

**A Response to *Canada Gazette* Part I,
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NGO comments on Draft Assessment for 1,4-
Dioxane in 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. 143, No. 36— September 5, 2009 release of the proposed risk management approach reports 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 6, including the final assessments and draft risk management options for Batch 1 to 5.

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 draft assessment of one substance in Batch 7 – 1,4-dioxane, a substance that has not been found to be toxic under CEPA based on the draft assessment report and, as a result, risk management measures were not proposed. In our submission below we will outline the gaps and concerns we have with the government assessment. Based on these gaps, we encourage your departments to reconsider the findings of the draft screening assessment and conclude that this chemical meets the criteria for CEPA toxic.

Please note that our organizations, for the first time in the implementation of the Chemicals Management Plan, are submitting comments on only one substance. This approach was undertaken because of the limited time available for public comment period between Batch 5 (Final Assessment Reports) and Batch 7 (Draft Assessment Reports). It is unfortunate that very little opportunity is provided to the public to review the findings of the assessments of other

chemicals under Batch 7. We are concerned that the lack of comments submitted on these assessment reports will provide a false impression that there are no concerns regarding the findings under these assessments. On the contrary, many of the comments we have outlined to date under the first six batches released contain commentary regarding the many issues and gaps in the government assessments. These issues and gaps have not been substantially addressed through the current government approach. The lack of response to the on-going issues has resulted in very few regulatory actions aimed to eliminate chemicals of concern.

In the following submission, we may not have addressed all aspects of the draft assessment for 1,4-dioxane but have commented on specific issues outlined in the draft that are considered essential to our organizations. We hope that these comments will be carefully considered and a change in decision on 1,4-dioxane will follow. These comments are intended to provide you with a broad understanding of the public interest expectations of the government to protect Canadians and their environment from this toxic chemical.

Through these submissions, 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. The commentary below identifies areas in the assessment report where government should strengthen its approach on the conclusion of toxicity under *CEPA* for this chemical.

General Information & Comments

Based on the categorization process, 1,4-dioxane was determined to be a high priority for assessment with respect to human health. It 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

However, the draft screening assessment has proposed 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.

Using the data from the draft assessment, characterization of the usage of 1,4-dioxane in Canada is somewhat difficult since the imported, manufactured and use volumes all give the same range: 10,000 – 100,000kg. Because of the wide range, it is not possible to decipher if the actual usage is closer to the higher end or the lower end of the range.

For the general population, the principal routes of exposure to 1,4-dioxane are consumer products, food, drinking water, and air (ambient and indoor). However, from the usage volumes in Table 1, some occupational exposure in Canada is expected. Any discussion pertaining to this exposure was noticeably absent in the draft screening assessment, although this substance is a potential carcinogen. This again, is seen as a significant gap in the government's approach when assessing a toxic chemical and should be addressed regardless of whether or not the exposure is occupational.

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

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 with similar metabolic pathways for this substance in humans and experimental animals. The draft assessment indicates that there is uncertainty regarding the mechanism of 1,4-dioxane-induced tumorigenesis following oral exposure. However, it concluded that available epidemiological data has not provided adequate evidence regarding 1,4-dioxane carcinogenicity in humans.

The three routes of exposure – inhalation, dermal and oral can result in health implications for other organs, but in mice, reproductive and immunological effects were also observed. Carcinogenicity is the major health endpoint but there is a lack of toxicity data for all routes of exposure as well as a lack of information on reproductive toxicity.

The draft assessment also concluded that the margins of exposure were adequately protective of human health when comparing the upper-bounding estimates of total daily human intake from the general environment to both the level at which no tumours or any adverse effects were observed and the lowest observed adverse effect level (LOAEL) for non-cancer effects. It is noted that a dermal LOAEL was not used. However, the rationale was not clearly defined for concluding that there is a threshold for the carcinogenicity for 1,4-dioxane.

Given these uncertainties as pointed out above, we are not in agreement with the government's conclusion in the draft assessment that 1,4-dioxane is not CEPA toxic. A more precautionary approach for 1,4-dioxane is required with the result of a CEPA toxic designation. However, it would appear that the conclusions from other agencies suggesting were influential in shaping the government's decision that 1,4-dioxane is not a likely a mutagen, although potential modes of action have not been fully elucidated and also, all tests for mutagenicity have been negative.

The National Pollutant Inventory Release 2006 data indicate that 13,800 kg of 1,4-dioxane were released into the air and 6,500 kg went to water. From submitted data 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. Not possibly recorded are the lower levels of release – those below the threshold for reporting. With most of the releases going to the water, it is noted that there is possibly no STP removal for this chemical. This is problematic given that the resulting sludge can be used in agricultural fields. It is not clear if facility disposal is mainly to water. Not addressed were product releases – both from consumer and industrial products as well as disposal of products containing this chemical. There is a need to expand the assessment to include these areas, and if not, to specifically indicate that this type of information is not available.

We are in agreement with the inclusion of 1,4-dioxane in the upcoming Domestic Substances List inventory update initiative. However, we are uncertain as to how the government will actually make it public if changes are made to this draft assessment (apart from the final assessment), based on other relevant research and monitoring data that will support the assumptions made in this screening assessment.

Table 1: Final results of Categorization and Draft 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	Draft 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</p> <p>Manufactured – 10,000 – 100,000 kg</p> <p>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.

Based on the carcinogenicity of 1,4-dioxane and the information provided on use, release, manufacture and imports, the finding that this chemical does not meet the criteria for CEPA toxic is under question.

Recommendation: We do not support the finding that 1,4-dioxane does not meet the criteria for CEPA toxic. The assessment results should be revised to a finding of CEPA toxic based on the carcinogenicity of 1,4-dioxane.

The values provided for use, imports and manufacture in Canada are very confusing. It appears that the range for use of 1,4-dioxane is not transparent. The range considered is large and it is difficult to determine whether the use, import and manufacture levels in Canada fall at the lower end or higher end of the range. The government should improve its method of reporting use, manufacture and import levels to provide more transparent information on these chemicals.

Recommendation: The departments should outline in a transparent manner, accurate range volume for use, imports and manufacture in Canada for all chemicals including 1,4-dioxane.

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

Issue	CELA & CSM - comments	Recommendations
<p>Presence of 1,4-dioxane 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 would not be specified on the product label. • The ethoxylation process received a passing mention in the assessment of this chemical although it appears that it is a major contributor to the presence of 1,4-dioxane in pharmaceutical and consumer products. The assessment has provided some mention of chemicals involved in the ethoxylation process although Canada's previous Priority Substances List targets a few significant ethoxylated compounds such as nonylphenol and its ethoxylates, which have been targeted for management measures. Therefore, a more comprehensive investigation on the ethoxylation process in the assessment of 1,4-dioxane is warranted. • The issue of the ethoxylation process is of importance as it highlights a gap in the assessment process. The focus of assessment targets mainly chemicals and not residues. However, if a chemical is found as a residue, priority must be placed on the source of the residue as well as the process. • 1,4-dioxane is listed as a prohibited substance on the Cosmetic Ingredient Hotlist but there are no restrictions for this chemical as a residue. We consider this as a gap that should be addressed through changes in the Hotlist. There needs to be a strengthening in the approach of how residues in products are addressed as the current approach is inadequate. Given that 1,4-dioxane is a likely human carcinogen its presence as a residue in consumer products should not be underemphasized. • The governments should be aware that there are cosmetics available that specifically state that they are free of 1,4-dioxane. This type of information indicates that it is possible to formulate products that do not have residual 1,4-dioxane present in the final product. This information could potentially inform the government about substitution chemicals that do not contain 1,4-dioxane. • 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. With the absence of this 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. It is unclear how well the issue of identifying all the major products that may contain 1,4-dioxane has been covered in the assessment. 	<p>Rec: The assessment should investigate the ethoxylation process more comprehensively in its contribution to the presence of 1,4-dioxane. This process would require a substantial investigation of feedstocks used in the process and their contribution to the production of this chemical.</p> <p>Rec.: A full prohibition of 1,4-dioxane is warranted including residual 1,4-dioxane present in consumer products. Amendments to the Cosmetics Ingredient Hotlist are required as part of a substantial regulatory elimination strategy of this chemical.</p> <p>Rec.: The scope of the assessment should be increased to take into account all consumer products that contain 1,4-dioxane as a residue. The current approach may be under-estimating the human exposure level of 1,4-dioxane.</p> <p>Rec.: Similar to its presence in consumer products, 1,4-dioxane in food products requires further consideration given that this chemical is a residue.</p> <p>Rec.: Based on its carcinogenicity, 1,4-dioxane should be eliminated in consumer products including food products. For the food industry, this effort should include a requirement for industry to find a safe replacement for polysorbate products and polyethylene glycol (e.g. food additives and food processing aids).</p>

	<p>This gap suggests that the values gathered in this assessment report may 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.</p> <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. The residue can only be present when a provision exists for the use of these additives in accordance with the <i>Food and Drug Regulations</i>. 	<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>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 focus of the assessment relies on test data on water from a municipal water treatment plant in the Great Lakes region. 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. • Furthermore, sewage treatment plants cannot effectively treat all chemicals before they are released to the receiving water as effluent or as part of the sludge or waste product. As noted, the presence of 1,4-dioxane in municipal waste which could end up in sludge, has not been addressed in the draft assessment. In order to understand the full impact of this chemical, the consideration of the waste stream should represent an important source of potential exposure. 	<p>Rec.: The government assessment approach to investigate releases of 1,4-dioxane to water should be strengthened to take into account types of wastewater treatment plants and the receiving waters.</p> <p>Rec.: The government's assessment should provide consideration of the full life cycle of the chemical including the waste and disposal stream, since final products such as sludge may contain these chemicals but may be disposed of in landfills or on agricultural lands as fertilizers. Similarly, products that may contain this chemical may be incinerated and the combustion products from this activity should be considered in the process.</p>
<p>Occupational exposure</p>	<ul style="list-style-type: none"> • Several epidemiological investigations did provide evidence of 1,4-dioxane-induced tumour formation in occupational environments. • 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 were significantly higher than the expected rates for liver tumours. • Also, an increase in liver cancer incidence of 50% was identified in one 	<p>Rec.: Occupational exposure is just as important as exposure to the general population and this route of exposure requires consideration in the assessment process.</p> <p>Rec.: With the evidence of an increased rate of liver tumours and significant increases in chromosomal aberrations in some workers</p>

	<p>workplace where only 1,4-dioxane was used.</p> <ul style="list-style-type: none"> • Significant increases in chromosomal aberrations have been observed in 11 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. • 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>exposed to 1,4-dioxane, it is recommended that occupational exposure should be an integral component in the assessment 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.</p>
<p>NPRI releases</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 low. These figures are quite troubling if reviewed together with the data presented for use, manufacture and import. It demonstrates a limited understanding of the fate of 1,4-dioxane. These volumes are significant when considered together. In fact, given the low numbers presented in NPRI because of the threshold reporting limit, they would suggest that the numbers are underestimated (there would be releases under the threshold that are not reported). These numbers are significant as we consider the evidence that this chemical is persistent in water, soil and sediment. A further investigation of these environmental media is warranted because of its persistence and possible carcinogenicity. • 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 (e.g. children’s health, Aboriginal</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 respects to the number of products that contain 1,4-dioxane. The assessment includes an extrapolation on exposure to specific age groups 	<p>Rec.: The assessment report should ensure that the margin of exposure to children is strengthened to consider the unique vulnerabilities of developing children to toxic chemicals.</p>

<p>communities and people with chemical sensitivities, etc.)</p>	<p>in children. It is unclear whether the assessment results provide the most protective safety margins when considering exposure to children. Furthermore, it is also unclear if the assessment 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.</p> <ul style="list-style-type: none"> • Similarly, additional focus in these assessments is required to consider the impacts of this chemical on other vulnerable populations such as workers, Aboriginal communities, people of low income and people with chemical sensitivities. The current approach for assessment has not provided any consideration to the challenges faced by these communities or sub-populations regarding chemical exposure. 	<p>Rec.: The assessment should be expanded to consider the vulnerabilities of other subpopulations to the exposure of 1,4-dioxane including pregnant women, workers, Aboriginal communities, people of low income and those with chemical sensitivities.</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 health effects. This gap is important and should be explored more substantially to gain a better understanding of the impacts from this chemical.² The background studies used by the ATSDR should be investigated for these purposes. • Furthermore, on the issue of carcinogenicity, the draft assessment 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.”³ However, on its own web site the ATSDR notes “1,4-dioxane as reasonably anticipated to be a human carcinogen.”⁴ These two statements may need to be further explained. The statement from the website may better reflect the impacts of 1,4-dioxane on carcinogenicity. 	<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 additional data on this exposure route using section 71 (1) (c) of CEPA.</p>

² Agency for Toxic Substances and Disease Registry at <http://www.atsdr.cdc.gov/tfacts187.html#bookmark05>

³ Environment Canada and Health Canada. September 2009. Draft Screening Assessment for the Challenge: 1,4-Dioxane Chemical Abstracts Service Registry Number 123-91-1.

⁴ Agency for Toxic Substances and Disease Registry at <http://www.atsdr.cdc.gov/tfacts187.html#bookmark05>

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