A Response to the Proposed Risk Management Approach for Chemicals Management Plan Industry Challenge Batch 2 Substances Published in *Canada Gazette* Part I, Vol. 143, No. 5 — January 31, 2009

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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. 5 — January 31, 2009 release of the proposed risk management approach reports for selected substances identified under the Chemicals Management Plan (CMP), Batch 2 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 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.

1.0 General Comments

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 Batch 1, 2, 3, and Batch 4 substances, including the final assessment and risk management for Bisphenol A (under Batch 2 of the Industry Challenge). Our organizations have expressed support for proposed assessment results and some aspects of proposed management instruments on specific chemicals but we have also elaborated on their gaps and limitations. Consequently, we have developed appropriate substantial recommendations to address these gaps and limitations.

Before we proceed to outline our comments, please note that we have not provided commentary on the final assessment results or proposed measures to be undertaken on all substances in Batch 2 found to be toxic under the *Canadian Environmental Protection Act* (CEPA). The absence of such commentary does not mean that we do not have concerns about the final assessment results or the proposed risk management options by the departments. The comments presented below may be considered as examples of the range of concerns we have had on final decisions made by government on toxic chemicals assessed to date.

Furthermore, the commentary and range of issues presented below on the proposed measures on toxic chemicals demonstrate the level of protection that should be considered for human health and the environment. Our organizations want to ensure that the government utilizes the full extent of its authority to promote and implement the elimination or phase out of the most toxic chemicals in the Canadian market.

In this submission, our organizations continue to highlight concerns about substances that have been previously noted for other substances under the Industry Challenge. These issues continue to be relevant as we discuss proposed risk management options for Batch 2 substances. We have provided specific comments on the following substances:

- C.I. Pigment Red 104 (CAS RN 12656-85-8);
- C.I. Pigment Yellow 34 (CAS RN 1344-37-2);
- Decamethylcyclopentasiloxane (D5) (CAS RN 541-02-6);
- Octamethylcyclotetrasiloxane (D4) (CAS RN 556-67-2); and
- Cyclohexasiloxane, dodecamethyl (D6) (CAS RN 540-97-6)

1. Safe substitution: There is an urgent need in the proposed risk management approach documents for more consideration of safe alternatives for substances in Batch 2 as the current information is extremely limited. It is our view that the identification of all possible safe alternatives should be included in the assessment process. This type of information would be a positive contribution to the overall assessment and management process, particularly as the government makes a determination of toxicity on these substances. It is also necessary that a process be in place to assess or screen the safety of the substitutes under CEPA. This process should include the review of toxicity data (both acute and chronic), pertinent to both human health and the environment. The safety of alternatives is as important as taking action on the substance it is intended to replace. Finally, the screening of safe alternatives should incorporate an effective public engagement component so as to promote full transparency.

2. Carcinogens: Some substances in Batch 2 were identified as human carcinogens with possible reproductive toxicity and developmental toxicity. For example, D5 (CAS RN 541-02-6) was classified as a possible carcinogen by the Danish EPA. For these substances, we are of the opinion that the establishment of safe levels for human exposure to these substances cannot be accurately determined. Therefore, for any substances found to be carcinogenic or having the potential to be carcinogenic, we maintain that the appropriate government approach should be to phase out or eliminate these substances. In exceptional cases where there is an essential use of a substance and where safe substitutes may not currently exist, a time limited exemption to a phase out should be considered. However, this is only recommended on a case by case basis with a goal to phase out carcinogens within a specific timeframe. This provides time for identification of an alternative with the ultimate goal of a phase out.

For many of the substances considered carcinogenic, the government has not considered a phase out approach but rather, has relied on weaker measures such as

future notifications or substance reduction. This current approach does not adequately protect human health.

3. Full life-cycle consideration: While there has been some progress in acknowledging the need to consider the life cycle of a substance, government assessments require improvement in this area. A complete investigation and consideration of the full life cycle of a substance is necessary to make decisions on the impact of its toxicity to the environment and human health. All final assessments for Batch 2 substances have not considered the full life cycle fate of these substances. For example, the residues or contaminants that may be produced at different phases of production or degradation products or metabolites have been generally ignored in the assessment process. Degradation products may result from leaching due to disposal methods such as landfills. The consideration of each phase, including post disposal method is essential for each assessment. Similarly, the consideration of impacts of metabolites or degradation products from these substances would also enhance the quality of the assessments.

It is critical that the government improves its assessment process to account for exposure and fate of a substance throughout its life cycle (e.g., breakdown products, metabolites) including at the disposal phase. In our view, the absence of a full life cycle consideration affects the final decision on toxicity as well as the quality and type of the management measures necessary to protect health and the environment.

4. Vulnerable populations: The assessments completed under the CMP to date have included information on exposure of substances for some vulnerable subpopulations such as children. However, other vulnerable subpopulations (e.g., people with chemical sensitivities, people of low income, workers, and aboriginal communities) are not considered in the assessment process and the approach to address vulnerable populations has not been consistently applied to all substances. This is the case with Batch 2 substances.

The impacts of exposure to substances to other vulnerable subpopulations such as aboriginal communities in the far north, for example, have not been adequately assessed with regards to Batch 2 chemicals such polysiloxanes, despite evidence that these substances have the potential for long range travel.

Although the government's assessment noted that these siloxanes are persistent and would likely undergo degradation, the government has failed to further investigate, in an appropriate manner, the extent of impact to populations that may be the recipients of these substances.

Even for substances found to be human health priorities, the consideration of specific vulnerable subpopulations such as aboriginal communities that may be living in close proximity to some sources of toxic substances should be considered in the assessment processes as exposure to these substances could result in significant health

implications for members of such communities. Government attention is needed to address this gap.

For chemicals such as siloxanes which are found in thousands of products, including consumer and personal products, the impacts to vulnerable groups should be carefully considered. Government should expand the scope of the assessments to consider the impacts of exposure to the mentioned vulnerable subpopulations.

The quality of risk assessments conducted under the CMP may be enhanced and the final decisions on these substances may differ if the above issues were to be addressed in a more fulsome and rigorous manner.

2.0 Comments and recommendations specific to some substances in Batch 2

Some of the five substances listed below were initially identified as having a high priority for screening assessment as they were originally found to meet the ecological categorization criteria for persistence, bioaccumulation potential and inherent toxicity (PBiT) to non-human organisms and are believed to be commerce in Canada. Based on the draft screening level risk assessment results, some of these substances did not satisfy the criteria for CEPA 'toxic' and others did. The tables below highlight the draft and final assessment decisions for these five substances (see Table 1), outline the proposed risk management strategies, and comments and recommendations to government proposals for the two pigments (C.I. Pigment Yellow 34 and C.I. Pigment Red 104) (see Table 2), and two siloxanes (i.e., D4 and D5) (see Table 3).

Table 1: Results of categorization and Screening Level Risk Assessment (SLRA) for selected substances in Batch 2 of the Chemical Management Plan (CMP) Industry Challenge

Substances & CAS RN	Proposed draft SLRA result* under CEPA S. 64 toxic	Results of SLRA* Human health concerns	Draft SLRA*- Persistence, Bioaccumuation and inherent Toxicity* (PBiT)	Final SLRA decision* under CEPA S. 64	Final SLRA decision* on P, B, iT
C.I. Pigment Yellow 34 **CAS RN 1344-37-2**	Toxic	• Greatest potential for exposure to humans (GPE) • Carcinogenicity, • reproductive toxicity, • developmental toxicity	PBiT	Toxic	P
C.I. Pigment Red 104 **CAS RN 12656-85-8**	Toxic	• Greatest potential for exposure to humans (GPE) • Carcinogenicity, • reproductive toxicity, • developmental toxicity	PBiT	Toxic	P
Decamethylcyclopentasiloxane (D5) **CAS RN 541-02-6**	Toxic	• Intermediate potential for exposure (IPE) • Danish EPA - carcinogenic	PBiT	Toxic Under Section 64(a)	P, iT**
Octamethylcyclotetrasiloxane (D4) **CAS RN 556-67-2**	Toxic	• Intermediate potential for exposure (IPE) • Possible reproductive toxin	PBiT	Toxic Under Section 64(a)	P, iT**
Cyclohexasiloxane, dodecamethyl (D6) **CAS RN 540-97-6**	Toxic	• Intermediate potential for exposure (IPE)	PBiT	Toxic	Not P or B

*SLRA - Screening Level Risk Assessment reports, see: http://www.chemicalsubstanceschimiques.gc.ca/challenge-defi/batch-lot_2_e.html
** Bioaccumulation (B) is uncertain due to conflicting data.

Table 2: C.I. Pigment Yellow 34 (CAS RN 1344-37-2) and C.I. Pigment Red 104 (CAS RN 12656-85-8) - Commentary and recommendations to specific management proposals

Specific sections of Risk management scope documents for C.I Pigment Red 104 and C.I Pigment Yellow 34	Proposed government measures & other existing measures	CELA & CSM - Comments	Recommendations
7.1 Alternative Chemicals or Substitutes	Substitutes - may **not** have been assessed under section 64, CEPA 1999.	This is a gap in the document. Steps should be undertaken to establish a process to assess effectiveness and safety of alternatives to these pigments.	**Rec: All substitutes for these pigments should be adequately assessed for effectiveness and safety under CEPA 1999 before they are used as replacements.**
7.1 Alternative Chemicals or Substitutes	For specialized industrial and military applications – possibly no suitable replacements for C.I. Pigments Yellow 34 & Red 104 - for colour-fastness and corrosion resistance	• The government's claim that no substitutes are available for specialized industrial and military applications requiring colour-fastness and corrosion resistance are not specific enough as descriptions for actual end use. This is to broad and does not outline the type of efforts and challenges faced for these applications. However, we do recognize that for military uses, the exact nature of uses may not be public knowledge. • Further investigation for these applications is required before such exemptions should be considered. • Special industrial application for corrosion resistance – there is established literature reviewing corrosion resistance using various combinations of corrosion inhibitors. This is not new science. • Special industrial application for colour fastness – depending on application, colour fastness is attainable with substitutes but generally at an increased price.	**Rec: Exemptions should not be considered for specialized industrial applications for corrosion resistance and colour fastness unless additional details are provided. Responses to these potential exemptions should be investigated in a precautionary manner and be undertaken on a case by case basis. Furthermore, time limited exemptions should be granted to ensure resources are directed to the identification and/or development of safe substitutes.**
7.2 Alternative Technologies and/or	Several grades of C.I. Pigments Yellow 34 and Red 104 have a	• It may be appropriate to use these encapsulated pigments for INDUSTRIAL use only and where safe, alternative pigments are not available.	**Rec: Further explanation is required as to the mode of action and benefits for the encapsulated versions of these**

Specific sections of Risk management scope documents for C.I Pigment Red 104 and C.I Pigment Yellow 34	**Proposed government measures & other existing measures**	**CELA & CSM - Comments**	**Recommendations**
Techniques	dense amorphous silica encapsulation around the particles – reduction of solubility and bioavailability.	However, the current proposed risk management report provides very little information in this regard. A further investigation on the impact and toxicity of these encapsulated pigments is required, similar to the approach recommended for alternatives. • It should be further noted that it is inappropriate to use price as a significant criteria for determining the use of these encapsulated pigments. We recognize that alternative to lead chromate free pigments can cost more depending on the end use and desired properties. The priority in this regard should always be based on the safety to human health and the environment rather than price of the alternatives.	**pigments as an anti-corrosive pigments, if they are to be considered to be replacements for CI Pigment Red 104 and CI Pigment Yellow 34.** **Rec: The government proposed risk management report should be expanded to explain how these encapsulated pigments could be used in plastic processing, particularly if this is a special application because of heat stability. This should be specifically noted.** **Rec: Also, we recommend that industry evaluate other safe heat stable pigments for this type of application.**
9.1.1 Future uses	Proposed creation of a provision whereby any proposed future uses of C.I. Pigments Yellow 34 and Red 104 would be subject to notification of the federal government under CEPA 1999.	• Apart from notification, the purpose of this action is unclear, particularly if this notification is similar to a Significant New Activity. We ask whether this notification is required solely to inform the government of intended use or is it a process whereby which the notifier has to justify any future uses of these pigments? • The use of notification provision is an insufficient measure to deal with CEPA toxic substances. It represents the status quo in the use of these pigments in Canada.	**Rec: We do not support the use of future notification only as a measure for these substances** **Rec: These pigments should be targeted for phase out. In achieving this goal, industry should be given clear timelines to reduce and phase in other government assessed alternatives, where possible.**
9.1.2 Pigment and Plastics Sectors	Continued use of these pigments in commercial and non-consumer uses including plastics and some outdoor	• There appears to be no adequate justification to use these pigments because of their carcinogenic effects. • Furthermore, the government has evidence that for specific application such as pavement markings,	**Rec: We recommend that a goal to phase out the use of these pigments should be adopted based on its carcinogenic properties.**

Specific sections of Risk management scope documents for C.I Pigment Red 104 and C.I Pigment Yellow 34	Proposed government measures & other existing measures	CELA & CSM - Comments	Recommendations
	applications. Phasing out of traffic coatings containing these pigments by December 2009.	many companies have successfully produced lead free pavement markings. • There may be cases which require special applications of these pigments. In these cases, consideration should not be given until full details of its use and length of continued use are provided.	**Rec: In cases where exemptions may be considered, decisions may be made on a case by case basis only. Should exemptions be granted, a time-limited exemption with an ultimate goal of phase out is essential.** **Rec: The use of encapsulated versions for anti-corrosion usage requires further investigation as a possible alternative technique for these pigments.**

Specific sections of Risk management scope documents for C.I Pigment Red 104 and C.I Pigment Yellow 34	**Proposed government measures & other existing measures**	**CELA & CSM - Comments**	**Recommendations**
9.1.3 Industrial Use Sector	Controlled Products Regulations - compliance	• There are concerns that information and decisions pertinent to these pigments as a result of the CMP may not be adequately relayed to other levels of government, occupational and health institutions, unions and the workplace. • The matter of compliance continues to be a concern for the public regarding progress on reducing and eliminating the use of toxic substances in Canada. There has been very limited evaluation on the effectiveness of the measures taken to date under CEPA on all CEPA toxic substances. As implementation efforts under CMP progresses, the focus on compliance for managing toxic chemicals will increase. Some areas of concern focus on the progress towards reduction as well as the appropriate use of chemicals for industial applications and use in consumer and personal care products.	**Rec: We recommend that measures be taken to disseminate information and decision making resulting from the CMP about these pigments to occupational and health institutions, unions, and workplaces. This is seen as an integral part of the link with civil society and one that is essential in determining the effectiveness of government's implementation of decisions regarding the management of these industrial chemicals.** **Rec: Government should set timelines for this dissemination of information.** **Rec: The government should review the effectiveness of its compliance mechanism to monitor the progress towards reduction for on CEPA toxic substances.** **Rec: The government should enhance its enforcement efforts to ensure compliance with regards to the management of toxic substances including these two pigments.**
9.1.4 Cosmetics Use Sector	Cosmetic Ingredient Hotlist – lead and its compounds and lead acetate are listed as prohibited compounds on the list. No further risk management	• Despite the current regulations, lead has been detected in some lipsticks. It is not known if cosmetic manufacturers analyze their pigments for lead contamination, despite claims from Health Canada that companies are required to comply with the Cosmetic Ingredient Hotlist. There is no safe exposure level for lead. Some may argue that these	**Rec: Improve government compliance and enforcement mechanism on substances identified as toxic under CEPA. One way to support this recommendation is to require increase government enforcement through random testing of cosmetic products**

Specific sections of Risk management scope documents for C.I Pigment Red 104 and C.I Pigment Yellow 34	**Proposed government measures & other existing measures**	**CELA & CSM - Comments**	**Recommendations**
	proposals were considered necessary under CEPA 1999.	levels are very low and do not pose a human health risk. • Despite the listing of lead on the Cosmetic Ingredient Hotlist, the addition of these pigments should be made to the Hotlist to ensure clarity on the type of substances that lead be present in and can affect human health.	**therefore ensuring that these products do not contain prohibited substances such as lead.** **Rec: Results from random testing should be made available to the public.**
9.1.5 Food and Beverages	Pigments not listed in the Food Additive Tables of Division 16 of the *Food and Drug Regulations* - not permitted as a food colour in Canada. Risk management considerations not applicable.	• Although government has indicated that these pigments are not permitted in food packaging materials, the government should consider a requlation to stipulate these restrictions.	**Rec: Government should develop regulations to prohibit the use of these toxic chemicals in food packaging materials.**
The *Surface Coating Materials Regulations* issued under the *Hazardous Products Act* (Canada 2005) – there are **exemptions** for the total lead concentration in surface coating materials not to exceed 600 mg/kg when a dry sample is tested.	Seven (7) coatings were cited as being exempt but a warning label is required to indicate the presence of lead (chromate) if the 600 mg/kg limit is exceeded.	• It is not understood why some of these coatings would be exempt since most will chip and degrade with time. • The regulations currently outline exemptions for materials used for purposes of arts, crafts or hobbies, other than those materials targeted for use by children. Our concerns focus on the fact that these exemptions do not guarantee that these materials are not be used by children, regardless of the warning labels. Such exemptions should not be permitted. It is more protective to prohibit the use of these pigments in all surface coatings to ensure protection to all users, particularly children. • *Surface Coating Materials Regulations* do not apply to surface coatings on playground structures but the Canadian Standards Association has a voluntary standard that requires the coatings of children's	**Rec: The Surface Coating materials Regulation should be revised to reflect recent advancements in pavement markings.** **Rec: The regulations should have a goal of phase for uses of these pigments. Where exemptions are required, these should be considered on a case by case basis and be time limited. In those situations where exemptions are considered, pigments may be used when there are no safe suitable alternatives.** **Rec: We recommend that the exemptions lead concentration for**

Specific sections of Risk management scope documents for C.I Pigment Red 104 and C.I Pigment Yellow 34	Proposed government measures & other existing measures	CELA & CSM - Comments	Recommendations
		play spaces and equipment have non-toxic and non-lead-based coating for all new equipment and refinishing of existing equipment. The voluntary requirement should be changed to a mandatory requirement. • The government assessment and risk management documents do not acknowledge or discuss the on-going international initiative which aims to phase out the use of lead in paints. This is a relevant international development that should be included in the risk management document for these pigments.	**surface coatings materials for arts, crafts or hobbies should be deleted in the *Surface Coating Materials Regulations* to ensure protection of all users, particularly children.** **Rec: The government should require mandatory use of non-toxic and lead free coating for all children's play areas and equipment. Currently, there is a voluntary standard in place.** **Rec: We recommend that the use of lead chromate containing coatings for agricultural and industrial purposes should not be granted an exemption.** **Rec: Since there is an expectation that obsolete industrial and, in particular, agricultural equipments are often abandoned outdoors, we recommend that appropriate safe disposal methods are developed for these equipments to address the degradation of coating over time.** **Rec: We urge the government to support the on-going international initiative to phase out lead in paints.**

Table 3: Cyclotetrasiloxane, octamethyl- (D4) (CAS RN: 556-67-2) and Cyclopentasiloxane, decamethyl-(D5) (CAS RN: 541-02-6) - Comments and recommendations to specific sections of proposed risk management approach

Specific sections of Risk management components report	Proposed government management measures & other considerations	CELA & CSM Comments	Recommendations
1.2 Final Screening Assessment Reports for D4 and D5	D4 and D5 are entering the environment in a quantity or a concentration or under conditions that have or may have an immediate or long term harmful effect on the environment or its biological diversity. The final assessment reports "also indicated that while D4 and D5 have bioaccumulation potential in biota, it is not possible to conclude at this time that they meet the criterion for bioaccumulation.	• We are in agreement with the conclusion that D4 and D5 be classified toxic under S.64 (a) of CEPA. • However, we question the conclusion that D4 and D5 "are not entering the environment in a quantity or a concentration or under conditions that constitute or may constitute a danger in Canada to human life or health." • Furthermore, we strongly disagree with the government's conclusion on bioaccumulation of D4 and D5. • Given the available scientific data presented in the assessment reports, the precautionary principle should have been applied to make a conclusion on the toxicity of these substances, particularly on bioaccumulation criteria. In our view, the data on bioaccumulation indicate that D4 and D5 meet the threshold for bioaccumulation and appropriate action should be taken based on the data. The assessment reports do not provide sufficient rationale to indicate that the new data considered on bioaccumulation has been reviewed extensively by a third party. • An appropriate measure for D4 and D5 should be elimination or phase out.	**Rec: We support the conclusion of toxic under CEPA for D4 and D5.** **Rec: We strongly oppose the decision by government for not concluding the bioaccumulation of D4 and D5 as it does not reflect the application of the precautionary principle.** **Rec: Due to the properties for P, B and iT as well as the high volume use for D4 and D5 presented in the assessment report, the government should establish a goal of elimination or phase out of D4 and D5 in industrial applications as well as consumer products and personal care products. Measures that do not support these goals will result in continued exposure to Canadians and the environment.** **Rec: D4 and D5 should be added to the Toxic Substances List (Schedule 1) of CEPA.**
7.1 Alternative Chemicals or Substitutes	Possible alternatives to D5 and cyclomethicone in personal care products cited. Possible D5	• It is appreciated that replacements/alternatives for both D4 and D5 cross a wide spectrum of products may exist. But the document has not explored, to any degree, these alternatives and the potential challenges that exist to determine the equivalent their effectiveness. In general, our concerns focus	**Rec: The government should undertake a process to identify and assess the effectiveness and safety of alternatives that exist for any alternatives for D4 or D5. No alternatives should be considered safe**

Specific sections of Risk management components report	Proposed government management measures & other considerations	CELA & CSM Comments	Recommendations
	replacements in the dry-cleaning process, repair and maintenance cleaning operations. Effectiveness as substitutes not known. Assessment not determined section 64 of CEPA 1999.	on the lack of process or discussion in the government's document for assessing the safety of alternatives. • Due to the properties of D5 and D4, it would be expected that any alternatives that exist should be identified for the purposes of developing protective management options. Therefore, the process to assess alternatives should highlight the overall functions and properties that are similar to those achieved when D5 and D4 are used. • The proposed risk management document does not identify any possible D4 alternatives. Even for industrial uses (silicone polymers, etc), alternatives have not been listed for consideration and the rationale for this was not stated. We recognize that alternatives for some of these applications could be quite problematic particularly for specialized applications. However, these matters should not be a basis for requiring the information.	**unless this type of assessment is undertaken by government.** **Rec: Since D4 and D5 are used and imported in very high volumes and no information on alternatives have yet to be included in the government reports, we recommend the formation of a task force consisting of industry, government and other stakeholders, to assess the impacts to environment and health of all alternatives to D4 and D5 in consumer products, including personal care products (domestic and imported).** **Rec: Where polysiloxanes are traditionally used in cosmetics, there are some equivalent products on the market that do not contain polysiloxanes. This indicates that some manufacturers have been progressive in this regard therefore indicating that it is possible to eliminate D4 and D5, at least as a starting point for these cosmetics items that are considered non-essential. We recommend that this fact be included as a topic for discussion by the task force mentioned above.**
7.2 Alternative Technologies and/or Techniques	No information available in government report.	• It is essential that government promotes alternative technologies that do not use or promote the production of chemicals that exhibit similar impacts to health and the environment as these chemicals.	**Rec: Similar to alternative substances or products noted above, the government should seek to identify alternative technologies and**

Specific sections of Risk management components report	Proposed government management measures & other considerations	CELA & CSM Comments	Recommendations
		Similarly, if any safe alternatives that have been identified as a replacements for these toxic substances, a process by which the safety of alternative technology or techniques to the environment or human health should be assessed. The proponent of the alternative technology should be accountable for providing the appropriate results to demonstrate this safety.	**techniques that do not use D4 and D5 but achieve the same functionality of the substances.**
9.1.1 Releases from Products	Proposed risk management for D4 and D5 - regulations limiting the concentration of both substances in certain personal care products and, where appropriate, in consumer products that are manufactured in and imported into Canada. Focus will be on products that have the potential to result in releases to the aquatic environment. Certain personal care products such as those with a recognized therapeutic purpose will be given due consideration during instrument development to ensure continued effectiveness and access.	• The government's use of regulations to focus on "limiting the concentrations of both substances in certain personal care products and, where appropriate, in consumer products" is not an effective measure for protection of the receiving environment or human health. We do agree that impacts of D4 and D5 released from personal care products and consumer products with releases to the aquatic environment is a route of exposure that needs to be addressed. This route of exposure could only be addressed if a regulation that aims at prohibiting through a phase out of D4 and D5 in personal care and consumer products is undertaken. The proposed control measure to limit concentration will simply reduce concentration levels of D4 and D5 but does not prevent the release of these substances into the environment. • In our view, an approach with a goal to prohibit and phase out D4 and D5 in consumer products and personal care should be applied to all products, including products imported into Canada that may contain these substances. This approach is more appropriate to protect human health and the environment. • The government reports does not provide a comprehensive list of consumer and personal care	**Rec: The objective of the management strategy for D4 and D5 should be elimination of these substances.** **Rec: We do not support the use of a regulation aimed to limit concentration levels as it represents a control measure rather than a preventative measure. A regulation that aims to eliminate the use of these substances is appropriate to protect human health and the environment (i.e., aquatic environment) as this approach focuses on preventing the use of these chemicals at use.** **Rec: To facilitate or achieve elimination of D4 and D5, these substances should be added to the Prohibition of Certain Toxic Substances Regulations under CEPA. This addition would aim to prohibit use, sale, import and manufacture of D4 and D5, including all imported products that may contain these toxic substances.**

Specific sections of Risk management components report	Proposed government management measures & other considerations	CELA & CSM Comments	Recommendations
		products that potentially release D4 and D5 into the environment. This information is essential to understand the impact of the government's proposed measures. The absence of this information does not give stakeholders a sense of the overall impact these measures will have. Therefore, we seek clarification on the percentage of personal care products and consumer products that have the potential to release these toxic substances to the environment and the impact of the government's measures. The government's focus on control measure rather than adopting an overarching approach that will aim to prohibit these substances may lead to on-going exposure to D4 and D5. • The government's air monitoring program which aims to collect data between 2008–2010 for these chemicals is appropriate. However, the government has sufficient evidence of the impact of these siloxanes on the environment and should outline a commitment for eliminating these substances. The results of the monitoring should not be used to inform the measures needed to be taken by government rather the data should be used to evaluate the effectiveness of measures that promote phase out and elimination of these toxic chemicals.	**Rec: The prohibition of D4 and D5 should also apply to all consumer and personal care products that contain D4 and D5. For personal care products, D4 and D5 should be added to the Cosmetic Ingredient Hotlist as prohibited ingredients.** **Rec: For products where safe substitutions are not available and the products are viewed as essential, exemptions would be reviewed on a case by case basis. These exemptions should be granted with specified timefames to provide opportunity for the user to identify safe substitutes.** **Rec: Stakeholders should be provided the information on the range and approximate percentages of the personal care products and consumer products that are viewed as having the potential to have releases into the aquatic environment.** **Rec: While we do not support using regulations to limit concentration levels of D4 and D5, the government should provide additional information on the concentration ranges expected from consumer and personal care products to be targeted for action. This information would demonstrate in a transparent manner the extent of use**

Specific sections of Risk management components report	Proposed government management measures & other considerations	CELA & CSM Comments	Recommendations
			of D4 and D5 in these products. **Rec: The government should use air monitoring data (indoor and outdoor) on toxic chemicals such as D4, D5 and D6 to evaluate progress towards a goal of eliminating these chemicals**
9.1.2 Industrial Releases	Consideration of a regulation to prevent or minimize releases of D4 and D5 to the aquatic environment with the establishment of allowable maximum D4 and D5 concentrations in effluents and implementation of a management system to ensure that best management practices are adopted at facilities where D4 and D5 are used. Some details on the risk management system – see proposed risk management document.	• Given the impacts of D4 and D5 in the aquatic environment, the proposed regulation with a goal of prevention is appropriate. However, the establishment of allowable maximum concentrations for D4 and D5 will not guarantee that impacts to the environment and human health be prevented. The government should commit to an ultimate goal of elimination with these substances given their extensive use in products (consumer and personal care products) and industrial applications. • Rather than develop regulations that control the release of D4 and D5 through establishing allowable maximum concentrations for D4 and D5, the government should promote the goal of prevention at source. This could only be achieved through a goal of elimination. The process to establish allowable maximum concentrations would be challenging given that the government reports (assessment and risk management documents do not provide emission data reporting for D4 and D5 and also, emissions releases for these substances are not required under the National Pollutant Release Inventory (NPRI). Furthermore, these levels could only be established based on the current technology.	**Rec: We support the use of regulations to act on D4 and D5, however, the use of regulations to establish maximum allowable concentrations is inadequate to protect the environment and human health.** **Rec: D4 and D5 releases be added for reporting to NPRI reporting with a low threshold for all industrial activities** **Rec: Given the toxic designation of D4 and D5, the government should ensure that D4 and D5, both volatile polysiloxanes, are note used as acceptable alternatives for VOCs for specific applications.** **Rec: To further promote a goal of elimination and phase out of D4 and D5, the Government should require proponents using D4 and D5 to complete pollution prevention plans outlining strategies to account for and eliminate residual D4 and D5 in silicone polymers and copolymers.**

Specific sections of Risk management components report	**Proposed government management measures & other considerations**	**CELA & CSM Comments**	**Recommendations**
9.1.3 Pest Control Products Sector	D4 and D5 - formulants in approximately 150 pest control products registered under the *Pest Controls Products Act* (PCPA). All concentrations of D4 and D5 are less than 1.0% except for one product. D4 and D5 now reclassified as List 2 formulants by the *Pest Management Regulatory Agency* (PMRA). The formulant reassessment program will determine if D4 and D5 current usage levels in these products need to be decreased.	• Despite the government's conclusion of toxicity for these substances and the use of D4 and D5 in 150 pesticide products in Canada, the government's approach does not provide rigorous measures to address D4 and D5 contained in pest control products. There is an expectation by government that the current schedule for reassessment for these substances under the *Pest Control Products Act* will remain on track. The government should require a reassessment of the priorities for these substances. • There were no indications whether the reassessments of D4 and D5 would include a consideration of alternatives for D4 and D5 in the pest control products. • For one product that contains greater than 1% of combined D4 and D5, there was no indication whether the quantity was significantly greater than 1 % and if so, are there specific properties requiring a higher level of polysiloxanes. The government report does not indicate if efforts will be taken, even on an interim basis, to require a review of this product. • The government's document is also lacking in information regarding available replacements of D4 and D5 in pest control products that could be considered for preventing its on-going use.	**Rec: The government's approach on D4 and D5 in pest control products is weak. Recognizing that reassessments of specific pest control products are scheduled, D4 and D5 should be raised in priority for such assessments.** **Rec: These reassessments should also include a significant focus on the identification and use of alternatives to D4 and D5 in these products.** **Rec: As previously mentioned, there should be a task including government, industry and stakeholder when formulation reassessment is initiated. There is a need for transparency in this process mainly because of the lack of adequate labeling to more accurately indicate the substances in a pesticide. There is often speculation as to the nature of the so called 'inert' ingredients and their actual role in the formulation.** **Rec: If alternatives are to be recommended, full assessments on the safety of these alternatives under CEPA 1999 should be undertaken prior to use.**

3.0 Additional comments and recommendations for D4, D5 and D6 siloxanes

Sewer treatment plants (STPs)/sludge:

The assessment reports for D4 (CAS RN: 556-67-2); D5 (CAS RN: 541-02-6), and D6 (CAS RN 540-97- 6) included evidence that siloxanes have been detected in various environmental media, including the Great Lakes basin. Since these substances are considered high volume use chemicals and evidence show that their use in consumer and personal care products as well as their release from industrial processes may be increasing annually, we have growing concern regarding the detection of these substances in effluent discharges from sewage treatment plants and potential leaching from landfills. Due to their disperse nature, releases of these polysiloxanes are expected to be in wastewater (influent and effluent), the atmosphere, indoor air, and in the proximity of manufacturing plants. In addition to effluent discharges from sewage treatment plants, these substances are also expected to be detected in landfills from leachates or degradation products.

In addition to the comments and recommendations provided on D4 and D5 in Table 3 (see above) addressing proposed government measures, we would like to highlight further the issue of discharge of effluents from sewage treatment plants, which has not been adequately addressed in the SLRA or the risk management document. It is our view that this provides a less than comprehensive investigation and understanding of this source for polysiloxanes. The government's proposed measures to control releases of D4 and D5 provides further evidence that a preventative approach is the most appropriate measure to adopt for these substances. Without release information from industrial operations, there was a general assumption presented in the government documents that releases to wastewater were uniformly distributed among the industrial sites evaluated, equal distribution to the municipal discharging sites and instantaneous dilution of the effluent from the STPs into the receiving water. While all these assumptions were recognized as not being accurate, it raises many concerns in regards to D4, D5 and D6 having the potential to do harm to the aquatic environment, particularly in areas of high discharge.

D4, D5 and D6 are released to different environmental media. The chemical treatment by sewage treatment plants can potentially discharge effluents to water bodies or produce sewage sludge that may contain these toxic substances. This sludge may ultimately be disposed of in landfills or used in agricultural applications. The assessment reports do not provide adequate documentation to indicate if treatment plants are able to treat or remove all these substances in order to produce effluent or sludge that will have no impact to the receiving environment.

The effectiveness of the sewage treatment process to eliminate these toxic chemicals is determined by the level and type of treatment applied. This information was lacking in the assessment reports. From a public policy perspective, the quality of the discharge of

effluent from sewage treatment plants could be improved by promoting source prevention of these toxic substances. The assessment process should include a better analysis outlining the fate and impacts of these substances being treated by sewage treatment plants. The enhanced consideration of this pathway will contribute to the full life cycle accounting of the fate and decision making on the toxicity of these substances.

Finally, the government's assessment reports on D4 and D5 do not fully investigate the extent of degradation of these substances after they have been disposed of in landfills (whether as sludge or in consumer products). The absence of this information leaves a significant gap in the assessment process as well as in the process of developing effective management strategies.

Recommendation: Recognize the limitations of sewage treatment plants to remove all toxic substances. The government should acknowledge that sewage treatment plants are unable to effectively treat and remove all toxic substances. Hence, the government should apply a preventative approach on the use of toxic chemicals such as the polysiloxanes (D4, D5 and D6).

Bioaccumulation for D4 and D5:

Currently, the government has received conflicting data on the bioaccumulation of D4 and D5. We are surprised by the evidence presented in the final assessment report on D4 and D5 raising the questions on the bioaccumulation of these substances. This is a significant shift from the evidence presented in the draft assessment reports. This shift also has a dramatic impact on the government's final conclusion of toxicity and determination of P, B, iT of these chemicals. The current government position not to make a conclusion on bioaccumulation is disappointing as it has contributed to proposed management response that relies on control measures to address these substances. Despite the shift in the final decision by the government on D4 and D5, we are of the position that the uncertainties attached to the bioaccumulation data for D4 and D5 should be viewed in a precautionary manner.

We urge the government to accept the data that demonstrates that D4 and D5 have the potential to bioaccumulate using the precautionary principle and to adopt a preventive approach to these substances. The current government proposal to use control measures in place for D4 and D5 would not ensure that there is adequate protection to the environment and human health. If the government accepts the available data demonstrating that D4 and D5 have the potential for bioaccumulation and commit to an approach towards elimination, there would be greater protection for human health and the environment. Furthermore, the industry proponents using these substances should be required to provide all their test data for review. In the meantime, the government should be committing to preventive measures on D4 and D5 for the protection of the environment. Permitting the ongoing use of D4 and D5 at the current levels with uncertainties on the bioaccumulation data demonstrates a less than protective approach by decision makers.

Recommendation: D4 and D5 meet the bioaccumulation criteria. We disagree with the government's current position that D4 and D5 do not meet the threshold for bioaccumulation criterion in the Persistence and Bioaccumulation Regulations. This position has resulted in less than protective measures to protect human health and environment from D4 and D5 exposures

Recommendation: Use of precautionary principle. Apply the precautionary principle in the consideration of the bioaccumulation data on D4 and D5 to conclude that the current bioaccumulation supports the designation that D4 and D5 siloxanes are PBiT substances.

Conclusions on Assessment Decision for D6:

We are extremely dismayed to see the change in the government's decision on the toxicity of D6 under CEPA in the final assessment report. With such a significant change in decision, there should be questions and further reviews as it is unclear what new data was considered by the assessors that lead to the change in decision during this final phase of the process.

Our organizations are highlighting the following concerns regarding the assessment of D6:

- **Review of several analogues to conclude on the toxicity of D6:** The approach by government to use analogues to make determination on specific properties of a chemical remains an on-going issue for assessments of chemicals in general. We have concerns that several analogues have been identified and used to complete the assessment of D6. In this process, the government assessors rely on the specific properties of the analogues selected. The assessors have the ability to select which analogue they consider most appropriate to conclude on a specific property of the chemical under assessment. In our view, this approach is completely inappropriate and has the potential to lead to inaccurate decisions on toxicity and therefore affect possible management measures. With so much flexibility given to assessors in selecting among several analogues to make a decision on a chemical's property, we are concerned that the approach to find the 'best fit' is not the most appropriate approach. This does not appear to be either protective or scientific. The use of D4 and D5 in the case of the assessment of D6 is reflective of this approach. In the absence of available experimental data, the government assessment should only consider the use of one analogue. The chemical selected as the analogue should be the chemical that reflects the properties of the chemical under assessment and the government should provide the appropriate rationale for this selection. If the government undertook to use only one analogue to make a determination of specific properties of D6 for P, B and iT, the conclusion on toxicity of D6 may be significantly different.

- **Lack of cumulative and synergistic impacts from siloxanes:** While the assessment results for D4 and D5 supported the finding that these siloxanes were toxic under CEPA, the determination of D6 did not. The lack of consideration of the cumulative and synergistic impacts of D4, D5 and D6 and other substances found in this class of chemicals that may have similar use functions is a significant gap in the current government risk based assessment process. Given that D6 is often detected in the polysiloxanes mixtures that include D4 and D5, the assessment report should include a substantial explanation on the interaction and cumulative impact this may have for D6.
- **Potential use of D6 as a substitute for D4 and D5:** The government's conclusion to change the toxicity of D6 may result in the increase of D6 as a replacement for D4 and D5. In our view, the assessment should take that potential use into account when making its final decision. The lack of information that currently exists for D6 should not be acceptable as the two analogues considered in the process have been found to be toxic under CEPA and proposed measures on these chemicals are on-going under CEPA. The government should take steps to generate the necessary data regarding gaps that currently exist for D6 rather than making the conclusion that this chemical does not meet the toxicity criteria under CEPA.

Recommendation: Conclusion for D6 under CEPA. We do not support the decision made by government that D6 no longer meets the definition of toxic under CEPA.

Recommendation: Inappropriate use of analogues. We do not support the government's approach in the use of D4 and D5, as analogues to make a determination on P, B and iT for D6. One analogue should be selected from the available analogues and its properties considered in the review of D6. The current approach provides 'biased' flexibility when making assumptions about a chemical's behaviour which could lead to weak decisions.

Recommendation: Consideration of cumulative and synergistic effects. The government should include a review of the cumulative and synergistic effects of all siloxanes – D4, D5 and D6 and other siloxanes in completing the assessment of D6.

Recommendation: D6 not a suitable alternatives for other siloxanes. D6 should not be considered as safe alternative to D4 and D5 given that much of the assessment process relied on data from D4 and D5 as analogues, which are being proposed for management measures under CEPA.

CEPA toxicity for D4, D5: D4 and D5 were classified as being CEPA toxic under Section 64 (a) but not under S. 64(c). D4 is a possible reproductive toxin and D5 has been classified by the Danish EPA as a possible human carcinogen. Based on the extensive use of these substances in consumer products and in particular, cosmetics, there is concern that the general population is not adequately protected. Users of consumer products containing D4 and D5 are exposed through various routes including

dermal exposure and inhalation, which are the two major routes of exposure. It was not evident in the assessment reports if data on the presence or concentration of these chemicals in bathrooms where many cosmetics are applied are available and have been considered in the process.

Exposure to these substances through a variety of products is chronic and occurs during the length of a lifetime. This fact was not clearly articulated in the SLRAs. There are possible cumulative effects of these substances and the combined effects of these substances in this chemical family that should be considered in these assessments. Therefore, there are concerns that human exposure to these substances and the potential impacts outlined in the reports are being under-estimated.

Recommendation: CEPA toxic – Section 64 (c). We propose that government take a more precautionary approach to further protect the health of Canadians and declare D4 and D5 CEPA toxic under Section 64(c). See Table 3 for detailed recommendations on preventive measures.

Exposures to D5: A review of D5 Probabilistic Exposure Assessment was conducted by the Silicones Environmental Health and Safety Council (SEHSC) and was taken into consideration for the assessment of D5 together with the government's current assessment. Dermal absorption and inhalation were the primary routes of exposure for adults, babies and children. The government data had higher exposure rates as compared to SEHSC. The main reason cited for this difference was consideration of "user only" subpopulation in the current assessment compared to the "user" and "non-user" subpopulations considered in the SEHSC assessment. We question if there are other similar studies or reviews completed by a non industry organization to review the position of other stakeholders. The government should not rely primarily on the findings of the review completed by SEHSC to make conclusions on D5. The government should undertake to review the D5 Probabilistic Exposure Assessment as well as seek a third party review of the report.

Recommendation: Require a third party review on D5 Probabilistic Exposure Assessment. We recommend that a third party review of this assessment be conducted. The results of the third party review should be compared to the review conducted by SEHSC and the current government critique. In the interim period, the government's conclusion on D5 should follow the precautionary principle.

Underestimation of releases: D4, D5 and D6 are all imported into Canada in large volumes and also, imported into Canada in finished products. These three polysiloxanes belong to a group of cyclic volatile methyl-siloxanes (cVMS). Other poylsiloxanes in this group were not identified in this Batch or other batch of the Industry Challenge under the Chemicals Management Plan. It should be further noted that D4, D5 and D6 are the principal ingredients of cyclomethicone or polydimethylcyclosiloxane (PDMS) (CAS RN 69430-24-6). Given that the final assessment report has not considered the other siloxanes belonging to cVMS or other ingredients of PDMS, the results of the

assessment may represent an underestimation of the level of releases of D4, D5 and D6.

The Challenge to industry did not survey cyclomethicone CAS RN 69430-24, specifically. As a result of this gap, there are no accurate statistics for the individual cVMS components of PDMS as they relate to PDMS. The challenge to industry was intended to obtain as much information as possible on these substances to complete assessments. The expectation by the public on this challenge was high as it represented a shift in onus to industry to provide the information on these chemicals. Therefore, it was hoped that if cyclomethicone CAS RN 69430-24 was not specifically identified in the survey but industry knew its relevance to the other siloxanes, this information would have been still forthcoming from industry.

The absence of additional information on cyclomethicone is a significant information gap since the quantities imported into Canada, their uses in 2006 as well as their releases into the Canadian environment are not fully known. Approximations of the quantities in imported products are also not known and this is also true of the individual poylsiloxanes D4, D5 and D6 that are specifically identified under the Challenge Program. No rationale was given as to why the government did not include cyclomethicone CAS RN 69430-24 in the Challenge to industry.

The lack of this information impacts negatively on our understanding of the true exposure to the health of Canadians and the impact on the environment particularly since D4, D5 and D6 are widely used and have very dispersive characteristics. Without a more accurate picture of exposure and releases, risk management proposals for these substances as they relate to human health and the environment could be significantly weaker and, as a result, not fully protective of public health nor the environment.

Recommendation: Require industry to submit all information on D4, D5 and D6.
For high production volume, widely used and dispersive substances such as D4, D5 and D6, it is recommended that government fill in present information gaps as it relates to cyclomethicone CAS RN 69430-24.

***Recommendation: Require data on products imported into Canada. Require additional data on imported products containing polysiloxanes. Similar to cyclomethicone, the government should seek to require data from importers on range and quantity of imported products that contain polysiloxanes*.**

Long range transport potential: *A*s a result of categorization and the draft assessment results, D4, D5 and D6 were classified as being persistent, bioaccumulation and inherently toxicant (PBiT) with the potential for long range transport. It was also cited that these substances had the potential to behave like persistent organic pollutants (POPs) therefore predicting the deposition of these substances in far locations (soil and water), without degradation.

In the final SLRAs for these substances, the potential for long range transport was confirmed but information regarding deposition of these substances was changed. This change was not attributed to new information in the report. Therefore, it was very difficult to follow the logical sequence of changes regarding information about the behaviour of these substances and the rational for the final government decision. D4, D5 and D6 are capable of long range transport; however the final assessment indicated there is reactivity with hydroxyl radicals in the atmosphere which result in the degradation of these substances. This rate is also dependant upon humidity. The studies used to make these conclusions should be publicly discussed as it dramatically affects the government's response and management approach to these substances.

Deposition of Siloxanes:

We are concern that the comments made on deposition potential of siloxanes are based on very limited data. The SLRAs provided evidence regarding the lack of polysiloxane deposition in a remote area in Ontario. This evidence was used to make a conclusion that deposition for siloxanes in other parts of the Canada would be not expected. We find this approach weak unless a more comprehensive monitoring regime was undertaken by the departments to confirm this information. It is inappropriate to assume that siloxanes would not be detected in other northern parts of the Canadian environment. We are concerned that the government is making premature conclusions based on this very scant information. There is very little evidence presented in the assessment reports that indicate new data was submitted on these substances under relatively cold winter conditions consistent with that in the prairies, or further north in Canada, where humidity levels can be low in winter months. In addition, the assessments also relied on the use of other data, supplied by industry, indicating that these polysiloxanes are not likely to be persistent organic pollutants. The government failed to substantiate in the final assessment, the efforts the departments undertook to review the validity of this data.

In light of these current gaps and concerns, it would be appropriate to develop a monitoring program on siloxanes under the Chemicals Management Plan that considers the different climates of Canada which could affect the behaviour of these substances.

Finally, the issue of deposition and degradation of siloxanes was included in the final assessment. The report did not provide a sufficient rationale for the degree of confidence the government placed on the data that indicate that while these substances have long range travel potential, they completely degrade prior to deposition. Our concern regarding this gap is further emphasized given the lack of toxicity data presented on the hydrolysis by-products of these substances.

Recommendation: Require monitoring of D4, D5 and D6 in remote areas of Canada in winter months. Under the Chemicals Management Plan, D4, D5 and D6 should be included in the environmental monitoring program to assess its potential for long range transport and deposition. Monitoring of siloxanes should

include monitoring in remote areas across Canada and during the different seasons, particularly, in the winter season.

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