

No. 700

A Response to *Canada Gazette* Part I, Vol. 143, No.
48, November 28, 2009:
NGO comments on Proposed Risk Management
Approach for Specific Chemicals in Batch 6 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. 48, November 28, 2009 release of the proposed risk management approach reports for selected substances identified under the Chemicals Management Plan (CMP), Batch 6 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 unable to afford legal assistance. In addition, CELA also undertakes substantive environmental policy and legislation reform activities in the area 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 effects 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 7, including the final assessments and draft risk management options for Batches 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.

Background

For this submission, we have provided detailed commentary to the proposed risk management measures on one substance in Batch 6 considered toxic under

CEPA 1999: benzyl chloride, CAS RN 100-44-7. See Table 1 for detailed comments and recommendations.

Benzyl chloride was found to be toxic under CEPA based on its carcinogenicity. The assessment report also notes that evidence is available to indicate that this chemical has the potential for reproductive impacts, respiratory effects and neurotoxicity.¹ However, the information on those health impacts is limited to a few studies.

These impacts have been noted by the Scorecard web site as well. On the web site, it was noted that this chemical is suspected to be: a cardiovascular or blood toxicant, developmental toxicant, gastrointestinal or liver toxicant, neurotoxicant, respiratory toxicant, and a skin or sense organ toxicant.²

This information together with the knowledge that Canada imports high levels of benzyl chloride provide adequate justification for the development of a rigorous plan to address this chemical based on prevention and elimination. However, the assessment report spends considerable time emphasizing the use of this chemical is as an intermediate chemical.

Chemicals identified for use primarily as an intermediate chemical have not been subjected to management actions that follow a prevention strategy. The final screening report on benzyl chloride highlights the presence of this chemical as impurities in various household and personal care products such as dishwashing detergents and shampoos. The presence of this chemical in these products would support the need for substantial consideration on a prevention approach that would include source elimination and pollution prevention strategies.

We do not address every matter in respect to the measures proposed for this substance but provide comments on the major proposals made by your departments. 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 these toxic chemicals.

Furthermore, our organizations continue to have many concerns about the gaps in the assessment process conducted on the other chemicals under Batch 6. However, we will not provide further substantial commentary on the final risk assessment results for other substances in Batch 6 for this submission. Regardless of the absence of additional comments, we urge your departments to review comments and recommendations submitted by CELA and CSM in April

¹ Environment Canada and Health Canada. Screening Assessment for the Challenge Benzene, (chloromethyl)-(Benzyl chloride) Chemical Abstracts Service Registry Number 100-44-7. November 2009. Accessed at http://www.ec.gc.ca/substances/ese/eng/challenge/batch6/batch6_100-44-7.cfm.

² See Scorecard for chemical profiles for CAS no. 100-44-7. Accessed at http://scorecard.org/chemical-profiles/summary.tcl?edf_substance_id=+100-44-7+#hazards.

2009 in response to draft assessment reports for Batch 6 chemicals. Many of the issues we raised in these past submissions have not yet been addressed under the CMP. We continue to raise these issues to ensure greater transparency and accountability in these implementation activities. Finally, 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.

Table 1: Benzyl chloride (CAS RN: 100 – 44 – 7): Comments and recommendations to specific risk management proposals³

Specific sections of risk management scope for benzyl chloride (CAS RN: 100-44-7)	Summary of proposed government measures & other measures	CELA & CSM - Comments	Recommendations
Section 1.3 proposed measure	<ul style="list-style-type: none"> It is proposed for the Ministers to recommend the addition of TCP to the List of Toxic Substances in Schedule 1. Ministers to develop an instrument respecting preventive or control actions to protect the health of Canadians and the environment from the potential effects of exposure to benzyl chloride. 	<ul style="list-style-type: none"> Given that the European Commission has classified benzyl chloride as a class 2 carcinogen, it is appropriate for this chemical to be listed on the Toxic Substances List (Schedule 1) of CEPA. The assessment indicated that the total quantity of benzyl chloride used in 2006 was in the range of 100,000 – 1,000,000 kg. This use range suggests that this chemical is a high volume chemical. However, it is possible that this figure may be an underestimation of its presence in the Canadian market because the threshold for reporting is established at 100 kg. When used as an intermediate, this chemical has a wide range of uses in industrial and consumer applications and can also be present in imported materials/products as a residue. Therefore, we are concerned that the government's proposal to manage this chemical lacks the necessary details regarding what actions should be taken to seek a considerable reduction and perhaps aim for an elimination of this chemical. At this time, the proposals do not provide detail on the use of regulatory measure that should be undertaken for this chemical. 	<p>Rec: We support the listing of benzyl chloride on the Toxics Substances List (Schedule 1) of CEPA.</p> <p>Rec.: We urge the government to adopt a regulatory approach that aims for the elimination of benzyl chloride, particularly because residual benzyl chloride has been detected in consumer products including cosmetics. The goal of these measures should support a phase out and eventual prevention of benzyl chloride in those applications.</p> <p>Rec.: Benzyl chloride should not be present even in residual concentration in any product, including pharmaceutical products.</p>

³ Environment Canada Health Canada. *Proposed Risk Management Approach for Benzene, (chloromethyl)-(Benzyl Chloride) Chemical Abstracts Service Registry Number (CAS RN): 100-44-7*. November 2009. Accessed at http://www.ec.gc.ca/substances/esc/eng/challenge/batch6/batch6_100-44-7_rm.cfm.

Specific sections of risk management scope for benzyl chloride (CAS RN: 100-44-7)	Summary of proposed government measures & other measures	CELA & CSM - Comments	Recommendations
	<ul style="list-style-type: none"> • Benzyl chloride will be managed through a life-cycle approach to prevent or minimize its release into the environment as it does not meet the conditions set out in subsection 77(4) of CEPA 1999. Virtual elimination has not been recommended under CEPA 1999. 	<ul style="list-style-type: none"> • Identified as a possible residue in some domestic and possibly in imported products, it is possible that the exposure to human health and the environment are also underestimated. This level of uncertainty should be addressed in a more precautionary manner regarding the proposals for risk management. • Despite evidence to suggest that this chemical does not meet the criteria established for virtual elimination under CEPA, the health effects of benzyl chloride include carcinogenicity and suspicion of neurotoxicity, impacts to respiratory sensitivity, and reproductive impacts. They all of which justify the need for measures of prevention and elimination. • The consideration of non-regulatory instruments will not create the level of certainty required to address the various sources of this chemical while regulatory measures are enforceable and can be more protective of human health and the environment. A regulatory measure that aims for elimination and prevention at the source is essential based on the health impacts of this chemical. 	
<p>Section 6.1 Existing Canadian risk management</p> <p>Controlled Products Regulation under the Hazardous Products Act</p>	<p>The <i>Controlled Products Regulations</i> established under the <i>Hazardous Products Act</i> requiring the disclosure of any chemical ingredient on the Ingredient</p>	<ul style="list-style-type: none"> • The current regime is inadequate to manage benzyl chloride. Given that the existing management regime focuses on the presence of the chemical at the end of the pipe rather than preventing its use in the workplace, a more comprehensive regulatory framework aimed at a phase out should be considered. The government approach should address the full life cycle approach of the chemical (cradle to grave to cradle). The requirement to list this chemical in a MSDS only above a prescribed concentration is inadequate. 	<p>Rec.: The current regime described under Section 6.1 of the draft risk management scope document is inadequate, particularly because of the emphasis on the end of pipe measures.</p> <p>Rec: We recommend that there be no prescribed levels of disclosure for the listing of hazardous substances in the workplace. Its presence should warrant</p>

Specific sections of risk management scope for benzyl chloride (CAS RN: 100-44-7)	Summary of proposed government measures & other measures	CELA & CSM - Comments	Recommendations
	Disclosure List to be disclosed on the Material Safety Data Sheet of chemicals in the workplace above a certain prescribed concentration (Canada 1988).	<ul style="list-style-type: none"> • Reporting under the MSDS does not require the development of strong measures that aim towards elimination. Furthermore, the listing of this chemical on an MSDS is further weakened: <ul style="list-style-type: none"> ○ Reporting occurs above an established concentration threshold. It is our view that there should be no concentration restriction for disclosure of benzyl chloride on a MSDS. The absence of the concentration restriction will promote full disclosure to workers regarding its application and presence in a product. ○ Listing does not necessarily result in a full understanding of the application of this chemical in its wide range of uses. 	<p>full disclosure on a Material Safety Data Sheet.</p> <p>Rec.: Disclosure of the use of benzyl chloride in a MSDS in the workplace should be broader than this listing. It should include reporting for releases, uses, disposal and manufacture.</p>
Section 6.1 Existing Canadian risk management Pest Management Regulatory Agency	Pest Management Regulatory Agency's List of Formulants as a List 2 formulant in pest control products (Canada 2007b).	<ul style="list-style-type: none"> • Since benzyl chloride has been identified as a CEPA toxic chemical, its use as an active ingredient under PCPA should not be permitted. The role of benzyl chloride as an active ingredient should have been defined in the government documents to allow for some commentary on the adequacy of this listing under the List of Formulants of a carcinogenic chemical. These pesticides are used by the general public in the presence of children, babies and other vulnerable individuals. 	<p>Rec.: We urge the government to propose a prohibition on the use of benzyl chloride in pest control products as an active or inert ingredient.</p>
Section 6.1 Existing Canadian risk management	Releases are reportable under the National Pollutant Release Inventory (NPRI 2006).	<ul style="list-style-type: none"> • Under the National Pollutant Release Inventory, industrial facilities in Canada reported releases of 5 kg and 1 kg of benzyl chloride to air in the years 2000 and 2006, respectively with no releases to water or land. From recent information gathered through CEPA 1999, s. 71 notice, 	<p>Rec.: For benzyl chloride and all CEPA toxic substances, there should be no reporting threshold under the NPRI to ensure that all facilities releasing benzyl chloride or other CEPA toxic chemicals</p>

Specific sections of risk management scope for benzyl chloride (CAS RN: 100-44-7)	Summary of proposed government measures & other measures	CELA & CSM - Comments	Recommendations
National Pollutant Release Inventory (NPRI 2006)		<p>companies reported no release of benzyl chloride in 2006 (Environment Canada 2008a). With the high and diverse usage of benzyl chloride as an intermediate, these reported releases are questionable – they appear to be low and also, none are reported to water or land. The NPRI reporting requirements are high and therefore such releases to the environment may be underestimated.</p> <ul style="list-style-type: none"> • The risk management scope document has not provided any proposal to improve the reporting of releases and transfers of this chemical under the NPRI. To date, the government has been slow to make adequate reforms to the NPRI regarding chemicals targeted under the CMP and the NPRI Work Group. • Also, the government needs to consider the removal of the reporting threshold for all CEPA toxic chemicals. 	are required to report releases and transfers.
<p>Section 6.1 Existing Canadian risk management</p> <p>Airborne Contaminant Discharge Monitoring and Reporting Regulation of Ontario (Ontario MOE 2006)</p>		<ul style="list-style-type: none"> • The reporting of this chemical under the Ontario regime does not explicitly require the reduction of this chemical over time. • This chemical has been identified as a priority substance under the Ontario's <i>Toxics Reduction Act</i> which will require industry to prepare pollution prevention plans. However, at this time there is no mandatory requirement under the Act to implement pollution prevention plans. If these pollution prevention plans are implemented, the results for reduction on these chemicals will be unknown. • Furthermore, no other provinces have this type of Act in place. This may result in an inconsistent management regime on a chemical identified as toxic under the federal regime. 	Rec.: The federal government should establish an action plan which aims to eliminate cancer causing chemicals such as benzyl chloride from industrial and consumer products, alike. Such an approach will ensure full protection to all Canadians and the environment.

Specific sections of risk management scope for benzyl chloride (CAS RN: 100-44-7)	Summary of proposed government measures & other measures	CELA & CSM - Comments	Recommendations
Section 7.1 Alternative chemicals or substitutes	No potential substitutes for benzyl chloride were disclosed in the voluntary Challenge Questionnaire submissions or during the public comment period on the Risk Management Scope document.	<ul style="list-style-type: none"> • In our previous joint submissions, we have noted the absence of information in this section for many of the chemicals targeted under the CMP Industry Challenge. • The listing of possible alternatives or substitutes should be an integral part of the risk management document – unfortunately, this information has not been supplied by industry. • The government should be taking steps that support the identification and promotion of alternatives that do not exhibit toxic properties in the course of conducting its assessment work. The voluntary questionnaire has proven to be unsuccessful in gathering such information. Additional consideration should be undertaken to collect information in a mandatory manner. • To ensure that alternatives or substitutions do not possess toxic properties, the government should require a process to assess their safety. This requirement should contribute to innovation by industry. 	<p>Rec.: A phase out regime for benzyl chloride should include the preparation of an inventory of possible alternatives to this chemical. This should be prepared as part of the risk management process.</p> <p>Rec.: A process to determine the safety of substitutes available for benzyl chloride should be undertaken under CEPA.</p>
Section 7.2 Alternative technologies and/techniques	No alternative technologies and/or techniques were identified which would minimize or eliminate the use and/or release of benzyl chloride.	<ul style="list-style-type: none"> • Despite the lack of information provided through the voluntary questionnaire, additional efforts by government should have been directed to investigate any alternative techniques or technologies for benzyl chloride. 	Rec.: Similar to the approach required to assess the safety of alternatives, it is important to undertake an assessment of available alternative technologies and techniques to ensure that they do not produce other toxic chemicals or pose a hazard to the environment or human health.
Section 7.4 Children's	It is proposed that no risk management	<ul style="list-style-type: none"> • Regardless of the use of benzyl chloride as an intermediate chemical, there is a significant possibility of exposure to 	Rec.: Additional regulatory action to protect children from exposure to benzyl

Specific sections of risk management scope for benzyl chloride (CAS RN: 100-44-7)	Summary of proposed government measures & other measures	CELA & CSM - Comments	Recommendations
exposure	actions to specifically protect children are required for benzyl chloride – based on information received.	<p>children from this chemical because of the wide range of products that may contain residual benzyl chloride. The lack of information received through the industry challenge should not lead to a conclusion that no measures are required to protect children's health nor that this substance has no impact on children.</p> <ul style="list-style-type: none"> • The current approach to collect information on exposure to children is conducted through a voluntary questionnaire, is highly inadequate. The government should use its full authority under Section 71, in particular Section 71 (1) (c) to require industry to provide toxicological and other test data that will address this information gap as well as better inform the assessment report. The absence of acknowledgement of this information will create a significant gap in the proposed management approach for benzyl chloride. • The government's decision not to propose management options to specifically protect children and babies is not sufficiently precautionary given that this chemical is found extensively in industrial applications and consumer products, even as an impurity. • In Sweden, this chemical has been identified for a 'phase out' in any new manufactured articles. In Canada, apart from the proposal to add benzyl chloride to the Canada's Cosmetic Ingredient Hotlist, there are no other bans or restrictions proposed. Unless a prohibition is being considered for the Hotlist, children may still be exposed to benzyl chloride through the use of cosmetic products and even household products. The lack of an explicit focus to protect children's health from such products has yet to be proposed. 	<p>chloride is warranted because of the type and number of consumer products that may contain this chemicals when it is a residue.</p> <p>Rec.: The government should use the full scope of its authority to collect data on the impacts to children's health from this chemical. Specifically utilize CEPA Section 71(1)(c), to seek mandatory toxicological data from industry focused on exposure to children's health.</p> <p>Rec.: Similarly, the management proposals should also recognize and take action to protect other vulnerable sub-populations of society such as people of low income, workers, people with chemical sensitivities and aboriginal communities.</p>

Specific sections of risk management scope for benzyl chloride (CAS RN: 100-44-7)	Summary of proposed government measures & other measures	CELA & CSM - Comments	Recommendations
		<ul style="list-style-type: none"> The lack of information gathered on children's health exposures to this chemical is also applicable for other vulnerable populations (e.g., workers, people of low income, people with chemical sensitivities and aboriginal communities). 	
Section 8.1 Human health objective	The proposed human health objective for benzyl chloride is to minimize human exposure to the greatest extent practicable.	<ul style="list-style-type: none"> The proposed human health objective for benzyl chloride is aimed at minimizing human exposure to it to the greatest extent. Minimizing exposure is not considered an adequate or appropriate measure for a chemical that has been identified for its carcinogenicity and genotoxicity. Given its extensive use as a high volume chemical and its potential as a residue or contaminant in consumer and cosmetic products, as well as industrial products, a goal of eliminating exposure to this substance is more appropriate. 	<p>Rec.: The human health objective for benzyl chloride should be strengthened to aim for the elimination of human exposure to this substance.</p> <p>Rec.: We urge the government to revise the word "minimize" to "eliminate" in its human health objective.</p>
Section 8.2 Risk management objective	The current exposures of Canadians to benzyl chloride were considered to be negligible under the current use conditions. The risk management objective is to prevent increases in exposure.	<ul style="list-style-type: none"> The focus on concentration or the prevention of increases in exposure that will protect human health will only result in controlling the use of the chemical at the end of the process rather than eliminating it at the source, the latter being more protective of human health and the environment. At the current time, the government position is that the role of benzyl chloride as an intermediate chemical will result in exposures that are not negligible. No comprehensive data has been provided in the assessment report to evaluate the additive and cumulative impacts from these 'negligible' sources of benzyl chloride. A requirement to look at prevention at the source will achieve the necessary protection for human health. 	<p>Rec.: We do not support the current risk management objectives for benzyl chloride as they do not fully protect human health from exposure.</p> <p>Rec.: We urge the government to shift its risk management approach to an approach that is more preventative - a focus on the prohibition of this chemical in consumer and industrial products.</p> <p>Rec.: The government should take steps to evaluate the cumulative and synergistic impacts from all sources of</p>

Specific sections of risk management scope for benzyl chloride (CAS RN: 100-44-7)	Summary of proposed government measures & other measures	CELA & CSM - Comments	Recommendations
		<ul style="list-style-type: none"> Given the properties of benzyl chloride and with several possible exposure routes that have not been fully assessed, a protective approach for managing benzyl chloride would be to aim to phase out its usage (including the presence of residues) in cosmetics, consumer and industrial products. 	benzyl chloride, even for chemicals used as intermediates.
<p>Section 9.1 Proposed risk management approach</p> <p>Notification requirement</p>	<p>The risk management being considered for benzyl chloride is to require notification to the federal government regarding any potential changes in the use pattern for benzyl chloride. This is to ensure that the potential for exposure to the Canadian population does not substantially increase.</p>	<ul style="list-style-type: none"> The notification process being proposed lacks any details as to how the process would fit into the current regulatory system for the management of chemicals. It does not specify if there is a public component to this proposed risk management element. Several comments from the public have been raised in regards to the lack of such information particularly as a proposed management measure. We are not in agreement with a proposal that does not outline details or does not appear to reduce the levels of usage of benzyl chloride. At the present time, the level of use for this chemical is extremely high. The notification requirement appears to be more of a means to notify the government of substantial increases in usage of this chemical which could imply that the current level of usage is considered acceptable by the government. The proposal does not specify what a substantial increase in usage entails. The use of a notification process will not promote a reduction of this chemical, let alone aim to phase out the chemical with time. Therefore, the status quo would be maintained. 	Rec.: We urge the government to work towards the goal of phase out through reduction in use of benzyl chloride, rather than rely on a notification system to inform the government of increased usage.
Section 9.1	The addition of	<ul style="list-style-type: none"> We have recently made comments to outline our concern on 	Rec.: We support the aim to prohibit the

Specific sections of risk management scope for benzyl chloride (CAS RN: 100-44-7)	Summary of proposed government measures & other measures	CELA & CSM - Comments	Recommendations
<p>Proposed risk management approach</p> <p>Cosmetics sector</p>	<p>benzyl chloride to the Health Canada Cosmetic Ingredient Hotlist.</p>	<p>the use of the Cosmetic Ingredient Hotlist (Hotlist) to prohibit the use of CEPA toxic chemicals in cosmetic products.⁴ While we agree with the intent of the Hotlist for prohibition, we are concerned that the use of a non-regulatory tool such as the Hotlist may not be sufficient to ensure that this chemical is not used in cosmetic products. We have stated our concerns with the post notification process required for submission of ingredients to the government and the absence of clear oversight for compliance to the Hotlist. These comments remain relevant for the listing of benzyl chloride under the Hotlist. However, this listing should be part of a strategy to phase out this chemical.</p> <ul style="list-style-type: none"> • There was a lack of consideration for the presence of benzyl chloride as a residue in imported cosmetic products (including other products). This could potentially increase the presence of this chemical in Canada, hence causing a possible increase in human exposure. • Canada should follow the lead of Europe which has prohibited the use of benzyl chloride in cosmetic products under Directive 2004/93/EC amending Directive 76/768/EEC⁵ 	<p>use of benzyl chloride in cosmetic products. Hence the addition of benzyl chloride, including its presence as a residue or a contaminant, to the Cosmetics ingredient Hotlist as a banned substance is supported as long as steps are taken to make the Hotlist a regulatory tool rather than a non-regulatory tool.</p> <p>Rec.: Other amendments to the Hotlist should also be undertaken including the change from a post notification process to a pre notification process for submission of ingredients by industry.</p>
Section 9.1	In the event that	• Based on our review of the Risk Evaluation Framework for	Rec.: The government should propose

⁴ CELA and CSM. Response to List of Prohibited and Restricted Cosmetic Ingredients (The Cosmetic Ingredient Hotlist) and Proposed Changes. December 2009. Accessed at <http://s.cela.ca/files/696CMP-CosmeticHotlist.pdf>.

⁵ Environment Canada and Health Canada. Proposed Risk Management Approach for Benzene, (chloromethyl)-(Benzyl Chloride) Chemical Abstracts Service Registry Number (CAS RN): 100-44-7. November 2009. Accessed at http://www.ec.gc.ca/substances/ese/eng/challenge/batch6/batch6_100-44-7_rm.cfm.

Specific sections of risk management scope for benzyl chloride (CAS RN: 100-44-7)	Summary of proposed government measures & other measures	CELA & CSM - Comments	Recommendations
<p>Proposed risk management approach</p> <p>Proposal to add benzyl chloride to the Environmental Emergency Regulations.</p>	<p>benzyl chloride were to enter the environment as a result of an environmental emergency, the government has concluded that the substance meets one of the criteria set out in section 200 of CEPA 1999. The Government has proposed to add benzyl chloride to the <i>Environmental Emergency Regulations</i> with a proposed threshold of 4500 kg set through the Risk Evaluation Framework for sections 199 and 200 of CEPA 1999 (Environment Canada 2002).</p>	<p>Section 200 of CEPA 1999, it remains unclear how the threshold of 4500 kg for this chemical was determined. Regardless of this threshold, this substance should be considered a candidate for environmental emergency plans based on its health impacts and the lack of flexibility in the government's proposal to account for the possibility of an increase in volume in the future. Environmental emergency plans support greater accountability to workers and the community.</p> <ul style="list-style-type: none"> • The government's current approach to benzyl chloride is not a prohibition and as such, there may be stockpiles of this chemical in facilities. The presence of stockpiles at the facility plants should provide additional justification for adding this substance to a list under the Environmental Emergency Regulations • The inclusion of emergency plans provides a response plan should accidents or spills occur, particularly for workers and the surrounding communities. 	<p>adding benzyl chloride to the <i>Environmental Emergency Regulations</i> based on its carcinogenicity and genotoxicity. However, such plans should be connected to other aspects of an action plan for elimination of this chemical.</p>

Application of Significant New Activity for selected chemicals under Batch 6

We would like to provide the following commentary on the government's proposal to apply Significant New Activity (SNACs) on three batch 6 chemicals:

- 1-Propene, 3-chloro-: CAS RN. 107-05-1,
- 1,2-Benzenedicarboxylic acid, bis(2-methoxyethyl) ester: CAS RN 117-82-8
- 2,7-Naphthalenedisulfonic acid, 4-amino-3-[[4'-[(2,4-diaminophenyl)azo][1,1-biphenyl]-4-yl]azo]-5-hydroxy-6-(phenylazo)-, disodium salt: CAS RN 1937-37-7

We have previously made very specific comments on the inappropriate use of SNACs for Batch 6 chemicals⁶ as well as other chemicals assessed under the Industry Challenge of the Chemicals Management Plan. We note these concerns again:

a) Toxic under CEPA 1999: These substances should be considered toxic under CEPA despite evidence that they are not in use in Canada and lacking other data (uses, volume, historical data) submitted by industry through the application of Section 71 of the Act. By designating these substances toxic under CEPA, a signal would be sent to any other potential users and importers that these chemicals are toxic and should not be permitted re-entry into the Canadian market. Government could use other tools under CEPA to ensure that future uses of these substances are not permitted in Canada, such as adding these substances to the *Prohibition of Certain Toxic Substances Regulation*. The application of SNAC provisions as proposed by government has limits and could not guarantee that these substances would be prohibited from future use in Canada.

b) Reporting threshold of 100kg: With the reporting threshold for the s. 71 survey set at 100 kg/year, the surveys conducted cannot account for the number of possible users that fall below the threshold and who are not required to report to the survey. The lack of consideration on the aggregate use of these chemicals raises significant concerns as to the validity of the conclusion made for a SNAC application. The application of the 100 kg threshold for reporting is viewed as a gap in the government approach.

⁶ See CELA and CSM. A Response to the Proposed Risk Management Approach for Chemicals Management Plan Industry Challenge Batch 6 Substances Published in Canada Gazette Part I, Vol. 143, No. 22— May 30, 2009. 2009. Accessed at http://s.cela.ca/files/661_CMP_CELA_and_CSM_batch_6_SLRA%20final.pdf.

c) Assessment under Schedule 6 of NSN – lack consideration of adequate chronic toxicity and other hazard data: The application of SNACs is inappropriate for these high priority chemicals as it does not result in a preventative approach but rather a ‘wait and see’ approach. This application will not guarantee that the Canadian environment and human populations will not be exposed to these substances in the future, despite the requirements by future notifiers to fulfill requirements outlined under Schedule 6 of the NSN Regulations. The toxicity data would be minimal as notifiers will not be required to submit data for chronic toxicity, endocrine disruption, or neurodevelopmental toxicity. It is our view that revisions to this program are required to accommodate future assessment of chemicals categorized as PBIT substances.

d) Lack of public comment under NSN regulations: Finally, we have an on-going concern that the application of SNACs on these substances will mean that the public will not have opportunities to engage in the assessment process as any subsequent assessments under the NSN regulations do not include such a provision. The public should have access to this process, particularly as it has now been expanded to address substances that were originally on the DSL.

Furthermore, we have attached as Appendix 1, a letter submitted by a number of non-governmental organizations to the government in 2007 on the use of SNACs. These comments continue to be relevant and have yet to be addressed.

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APPENDIX A

NGO Letter dated February 14, 2007 in response to *Canada Gazette*, Part 1, Vol. 140, No. 49, December 9, 2006 Notice of intent to amend the Domestic Substances List to apply the Significant New Activity provisions under subsection 81(3) of the *Canadian Environmental Protection Act*, 1999 to 148 substances

February 14, 2007

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**Re: *Canada Gazette*, Part 1, Vol. 140, No. 49, December 9, 2006
Notice of intent to amend the *Domestic Substances List* to apply the Significant New
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Canadian Environmental Protection Act, 1999 to 148 substances**

Environment Canada's Use of SNAcs

On December 9, 2006, Environment Canada posted a notice in the *Canada Gazette* indicating its intention to amend the Domestic Substances List (DSL) by applying the Significant New Activity (SNAc) provisions under subsection 81(3) to 148 substances. The proposal to limit the use of these substances through restrictive SNAcs is pragmatic in light of the fact that the government does not currently have the ability to delete these substances from the DSL. However, since the review of the *Canadian Environmental Protection Act, 1999* (CEPA '99) is now underway, the government should seek an amendment which would allow substances to be deleted from the DSL in these and other appropriate circumstances.

Following categorization, an industry survey under section 71, and a draft screening assessment under section 74, these substances are believed to be:

- Persistent, Bioaccumulative, and inherently Toxic (PBiT), and
- *Not* presently imported or manufactured in Canada in quantities above 100 kg per year, and therefore not considered to be CEPA-toxic under section 64 due to the lack of Canadian exposure.

The conclusion that these substances are not being imported or manufactured in quantities above 100 kg / year derives primarily from the results of an industry survey which was published in the *Canada Gazette* on March 4, 2006. In that survey, industry stakeholders were asked to indicate whether they manufactured or imported the substances in quantities more than 100 kg during the 2005 calendar year. While the intention of the survey was to identify those substances which are no longer in Canadian commerce (i.e. the 148 substances now subject to the SNAc notice), the survey had a

number of limitations.⁷ These limitations create the possibility that substances manufactured or imported in some year other than 2005, or in amounts smaller than 100 kg, continue to pose a hazard in Canada.

The SNAc proposal would require industry to reassess these substances under the New Substances Notification Regulations (NSNR) before undertaking any significant new use. The NSNR process is only triggered once the quantity of the substance reaches 100 kg / year, and the SNAc notice defines “significant new activity” as any activity involving more than 100 kg of the substance in a calendar year. This is problematic for two reasons. First, as noted above, such activities could already be occurring, and government would not be aware of them based on its 2006 survey results. It is unclear whether existing / ongoing uses not captured by the survey would be considered significant “new” uses and subject to the NSNR. Second, the threshold of 100 kg could still allow for damage to be done by these hazardous substances. The reasons for this could include their persistence in the environment, synergistic effects with other DSL substances, or potential for long range transport, to name a few.

There are other problematic aspects of the NSNR approach which should be modified with respect to these 148 substances. For instance, there is a lack of adequate and effective public transparency in the NSNR assessment process. Under that process, the Minister is required to post a notice in the *Canada Gazette* upon adding a substance to the DSL or the NDSL, granting a waiver, or imposing a condition, prohibition, or SNAc restriction. However, the public is not informed of new notifications, nor is the public typically given the opportunity to comment on draft risk assessment reports before final decisions are made.

Given the hazardous properties of these 148 substances, we urge the government to improve upon the NSNR process by imposing stricter transparency requirements through the Chemicals Management Plan. The public is entitled to be informed of, and comment upon, any proposed commercial use of these substances.

The SNAc notice goes on to indicate that, prior to the commencement of the proposed new activity, notifiers should submit the NSNR information requirements contained in:

- Schedule 4,
- Item 8 of Schedule 5, and
- Item 11 of Schedule 6.

Schedule 4 is the basic, minimal data set which is required of new substances which are being notified at the lowest volume trigger. The Schedule includes primarily identification information, and does not require the production of any test data (beyond

⁷ Note: early in 2006, NGOs voiced a number of concerns regarding the structure of the survey. Most notably, the survey failed to capture companies that used the substances in 2004 or previously, or planned to use the substances in 2006 or subsequently, or used the substances in amounts under 100kg. See J. Ginsburg and F. de Leon, “Letter to Environment Canada regarding a Domestic Substances List (DSL) categorization survey” (16 March 2006), online: <cela.ca/uploads/f8e04c51a8e04041f6f7faa046b03a7c/537EC_surveys.pdf>.

that which is already in the possession of the manufacturer or importer). Item 8 of Schedule 5 and Item 11 of Schedule 6 relate only to exposure information. Accordingly, should industry seek to (re)introduce the substances onto the market at quantities above 100 kg, they could be allowed to do so without submitting any test data whatsoever.

Government has indicated that “considering the hazardous profile of these substances, there is limited possibility that they would be reintroduced.”⁸ However, given the fact that 1) government conducted its categorization and screening assessment without requiring any new test data, and 2) these substances are already believed to be highly hazardous, there should be no opportunity for continued use without industry demonstrating through scientific testing that the substances are safe. This would require proponents to provide, at a minimum, substantive testing data equivalent to the most rigorous data schedule provided under the NSNR, including:

- Data from one repeated-dose mammalian toxicity test, of at least 28 days duration, which test is selected on the basis of the most significant route of potential human exposure;
- Mutagenicity data obtained from an *in vitro* test, with and without metabolic activation, for chromosomal aberrations in mammalian cells; and
- For chemicals having a water solubility of greater than or equal to 200 µg/L, adsorption-desorption screening test data, the hydrolysis rate as a function of pH and, if known, an identification of the products of the hydrolysis.

Further, we would augment the NSNR test schedules by requiring companies notifying these substances under the NSNR to also submit data on chronic toxicity, endocrine toxicity, neurodevelopmental toxicity, as well as information regarding safer alternatives. Additionally, the government should provide explicit guidance on how the precautionary principle will be applied to regulatory decisions affecting these substances, in light of their hazardous characteristics identified through the categorization process.

Recommendation: The Government of Canada should seek an amendment to CEPA ‘99 which would allow substances that are no longer in Canadian commerce to be deleted from the DSL.

Recommendation: Any existing or ongoing uses of the 148 substances which were not captured by the 2006 survey should be considered “new” and subject to the NSNR requirements. Before and until such time as they have received approval under the NSNR, government should impose mandatory risk management measures to eliminate these uses from the Canadian market.

Recommendation: The Government of Canada should establish a process to enhance public transparency and participation in any notification to the NSNR involving these 148 substances. The public should be informed of any notifications

⁸ Government of Canada, “Provisions for Significant New Activities and Outcome from DSL Categorization” (Presentation at the Chemicals Management Plan: Technical Briefing, Ottawa, 15 December 2006).

and have the opportunity to comment on draft assessments before final decisions are made regarding the use of these substances at any quantity.

Recommendation: Given the hazardous properties of these substances, the SNAC notice should define *any* activity involving these substances to be new, not merely those activities in excess of 100 kg / year.

Recommendation: These 148 substances should not be approved for import, manufacture, or use unless industry can demonstrate their safety through scientific testing. At a minimum, industry should be required to submit testing data equivalent to the highest schedule for non-NDSL substances under the NSNR. Additionally, notifiers should be required to submit data on chronic toxicity, endocrine toxicity, neurodevelopmental toxicity, as well as information regarding safer alternatives.

Health Canada's Use of SNACs

The Government of Canada has indicated that in early 2007, Health Canada will apply the SNAC provisions to certain substances that have inherently hazardous properties for humans. We have yet to see the details of this proposal, however, the comments provided above may also be relevant to Health Canada's process. We look forward to providing additional comments once further information becomes publicly available.

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