tests for mutagenicity have been negative. The government should have explored the modes of action for 1,4-dioxane further to confirm that the chemical was not a mutagen.

Lack of consideration of residual 1,4-dioxane from ethoxylation processes

The screening document has also failed to provide any details on the ethoxylation process which results in 1,4-dioxane as a residue. The presence of 1,4-dioxane as a residue is a very critical component of the assessment of this chemical. The lack of information on the fate and behaviour of 1,4-dioxane throughout its life cycle creates a significant gap in the knowledge of this chemical. It is necessary to understand this chemical in all of its use patterns, any breakdown products and, in particular, its presence as a residue as it relates to its impact on the environment and human health (e.g. what happens once a product containing 1,4-dioxane is flushed down a drain or disposed of as waste in a landfill). Chemicals do not act in isolation nor do they remain unchanged throughout their life cycles. The absence of this information in the assessment report is considered a significant gap. As a result of this gap, stakeholders have not been given the opportunity to provide more substantial comments on this matter. At the same time, the government should seek to fill in this important information gap providing specific attention to:

- estimating the level of residual 1,4-dioxane that ends up unused and disposed as waste in landfills or through other disposal methods;
- identifying and quantifying a wider variety of products that may contain residual levels of 1,4-dioxane in addition to the consumer products listed in the assessment report; and
- the fate of this chemical once these products are disposed in the environment.

This is the level of scrutiny that should be required by government in a screening process to improve the quality of the results.

Volume use, releases and transfer of 1,4-dioxane

In Canada, 1,4-dioxane use falls in the range between 10,000-100,000 kg in 2006 based on the Section 71 survey conducted; similar range in volumes are noted also for imports and manufacture in Canada. These numbers are significant and the range is considerably large to make accurate exposure estimation difficult. In addition, the volume of release and transfer of 1,4-dioxane for 2006 (based on data obtained through the National Pollutant Release Inventory for 2006) indicate that, 13,800 kg of 1,4-dioxane were released into the air and 6,500 kg went to water. According to the results of the 2008 survey conducted under the Industry Challenge, it would appear that 10,000–100,000 kg of 1,4-dioxane were released to the environment in 2006 – mainly to air and water. The 2006 findings may be an underestimate of the actual releases because facilities that do not meet the threshold for reporting under NPRI or the survey would not be required to report and their data are not reflected in these totals.

Given the range of use, manufacture and import of this chemical, the public does not have a definitive insight on the quantity of this chemical in use, imported or manufactured in Canada. One needs to question why such high levels of this chemical are released to the environment, particularly to water and air. According to NPRI 2008 data, releases to air and water have increased with reporting from 3 facilities across Canada. The releases to water of 1,4-dioxane

is 20,000 kg from one Alberta based facility.² In 2007, the releases to water and air from the same facility were 17,000 kg and 22,000 kg, respectively. A full understanding of the ability of a facility to capture, filter or modify the concentration level of this chemical before its release to the environment is required in this report. Similarly, it is also useful to gain some insight as to why there appears to be significant increases in annual releases from the major facility reporting under NPRI over the recent years.

When 1,4-dioxane is released to water, it is expected to remain in water; we therefore question the estimate of 1,4-dioxane in water. The government estimation considered using a conservative approach by “using the largest total amount manufactured at a single facility, assuming that a conservative fraction is released to water (5%), no removal in a sewage treatment plant and discharge to a relatively small receiving water body.” We have several questions regarding this approach to estimate releases from industry. We question why the 5% release level was applied in this scenario and what would be considered a small receiving water body. As noted in the NPRI data base, the largest releaser of 1,4-dioxane is based in Alberta at Fort Saskatchewan with releases to air and water. The government should conduct monitoring in the receiving waters from this facility to provide insight into this issue.

With this scenario in mind, no commentary was provided on the type of control-technology facilities possess to capture or treat 1,4-dioxane before it is released to the environment. It should be further noted that the government assessment approach has not included consideration of releases of 1,4-dioxane from products – neither from consumer and industrial products nor the disposal of products containing this chemical. The lack of consideration of these issues is important since it addresses the cumulative and potential synergistic impacts of a chemical. There has been a lack of commentary in assessments in these areas; there is a need to specifically indicate if this information is not available and how the government intends to address this gap.

² See National Pollutant Release Inventory for 1,4-Dioxane releases and transfer in 2007 and 2008 at <http://www.ec.gc.ca/inrp-npri/default.asp?lang=en>.

Table 1: Final results of Categorization and Final Screening for batch 7 substance – 1,4-dioxane of the Chemicals Management Plan (CMP), Challenge Program

Chemical name (CAS RN)	Categorization	Draft screening results under CEPA s.64	Final screening assessment – human health concerns	Risk management scope document	Uses
1,4-dioxane CAS RN (123-91-1)	<ul style="list-style-type: none"> • Greatest potential for exposure (GPE) • Possible carcinogen • Persistent (P), not bioaccumulative (B) or inherently toxic (iT) 	Does not meet criteria under S.64 of CEPA 1999	Carcinogenicity	None	<p>2006 data: Imported – 10,000 – 100,000 kg Manufactured – 10,000 – 100,000 kg Used in Canada – 10,000 – 100,000 kg</p> <p>Uses:</p> <ul style="list-style-type: none"> • Analytical reagent in laboratories • Solvent in pharmaceutical, research and development • In degreaser, anti-oxidants and anti-corrosion products • Cosmetics, agricultural products, food packaging, detergents among other products. It is not an intended product but a residue as a result of the ethoxylation process for some ingredients used in cosmetics and personal care products.

Table 2: Specific Issues and recommendations - 1, 4-dioxane

Issue	CELA & CSM – comments	Recommendations
<p>Presence of 1,4-dioxane as a residual in consumer products</p>	<ul style="list-style-type: none"> • The presence of 1,4-dioxane in consumer products results from the ethoxylation process and it is considered a residue. Hence this residue is present in a wide variety of consumer products but this information would not be included on the product label. The buying public should be given information on potentially carcinogenic chemicals contained in products. • The final assessment fails to adequately investigate the ethoxylation process assessment even though it appears that this process is the major factor for the presence of 1,4-dioxane in pharmaceutical and consumer products. This lack of consideration of the ethoxylation process is seen as a significant gap in this final screening report. • The assessment fails to consider the full life cycle of the chemical, which should include all residues. The absence of this information does not provide a complete picture of the impacts of this chemical on the environment or human health. A more complete commentary should be included in the assessment to explain why there are residues and any attempt to reduce the residue content. There should be a priority placed on the source and quantity of residue. • While we recognize that 1,4-dioxane is listed as a prohibited substance on the Cosmetic Ingredient Hotlist, this listing does not prohibit or restrict the presence of this chemical as a residue. We question the adequacy of and reliance on the Cosmetic Ingredient Hotlist to address these issues. The practice of periodic surveying of products on the market to ensure compliance with the Cosmetic Ingredient Hotlist appears to be very reactive in its approach. Given that 1,4-dioxane is a likely human carcinogen, its presence as a residue in consumer products should not be underemphasized. As a result, this gap should be addressed immediately. • While the assessment includes exposures as a result of some products containing 1,4-dioxane as a residue, it lacks the consideration of combining the residue found in a wider variety of products together with industrial releases and the synergistic impacts. These should be assessed and considered in the decision making process. 	<p>Rec: The assessment should include an investigation on the ethoxylation process and quantify its contribution to the presence of 1,4-dioxane in consumer products.</p> <p>Rec.: The current listing for a prohibition of 1,4-dioxane as an intentionally added substance, under the Cosmetic Ingredient Hotlist is inadequate. It does not address residual 1,4-dioxane that may be present in cosmetic and personal care products.</p> <p>Rec.: A full prohibition of 1,4-dioxane is warranted including residual 1,4-dioxane present in consumer products based on its potential carcinogenicity.</p> <p>Rec.: The scope of the assessment should be expanded to identify all consumer products that contain 1,4-dioxane as a residue. The current approach may be under-estimating the actual human exposure level of 1,4-dioxane.</p> <p>Rec.: Considering the extensive use of 1,4-dioxane in consumer products as well as in industrial products, chronic exposure data for inhalation, oral and in particular, dermal routes are warranted. This would be considered a validation exercise for the government’s assumptions in this assessment.</p> <p>Rec.: While we support the inclusion of the exposure assessment that includes consideration of children and women, this approach should be expanded to consider all</p>

		products that may contain 1,4-dioxane as a residue and synergistic impacts of other potential or known carcinogens used in these products.
1,4-dioxane in consumer products – lack of public transparency	<ul style="list-style-type: none"> In other consumer products such as detergents and soaps, 1,4-dioxane can be present but companies are not required to label these products because of our current labeling regulations or lack there of. With the absence of such a regulation, industry is not obligated to list the ingredients. This is a significant gap in transparency and accountability to the public on chemicals that are likely human carcinogens. While many major consumer and personal care products have been identified as those that would result in greater human exposure, it is unclear how many other products the government has actually identified that actually contain 1,4-dioxane as a residue. This gap may suggest that the values gathered in this final screening report could be under-estimating the amount of 1,4-dioxane that is in products, thereby affecting the results obtained for estimating potential exposure from such products. 	Rec.: The government should require labeling protocol for all consumer products that contain all potential and known carcinogens. This provision would support right to know efforts and provide consumers with information to make informed decisions about their purchases. A labeling protocol should be part of a comprehensive phase out and elimination strategy on toxic chemicals.
1,4-dioxane as a food additive and its application in food packaging	<ul style="list-style-type: none"> 1,4-dioxane can be found as an impurity in food additives or food processing aids as a result of by-product formation during manufacturing of polysorbates 80, 65 and 60 and polyethylene glycol (which may have food additive or processing aid uses), with a maximum residue limit of 10 mg/kg, according to the Food Chemicals Codex. Because of its volatility, the initial concentration may be higher. The residue levels are acceptable only when a provision exists for the use of these additives in accordance with the <i>Food and Drug Regulations</i>. It is very troubling to know that the government would allow the use of potential carcinogens in contact with any aspect of food preparation, packaging or as an additive. This practice exists for food intended for the general public as well as children, despite the listing of alternatives of specific additives that are available under the Food and Drug Regulation.³ Very limited information is provided in the assessment report on the use of food additives such as polyethylene glycol and the potential presence of 1,4-dioxane in food product. These issues are relevant if the assessment report would have considered the potential synergistic and cumulative impacts of these chemicals 	<p>Rec.: Similar to its presence in consumer products, the assessment report should be further expanded to address the potential of 1,4-dioxane in food products as a residue.</p> <p>Rec.: Based on its potential carcinogenicity, 1,4-dioxane should be eliminated in consumer products including food products. For the food industry, this effort should include a prohibition of food additives such as polysorbate products and polyethylene glycol and a requirement for industry to find a safe replacement for polysorbate products and polyethylene glycol (e.g. food additives and food processing aids).</p>

³ Environment Canada and Health Canada. *Draft Screening Assessment for the Challenge: 1,4-Dioxane, Chemical Abstracts Service Registry Number 123-91-1*. September 2009. Accessed at http://www.ec.gc.ca/substances/ese/eng/challenge/batch7/batch7_123-91-1.cfm. See Appendix 2, note # 4.

<p>Presence of 1,4-dioxane in drinking water, water and food.</p>	<ul style="list-style-type: none"> • The assessment suggests that this chemical is mostly released to the aquatic environment. However, the presence of monitoring data for Canada is very limited. The assessment relies on test data on surface water from a municipal water treatment plant located in the Great Lakes region. These tests did not demonstrate the detection of 1,4-dioxane in raw or treated effluent based on a detection limit of 10 ug/l. We believe this sampling is not representative for all of Canada because of a number of factors including temperature, flow, season, treatment technology applied, the potential sources of 1,4-dioxane etc. Furthermore, it is unknown if the detection limit of 10 ug/l represents the most sensitive levels. Evidence from other jurisdictions have demonstrated the detection of this chemical at much lower levels. Since this chemical is highly water soluble, its removal from the aquatic environment may prove to be a challenge. Therefore, enhanced efforts should be made to test for 1,4-dioxane across Canada. The government's approach does not appear to have scientific rigor because it lacks the additional information on the methods of testing. • The resultant findings suggest that 1,4-dioxane does not pose a harm. To effectively assess the impact of 1,4-dioxane as released in water, a more substantial consideration of receiving waters and the effectiveness of the treatment processes are required. It must be emphasized that there is a wide variation in treatment plants in Canada so that the level of effectiveness is not equal. To accurately determine the level of 1,4-dioxane in water from water treatment plants, testing must be expanded to include plants across Canada thereby including a broader spectrum of plants with varying treatment procedures. 	<p>Rec.: The government assessment approach to investigate releases of 1,4-dioxane to water should be strengthened and expanded to take into account types of wastewater treatment plants and the receiving waters across Canada.</p>
<p>Occupational exposure</p>	<ul style="list-style-type: none"> • Several epidemiological investigations provided evidence of 1,4-dioxane-induced tumour formation in occupational environments. However, the line of evidence presented in the assessment result has not influenced the final results of this assessment. Occupational exposure to toxic chemicals should be an integral component to all risk based assessment conducted. • The Danish Cancer Registry data indicated higher than expected standardized proportionate incidence ratios for liver tumours in male workers exposed to 1,4-dioxane and other chemicals in occupational settings. These were significantly higher than the expected rates for liver tumours. • Also, an increase in liver cancer incidence of 50% was identified in one workplace where only 1,4-dioxane was used. • Significant increases in chromosomal aberrations have been observed in 11 	<p>Rec.: Occupational exposure is a critical line of evidence for human health impact that should be considered in all assessment processes. Therefore, occupational exposure should be considered in the assessment as an indicator for potential general population exposure to these chemicals.</p> <p>Rec.: With the evidence of an increased rate of liver tumours and significant increases in chromosomal aberrations in some workers exposed to 1,4-dioxane, it is recommended that occupational exposure should be an integral component in the assessment</p>

	<p>workers exposed to alkylene oxides, including 1,4-dioxane, for more than 20 years in that occupational setting. However, these workers were also exposed to known mutagens, such as ethylene oxide and propylene oxide.</p> <ul style="list-style-type: none"> • Based on the above data, it is troubling to see that the occupational exposure component of the assessment was not available. It must also be noted that 1,4-dioxane has a wide variety of applications (industrial and consumer) and is most likely used with other chemicals in the workplace, making it more difficult to track health effects when thorough medical occupational histories are not the norm in the medical practice. • Furthermore, the absence of consideration of cumulative and synergistic exposures in the occupational environment as well as in the public setting continues to be a significant gap in all assessments conducted under the CMP. 	<p>process, including that of 1,4-dioxane. The CMP should be overhauled to address occupational exposure to chemicals, including 1, 4-dioxane.</p> <p>Rec.: Part of the strategy to improve the CMP should be to strengthen the communication and follow-up efforts between workers, unions, government and industry as well as occupation health clinics, universities, occupational and safety consultants, the medical community, etc. This should be clearly articulated in the final risk assessment document.</p> <p>Rec.: The evidence provided on occupational exposure should be considered in the decision on toxicity of 1,4-dioxane under CEPA. This evidence provides a strong line of evidence to demonstrate the impact of this chemical on human health and should contribute to a finding of toxic under Section 64 of CEPA.</p>
<p>NPRI releases for 2006</p>	<ul style="list-style-type: none"> • For 2006, from the submitted info, it was estimated that 10,000 – 100,000 kg of 1,4-dioxane were released to the air and water. But from the NPRI data 13,800 kg were released into the air and 5,600 kg to water. Judging from the usage data in Table 1, it would appear that the releases are possibly a significant underestimate for releases and transfer levels. These figures are quite troubling if reviewed together with the data presented for use, manufacture and import. It could possibly demonstrate a limited understanding of the fate of 1,4-dioxane in a Canadian context. These volumes are significant and the low numbers presented in the NPRI may be on the low side because the threshold for reporting under this inventory is high. Given the under reporting of releases and the evidence that this chemical is potentially carcinogenic and is persistent in water, soil and sediment, the government should take a more precautionary approach and investigate more closely, environmental releases. • These figures suggest that the NPRI reporting criteria should be reconsidered for 1,4-dioxane. There should be no reporting threshold for 1,4-dioxane – all releases should be reported. 	<p>Rec.: Reporting under NPRI for 1,4-dioxane should be revised to reduce the threshold for the NPRI so that <i>all</i> releases should be reported.</p>

<p>Consideration of vulnerable populations – pregnant women and children</p>	<ul style="list-style-type: none"> • Since this chemical is used in a wide variety of cosmetic products and household products, the exposure to human health may potentially be extensive with respect to the number of products that contain 1,4-dioxane as a residue. We are pleased to see the consideration of vulnerable populations such as women and children. The assessment includes an extrapolation on exposure to specific age groups in children. We want to highlight the following limitations with the approach taken. <ul style="list-style-type: none"> ○ It is unclear if the assessment results provide the most protective safety margins when considering exposure to children. ○ It is also unclear if the final screening report provides clear evidence on the safety level given for pregnant women exposed to 1,4-dioxane in products. This is an area that requires more consideration in the assessment to determine the potential impact to pregnant women as well as to the unborn fetus. ○ The assessment has not considered the full impacts of exposure to this chemical by not considering the exposure of 1,4-dioxane from industrial sources. • The assessment report also indicated one study focused on 1,4-dioxane in breast milk. However, further consideration of contamination of breast milk by this chemical investigated the potential of 1,4-dioxane being detected in blood is more likely than in milk samples. This is because this chemical is very hydrophilic rather than lipophilic. The rationale provided included the observation by Center for Disease Control and Prevention (CDC) which investigated 2000 blood samples, none of which detected 1,4-dioxane. While this may indeed be a valid conclusion, it is our view that there is some important missing information in this commentary. It would include the absence of the threshold for detection used to test for 1,4-dioxane. This information should have been presented in this study to validate this finding. The monitoring results may not necessarily reflect the Canadian experience and government should pursue opportunities to include this chemical in biomonitoring efforts that are ongoing in Canada. 	<p>Rec.: The government should ensure that consideration of vulnerable populations such as women and children are assigned adequate margins of exposures and consideration of all sources of exposure to 1,4-dioxane are considered including industrial exposures.</p> <p>Rec.: The final screening report should include possible effects of this substance on pregnant women and the developing fetus.</p> <p>Rec.: The government is urged to conduct extensive biomonitoring for this chemical particularly in nursing mothers in breast milk and blood samples.</p>
<p>Additional health effects require emphasis.</p>	<ul style="list-style-type: none"> • According to the Agency for Toxic Substances and Disease Registry (ATSDR) web site, this chemical has several impacts to human health that require more consideration in the draft assessment. They include eye and nose irritation from exposure to low levels to this chemical and they have been noted as 	<p>Rec.: The focus on health effects should consider more explicitly the impacts from inhalation which has received a limited amount of attention in the assessment process. The government should seek</p>

	<p>health effects. This should be explored more substantially to gain a better understanding of the impacts from this chemical.⁴ The background studies used by the ATSDR should be investigated for these purposes.</p> <ul style="list-style-type: none"> • Furthermore, on the issue of carcinogenicity, the draft final screening report has a significant focus on the carcinogenicity of 1,4-dioxane. It outlines that the ATSDR suggests that, “collectively, the information suggests that 1,4-dioxane is a non-genotoxic compound, or at best a weakly genotoxic compound.”⁵ However, on its own web site the ATSDR notes “1,4-dioxane as reasonably anticipated to be a human carcinogen.”⁶ These two statements seem to be in contradiction and require further explanation. In applying the precautionary principle, the statement from the website may better reflect the impacts of 1,4-dioxane on carcinogenicity and should inform the government to take a position that reflects this finding. 	<p>additional data on this exposure route using section 71 (1) (c) of CEPA.</p> <p>Rec.; The government should consider the inhalation route for 1,4-dioxane and the additional evidence from organization such as ATSDR in finding 1,4-dioxane a potential human carcinogen and find this chemical toxic under CEPA.</p>
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⁴ Agency for Toxic Substances and Disease Registry at <http://www.atsdr.cdc.gov/tfacts187.html#bookmark05>

⁵ Environment Canada and Health Canada. September 2009. Draft Screening Assessment for the Challenge: 1,4-Dioxane Chemical Abstracts Service Registry Number 123-91-1.

⁶ Agency for Toxic Substances and Disease Registry at <http://www.atsdr.cdc.gov/tfacts187.html#bookmark05>.

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