Response Canada Gazette Part I, Vol., 142, No. 27 regarding Final Assessments and Proposed Management Options for Batch 1 Substances under the Chemical Management Plan

Submitted to:

Honourable John Baird
Minister of the Environment
Environment Canada

and

Honourable Tony Clement
Minister of Health
Health Canada

Submitted by:

Canadian Environmental Law Association
and
Chemical Sensitivities Manitoba

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Introduction

Canadian Environmental Law Association (CELA) and Chemical Sensitivities Manitoba (CSM) are submitting the following comments in response to the Canada Gazette Part I, Vol. 142, No. 27 dated July 5, 2008 to release the final assessment reports for substances identified under the Chemicals Management Plan, Batch 1 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 environmental law reforms. It is also a free legal advisory clinic for the public, and will act at hearings and in courts on behalf of citizens or citizens' groups who are otherwise unable to afford legal assistance. CELA is funded by Legal Aid Ontario (LAO). It is one of 80 community legal clinics located across Ontario, 18 of which offer services in specialized areas of the law. CELA also undertakes educational and law and policy reform projects that are funded by LAO as well as government and private foundations. CELA's public policy reform programs focus on four issue areas: pollution and health; water sustainability; land use planning; and access to justice. CELA participated and responded to government proposals in implementing section 73 of CEPA which focused on the categorization of the 23,000 substances under the Domestic Substances List. CELA's interest in the results of categorization and the government's efforts to complete screening level risk assessments and propose management regimes for substances continues. CELA advocates for the elimination of the most hazardous substances, including those substances identified as high priority substances due to their impact on the environment (persistent, bioaccumulative and inherently toxic) and/or human health (carcinogenic, reproductive and developmental, respiratory, genotoxicant, endocrine disruptors or neurodevelopmental toxicants).

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. All four individuals worked in science - chemistry (industry), biochemistry, entomology and veterinary medicine. 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. In the workplace, where safe substitution can often be a challenge, CSM also looks at preventive measures for reduced occupational exposure. CSM meets with politicians, union representatives and the medical community to bring awareness to the controversial medical condition of chemical sensitivities and the profound impact it has on one's personal life, job and the ability to work, as well as social life and financial stability. Outreach to the public, and lectures to university students are also part of CMS's activities. The group acts as a resource consultant for undergraduate students in the Department of Community of Health Sciences, Faculty of Medicine, University of Manitoba, who are working on environmental papers applicable to our organization. CSM has been involved in the Chemicals Management Plan stakeholder workshops and continues to be involved as the government publishes the draft risk assessment and risk scoping documents on substances identified through the CEPA categorization. CSM advocates for the elimination of those substances identified through the categorization process that pose a risk to human life and the environment.

CELA and CSM submitted submissions on the Batch 1 substances in March 2008. The comments and recommendations made in these submissions continue to be relevant and should be given closer consideration in light of the final assessment decisions and proposed management options for the following substances:

- Peroxide, (1,1,4,4-tetramethyl-1,4-butanediyl)bis[(1,1-dimethylethyl)] (DMHBP), CAS no. 78-63-7
- Peroxide, (1,1,4,4-tetramethyl-2-butyne-1,4-diyl)bis[(1,1-dimethylethyl)] (DMBP), CAS No. 1068-27-5
- Peroxide, (3,3,5-trimethylcyclohexylidene)bis[(1,1-dimethylethyl) (DBTMC), CAS No. 6731-36-8
- Propanedinitrile, [[4-[[2-(4-cyclohexylphenoxy)ethyl] ethylamino]-2-methylphenyl]methylene]- (CHPD), CAS no. 54079-53-7
- Oxirane, methyl- (Methyloxirane), CAS no. 75-56-9
- Oxirane, ethyl-, (ethyloxirane), CAS no. 106-88-7
- Benzene, 1,3-diisocyanatomethyl- (TDI mixed isomers), CAS no. 26471-62-5
- Benzene, 2,4-diisocyanato-1-methyl- (2,4-TDI), CAS No. 584-84-9
- Benzene, 1,3-diisocyanato-2-methyl- (2,6-TDI), CAS No. 91-08-7
- Naphthalene, CAS no. 91-20-3
- 1,2-Benzenediol (1,2-benzenediol), CAS no.120-80-9
- 1,4-Benzenediol (1,4-benzenediol), CAS No. 123-31-9

At the conclusion of the government's efforts to categorize the 23,000 substances under the Domestic Substances List, the results of the process set Canada ahead of other countries in efforts to address substances that have been used, manufactured, sold and imported into the market. The expectation by the Canadian public for government action to eliminate and reduce the 4,300 substances identified through the categorization process was high. When the Chemicals Management Plan was released in December 2006, Prime Minister Harper claimed that it "will make Canada a world leader in assessing and regulating chemicals that are used in thousands of industrial and consumer products".

General Comments

In January 2008, the government released the draft assessment results and proposed management options for Batch 1 substances under the Industry Challenge. CELA, CSM and other NGOs expressed concerns with regard to specific gaps in the assessment process. Many of the gaps identified in the assessment and management options remain in the final assessment decisions on these substances. In particular, we want to raise once again the need to (1) consider the cumulative impacts of these substances on human health and the environment; (2) request from industry specific toxicity data (i.e. neurodevelopmental toxicity and endocrine disruption) to complete the assessments; (3) consider the full life cycle of these substances, including consideration of exposure from disposal methods as well as by-products; and (4) give special consideration to vulnerable populations such as children and workers.

Specific Comments on the Batch 1 CEPA toxic substances

Inadequacy of risk management response.

We want to express our greatest disappointment in the government's proposed management regime for the 9 substances meeting CEPA section 64:

- Propanedinitrile, [[4-[[2-(4-cyclohexylphenoxy)ethyl] ethylamino]-2-methylphenyl]methylene]- (CHPD), CAS no. 54079-53-7;
- Oxirane, methyl- (Methyloxirane), CAS no. 75-56-9;
- Oxirane, ethyl-, (ethyloxirane), CAS no. 106-88-7;

- Benzene, 1,3-diisocyanatomethyl- (TDI mixed isomers), CAS no. 26471-62-5;
- Benzene, 2,4-diisocyanato-1-methyl- (2,4-TDI), CAS No. 584-84-9
- Benzene, 1,3-diisocyanato-2-methyl- (2,6-TDI), CAS No. 91-08-7;
- Naphthalene, CAS no. 91-20-3;
- 1,2-Benzenediol (1,2-benzenediol), CAS no.120-80-9; and
- 1,4-Benzenediol (1,4-benzenediol), CAS No. 123-31-9

The approach taken continues to entrench the government's approach focused on end of pipe measures, which does not support preventive measures. The proposed management options for these substances do not include elimination or phase out measures that would ensure that human health and the environment are effectively protected from existing or potential sources of exposure. Furthermore, the government's proposed risk management options do not include explicit recommendations to initiate processes that would promote the development, identification and assessment of safe alternatives for any of these high priority substances. For example, the management proposal outlined for Oxirane, ethyl-, (ethyloxirane) (CAS no. 106-88-71) and 2-Benzenediol (1,2-benzenediol) (CAS no. 120-80-9) calls for a government notification for future use of these substances. No reduction measures have been proposed for these substances which are used in Canada in relatively high volumes (10,000-100,000 kg) and have extensive documented industrial applications. This allows manufacturers and importers to continue their practice at the present levels despite evidence that these substances are considered carcinogenic. This represents a weak government response that contradicts several CEPA objectives, including the goals of pollution prevention and the application of the precautionary principle.

We are extremely surprised by the lack of government commitment to eliminate substances such as naphthalene, which is manufactured and imported into Canada in extremely high volume levels of 52,000,000 kg and 150,000,000 kg, respectively. The non-petroleum use of this substance provides extensive opportunities for human exposure that should be addressed comprehensively. Furthermore, the fact that the main route of exposure to naphthalene is through inhalation, suggests that very little can be done by the general public to adequately protect themselves against exposure to this substance. In our view, nothing short of a prohibition of naphthalene should be acceptable. The government's assessment report efficiently demonstrates the carcinogenicity of naphthalene but the fact that the assessment does not address the risk associated with the petroleum sector using naphthalene demonstrates a significant gap in the government's approach.

In the risk management document for Oxirane, ethyl-, (ethyloxirane) (CAS no. 106-88-7), one of the uses of this substance noted is as an alternate for dry cleaning solvent. Currently, only one dry cleaning facility is using this solvent. However, it is being considered by other facilities due to its minimal cost as a replacement. Given the toxicity of ethyloxirane, the use of this substance as a safe alternative to other toxic dry cleaning solvents should not be permitted, despite the minimal financial cost for operators to make the transition. The assessment report does not provide adequate evidence of the safety of this substance for use in dry cleaning facilities. Furthermore, the replacement of toxic solvents with another toxic substance is not appropriate, particularly since dry cleaning services are used extensively by the general public and exposure potential will increase significantly. Worker exposure also has to be considered, even if it falls under the jurisdiction of the provincial governments.

Recommendation 1: We oppose the weak government proposals for management of the 9 substances found to be CEPA toxic under s. 64. The substances are:

- ***Propanedinitrile, [[4-[[2-(4-cyclohexylphenoxy)ethyl] ethylamino]-2-methylphenyl]methylene]- (CHPD), CAS no. 54079-53-7;***
- ***Oxirane, methyl- (Methyloxirane), CAS no. 75-56-9;***
- ***Oxirane, ethyl-, (ethyloxirane), CAS no. 106-88-7;***
- ***Benzene, 1,3-diisocyanatomethyl- (TDI mixed isomers), CAS no. 26471-62-5;***
- ***Benzene, 2,4-diisocyanato-1-methyl- (2,4-TDI), CAS No. 584-84-9***
- ***Benzene, 1,3-diisocyanato-2-methyl- (2,6-TDI), CAS No. 91-08-7;***
- ***Naphthalene, CAS no. 91-20-3;***
- ***1,2-Benzenediol (1,2-benzenediol), CAS no. 120-80-9; and***
- ***1,4-Benzenediol (1,4-benzenediol), CAS No. 123-31-9***

Recommendation 2: All 9 substances mentioned in the previous recommendation should be added to CEPA Toxics Substances List (Schedule 1).

Recommendation 3: The government should reassess its management options for these 9 substances. The government approach should support an elimination or phase out strategy and initiate a process to identify and assess safe alternatives for these substances based on the government finding that they are PBiT (Propanedinitrile, [[4-[[2-(4-cyclohexylphenoxy)ethyl] ethylamino]-2-methylphenyl]methylene]- (CHPD), CAS no. 54079-53-7) or carcinogenic or mutagenicity for the following substances: Oxirane, methyl- (Methyloxirane), CAS no. 75-56-9; Oxirane, ethyl-, (ethyloxirane), CAS no. 106-88-7; Benzene, 1,3-diisocyanatomethyl- (TDI mixed isomers), CAS no. 26471-62-5; Benzene, 2,4-diisocyanato-1-methyl- (2,4-TDI), CAS No. 584-84-9; Benzene, 1,3-diisocyanato-2-methyl- (2,6-TDI), CAS No. 91-08-7; Naphthalene, CAS no. 91-20-3; 1,2-Benzenediol (1,2-benzenediol), CAS no. 120-80-9; and 1,4-Benzenediol (1,4-benzenediol), CAS No. 123-31-9.

Recommendation 4: All substances listed in above recommendation should be considered for addition to the regulation on Prohibition of Certain Toxic Substances, 2005.

Recommendation 5: Propanedinitrile, [[4-[[2-(4-cyclohexylphenoxy)ethyl] ethylamino]-2-methylphenyl]methylene]- (CHPD), CAS no. 54079-53-7 has been identified as persistent, bioaccumulative and inherently toxic. It should also be added to the Prohibition of Certain Toxic Substances, 2005 to support the goal of elimination.

Recommendation 6: We do not support the establishment of a limit of quantification as prescribed through the Virtual Elimination (Section 77) nor the use of a regulation to address releases of CHPD to the environment as such an approach supports an end of pipe measures only.

Recommendation 7: Due to their carcinogenicity, we oppose the government's proposal to apply a notice for future use to substances such as Oxirane, ethyl-, (ethyloxirane) (CAS no. 106-88-71) and 2-Benzenediol (1,2-benzenediol)(CAS no. 120-80-9).

Recommendation 8: Due to its carcinogenicity and the extremely high volume manufacture and import, naphthalene should be targeted for prohibition with particular emphasis on those industrial applications such as driveway sealants, paints, stains and coatings and all consumer products covered under the Pest Control Products Act.

Recommendation 9*: *We oppose the use of ethyloxirane in the production of n-propyl bromide dry cleaning solvent which is being considered as a viable alternative to other toxic dry cleaning solvents.

Recommendation 10: All substances found to be CEPA toxic should be listed for reporting under NPRI with alternate or lower thresholds for reporting to support monitoring and surveillance efforts in Canada and to ensure that full life cycle accounting for these substances are incorporated into the management regimes.

We offer the following additional comments on selected substances:

1,4-Benzenediol, CAS RN 123-31-9 (Hydroquinone)

As noted in the previous section, we support the government's intent to list hydroquinone (CAS RN 123-31-9) as toxic under CEPA and to add the substance to the List of Toxic Substances in Schedule 1 of CEPA. The final screening assessment concluded that hydroquinone will not be subjected to virtual elimination, as it does not satisfy the criteria in subsection 77(4) of CEPA. It was concluded that hydroquinone is not entering the environment in a quantity or concentration or under conditions that constitute or may constitute a danger to human life or health in Canada. It is proposed that preventive or control actions will be developed to protect the health of Canadians and the environment from the potential effects of exposure to hydroquinone and will be managed using a life-cycle approach.

Issues and recommendations:

A) Level of hydroquinone exposure (human)

While it is true that the general population may not be exposed to hydroquinone at concentrations or under conditions that constitute or may constitute a danger to human life or health in Canada, this is not true for those individuals who are exposed to this substance through chronic dermal contact of products containing hydroquinone. Such products of concern include photographic developing solutions, skin lightening creams (regulated), manicure cosmetics and hair dyes. The assessment and risk management reports do not give the necessary level of information to document how to protect the general public from the effects of these hydroquinone based products.

Recommendation 11: We believe that hydroquinone is entering the environment in a quantity or concentration or under conditions that constitute or may constitute a danger to human life or health in Canada. Since the range of consumer products containing hydroquinone is extensive and its application is mainly dermal, a higher consideration for long term dermal exposure, as compared to short term exposure to hydroquinone is warranted. The assessment should reflect this distinction.

Recommendation 12: A British study of professional darkroom workers, which utilized biological monitoring for hydroquinone exposure, concluded that there was no increase of hydroquinone in their urinary excretions. Not mentioned in the screening report is the possible role that mechanical ventilation and personal protective equipment (like gloves) would have had on this test data. We recommend that these and similar factors be taken

into consideration and mentioned when reviewing the effects of long term dermal exposure to hydroquinone.

Recommendation 13: Consideration should be given to prohibiting the use, import, export, sale and manufacture of hydroquinone in all consumer products, and particularly in photographic developing solutions, hair dyes, manicure products and skin lightening creams, since alternative products do exist.

Recommendation 14: We agree that the appropriate labeling of photographic solutions will have a positive impact on short-term, as well as long-term human exposure, but only if there is strict adherence to the instructions on the label. In reality, this is not always the case. It is not possible to fully protect all users of these developing solutions. There must be more aggressive action by the government to protect users (workplace) and consumers. The onus cannot be on the user. Therefore, we continue to recommend that the use of hydroquinone be prohibited from consumer products generally, and particularly those listed in the above recommendation.

B) Safe alternatives for hydroquinone in consumer products

Although there is mention of alternatives to hydroquinone for some consumer products in the risk management document, there were no proposals to encourage more of these alternatives, nor were there any details provided as to the type of available alternatives. Furthermore, a transparent and inclusive process by which safe alternatives are reviewed for their safety should be included to strengthen the screening and management documents. For example, it is understood that one alternative to hydroquinone is catechol, which has also been identified as CEPA toxic.

Recommendation 15: To promote the use of alternatives and support increased accountability on the part of industry, the government should ensure that the alternatives for hydroquinone in consumer products are safe, and that industry supplies complete documentation to demonstrate this. A task force to discuss alternatives for hydroquinone should be established.

Recommendation 16: As part of the risk management measures, the government should work together with industry and workers in the safe replacement of hydroquinone in consumer products.

Recommendation 17: The government should be instrumental in providing information to the public and the medical community, where necessary, on hydroquinone-free consumer products.

C) Further restrictions and notification for the use hydroquinone

Recommendation 18: Additional information is needed as to the nature of the additional restrictions proposed in the final risk management on the use of hydroquinone in cosmetic products (nail systems and hair dyes) through amendments to the Hotlist, since it is prohibited for use in cosmetics products applied on the skin or mucous membranes.

Recommendation 19: Risk management also included the regulation of hydroquinone-containing health products, such as a prescription drug, but criteria for this type of product should have been detailed.

Recommendation 20: As part of the risk management, there is a proposal to create a provision whereby any future uses of hydroquinone would be subject to federal government notification. Clarification is needed as to whether these are only new uses for this substance. We object to the use of notification for future uses of this substance if it is not part of a more comprehensive phase out approach for hydroquinone.

Recommendation 21: Also proposed is the creation of a provision that would require industry to notify the government if the proposed use of hydroquinone exceeds a specified level. This requires some clarification, since usage levels vary according to the type of industry. When a notification level is high, some industries would not be subject to notification requirements because of their low usage levels. We oppose the use of future notification alone as a risk management mechanism, as it entrenches a control regime and does little to promote prevention of hydroquinone use.

Toluene Diisocyanates: CAS RN 91-08-7, 584-84-9, 26471-62-5

We are in agreement with the proposal that Toluene Diisocyanates - CAS RN 91-08-7, 584-84-9, 26471-62-5 (TDI) does not meet the criteria in paragraphs 64(a) and 64(b) of CEPA 1999, but it does meet the criteria in paragraph 64(c) of CEPA, and that it is therefore, it is CEPA toxic. The government also recommended that TDI be considered as a substance that may be entering the environment in a quantity or concentration or under conditions that constitute or may constitute a danger in Canada to human life or health.

We are also in agreement with the Health Canada proposal that TDI be added to the Cosmetic Ingredient Hotlist so that these substances are prohibited from use in cosmetic products. In the assessment report completed on hydroquinone, it was noted that hydroquinone is listed on the Cosmetic Ingredient Hotlist, cosmetic products containing this substances were filed with Health Canada. Therefore, additional details are needed as to how the government enforces the Cosmetic Ingredient Hotlist, so as to validate its potential role in prohibiting the use of toxic substances in cosmetic products. In the various assessments conducted to date, references to the Hotlist have been made but there is an information gap regarding what mechanisms are used to ensure that cosmetic products do not contain prohibited substances.

At present, without replacements for these three TDI isomers, the government's approach to reduce emissions and residual TDI in products and, in particular, consumer products and food packing materials may be acceptable as long as the commitment to phase out these substances within 2 years is established. To achieve this goal, an action plan for reduction and elimination should be developed. Currently, the suggested risk management for the substances included air stack exhaust to control and reduce TDI releases to the environment from the foam industry, with additional actions being considered in the investigation of the management of non-foam consumer products. Although these are end of pipe control measures, it is our view that industry should actively invest resources to research and develop alternatives to TDI as well.

The government evaluators acknowledge that the isocyanate technology has challenges in efforts to find equivalent and safe replacements, and that the use of isocyanate technology is

extensive and increasing in its applications. We are concerned about this prospect, due to the potential for TDI isomers to be carcinogenic. They are all strong human sensitizers. We have concerns about the degree to which atmospheric TDI (short range transport) and residual TDI monomers in consumer products will be reduced or eliminated, even if the concentrations are not considered high.

Issues and recommendations:

A) Air emissions from plants using TDI

Recommendation: From data in the risk assessment, it is technically feasible to reduce TDI in stack exhaust to a concentration such that the level of TDI in the vicinity of a plant is non-detectable. With that supporting quantitative data, the risk management proposals should include similar reduction mechanisms with an overall goal of phase out and elimination. Although emphasis has been on the foam industry, all other industries using TDI should also be subjected to the same goals of reduction and phase out.

Recommendation 22: Despite the lack of TDI monitoring data for Canada (not including NPRI release data), concern must be shown for communities close to facilities using TDI, particularly where such communities include vulnerable populations, such as those with allergies, environmental sensitivities, or lung disorders, babies, children, and pregnant women. Hence, it is necessary for additional monitoring, including biomonitoring, for these substances to demonstrate levels in the environment and population.

Recommendation 23: The listing of TDI in the NPRI should be revised to require lower thresholds for reporting releases and transfers under the NPRI.

B) Consumer products, paints and coatings – exposure to TDI

Recommendation 24: The risk management refers to the need for non-foam consumer products in the above categories containing TDI to be further investigated. Because of the potential for TDI to harm human health, these products do not have to be a major source of free TDI in order to be investigated. In keeping with the precautionary approach, it is appropriate and necessary for government to collect and analyze data on the TDI levels from non-foam products.

Recommendation 25: There needs to be clarification as to the nature of the investigation for non-foam consumer products. For example, it should include product categories, levels of residual TDI in products and expanded data sets for these products. Theoretically, this information should be readily available from companies manufacturing large quantities of TDI-based products.

Recommendation 26: A process to evaluate the safe substitutes for some of the TDI-based products should be established as part of the risk management regime, even if some of the non-crucial properties are not identical or only partially maintained.

Recommendation 27: The use of TDI isomers should be prohibited for import, export and domestic use and manufacture where manufacturing with safe alternative substances for TDI is possible for some products. Should alternatives not be available, time limited exemptions may be applied to allow eventual phase out of TDI.

C) Food packing sector – residual TDI

Recommendation 28: The risk assessment document states that 'future submissions for the use of TDI in food packaging materials will be scrutinized by Health Canada so that residual levels in finished materials are as low as possible or there is a functional barrier between the packaging material and food to prevent contact and therefore minimize the potential migration into food.' There is concern as to what the recommendation for the safe level of residual TDI for food packaging material is. Theoretically, the safe level should be zero.

Recommendation 29: While we disagree with the usage of TDI-based food packaging, at a minimum, the following information should be supplied by industry: a listing of foods that are more likely to have this type of packaging, migration periods for TDI residues in those foods, the effect of temperature on migration of residual TDI, the possibility of reactions with the packaged food, the reaction products and the residual TDI after the reaction. Consideration must be given to the fact that some of these packaged foods are consumed on a daily basis.

Recommendation 30: Data on residual levels and potential migration of TDI in food packaging materials generated by Health Canada should be made available to the public. Included should be the rationale for using TDI-based materials for direct food packaging and data on the availability of safe alternative direct food packaging materials.

Recommendation 31: Given that safe alternative materials are available, TDI monomers should be prohibited from use in direct and indirect food packaging materials. This would include a restriction on the import, manufacture or export any of these TDI isomers in food packaging materials.

D) Other

Recommendations 32-34:

- ***The government to include a stakeholder consultation process to develop regulatory actions. This process should include participation from stakeholders including labour, health and environmental NGOs.***
- ***We urge government to require the isocyanate industry to research an alternative chemistry that is safer for the workplace and the consumer.***
- ***The government management approach should openly focus on formulation details for TDI-based formulations. Response by government to the following questions are relevant if exposure to TDI is to be managed effectively:***
    - ***Is there excess isocyanate in some formulations? If so, an investigation should be undertaken to assess the product performance, health and environmental impacts.***
    - ***Consideration should be given to determine the possibility that the polyols used in the 2-part isocyanate reaction may have carcinogenic residues.***
    - ***What type of mechanism is in place to ensure that the reaction is as complete as possible?***

Specific comments on Batch 1 substances identified as non toxic under CEPA

We are very disappointed to see that the substances targeted for virtual elimination for Batch 1 substances in January 2008 are no longer considered toxic under CEPA.

As noted in an earlier paragraph, we are disappointed in the government's determination that Peroxide, (1,1,4,4-tetramethyl-1,4-butanediyl)bis[(1,1-dimethylethyl)] (DMHBP) (CAS no. 78-63-7); Peroxide, (1,1,4,4-tetramethyl-2-butyne-1,4-diyl)bis[(1,1-dimethylethyl)] (DMBP) (CAS no. 1068-27-5); Peroxide, (3,3,5-trimethylcyclohexylidene)bis[(1,1-dimethylethyl) (DBTMC) (CAS no. 6731-36-8); and Propanedinitrile, [[4-[[2-(4-cyclohexylphenoxy)ethyl] ethylamino]-2-methylphenyl]methylene]- (CHPD)(CAS no. 54079-53-7) no longer meet the criteria for toxic under CEPA s. 64 and for virtual elimination under s. 77(4).

We have noticed that new data was considered in the final assessment results to make a determination on persistence or bioaccumulation and inherent toxicity. We offer the following questions, comments and recommendations:

1) Timing of data - Through the Industry Challenge and the categorization process, industry has been provided with ample time to generate data on these substances. Why was the data for persistence, bioaccumulation or inherent toxicity not included in the draft assessment reports or earlier on in the process for these substances? Or, was the information made available because of the possibility of more stringent risk management based on the government's initial assessment?

2) Role of Expert Panel in final decision - The Expert Panel on Precautionary Principle and Weight of Evidence was given the mandate to advise the government on the proposed decisions for these substances. According to the notes from the meeting of the Expert Panel there were no objections placed on the draft decisions on these substances. It is unclear if the government had the Expert Panel review the final decisions prior to their release or if substantive reviews of the final assessments of these substances were undertaken. Did the government seek the advice of the Expert Panel to review the final assessment for these substances given the change in data being considered or when there were data gaps or conflicting assessment data**?**

3) **Application of analogues** – We question the use of analogues to make a determination on persistence, bioaccumulation or inherent toxicity, in particular during the final phases of the assessment process. In some cases, the rationale and the information to demonstrate the chemical structure for the analogue was not provided in an adequate manner (i.e., CAS No. 78-63-7). This is a significant gap in the risk based approach. Why were analogues not identified and applied during the industry challenge or draft assessment phase? Furthermore, the assessment reports did not highlight other possible analogues for consideration. It is important to understand when analogues should be selected and utilized. According to the government response to public comments, the analogues for pigments were selected by industry. The public needs to be provided with the information necessary to understand the criteria applied by the government in supporting the analogues proposed by industry.

4) Results on inherent toxicity - The use of analogues for either persistence or bioaccumulation automatically results in a reconsideration of inherent toxicity. A shift in the decision on inherent toxicity for these substances would result in "no further action" required under section 77. The use of analogues to replace the use of QSAR models should be discussed in a fulsome way. This approach causes great confusion for the public interested in

responding to the government assessment results. Further, it demonstrates a significant flaw in the risk based approach which is rather subjective in nature.

5) Absence of further action – Further evaluation on the safety of these substances is warranted despite the government's final decision that they are not considered toxic under CEPA s. 64. Simply targeting these substances for the DSL update is inadequate. Some of these substances (i.e., CAS no. 6731-36-8) are used in very high volumes (greater than 10,000 kg). There are several CEPA tools that should be applied to further reduce and monitor the use of these high volume substances such as pollution prevention planning or application of Significant New Activity (SNAc). Application of a number of tools will promote new data generation and improved accountability by industry. In our view, government should aim to reduce the use of substances identified as being only persistent or only bioaccumulative in the environment. It is wholly inadequate to only require that these substances be part of the DSL inventory update initiatives. These substances should be targeted for full assessment.

Recommendation 35: We do not support the conclusion that these substances are not toxic under CEPA. Therefore, we propose that these substances be targeted for full assessments by government.

Recommendation 36: Substances that are found to be only persistent or only bioaccumulative or only inherently toxic should have management reqimes developed. In addition to a full assessment of these substances as recommended above, and following a precautionary approach, interim measures should be taken under CEPA including the requirement to report under the National Pollutant Release Inventory (if not yet listed); require pollution prevention plans; or notification of new uses.

Recommendation 37: Given that industry has been permitted to use substances for several decades, they should be required to produce experimental data on these substances rather than rely on the use of analogues. If analogue data has to be used, this data should be identified and accepted only in the initial stages of the assessment, not as a result of the 60 day comment period on draft assessment decisions. We reject the use of analogues to make a determination of persistence, bioaccumulation and inherent toxicity. At the final stage of assessment, the use of experimental data with adequate rationale should be the only data acceptable to determine persistence or bioaccumulation.

Recommendation 38: Given the amount of time industry and interested stakeholders have been provided to submit data during the categorization phase and again during the industry challenge, experimental data for the substance in question should be the only data considered adequate for making assessment decisions on high priority substances. This approach would support an increased accountability for industry in their use of these substances.

Recommendation 39: The Expert Panel on Precautionary Principle and Weight of Evidence should be given the opportunity to review the changes to assessment decisions to ensure that the precautionary principle is applied appropriately.

For more information, please contact:

Sandra Madray
Chemical Sensitivities Manitoba
71 Nicollet Avenue
Winnipeg, MB R2M 4X6
Tel: 204-256-9390; Email: madray@mts.net

Fe de Leon, Researcher
Canadian Environmental Law Association
130 Spadina Ave., Ste. 301
Toronto, ON M5V 2L4
Tel: 416-960-2284; Fax: 416-960-9392; Email: deleonf@cela.ca