An ENGO Response to Canada Gazette Vol. 142, No. 3 — January 19, 2008 – Results of Batch 1 Screening Level Risk Assessment and Proposed Risk Management Options

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Environment Canada
Health Canada

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The Canadian Environmental Law Association (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 acts at hearings and before administrative tribunals and courts on behalf of citizens and citizens' groups who are otherwise unable to afford legal assistance. Funded by Legal Aid Ontario, CELA is one of 79 community legal clinics located across Ontario, 15 of which offer services in specialized areas of the law. CELA also undertakes additional educational and law reform projects funded by government and private foundations. One of its main program areas is pollution and health. CELA was actively engaged in the government's process to categorize the 23,000 substances under the Domestic Substances List as required under the Canadian Environmental Protection Act, 1999 (CEPA).

CELA is submitting the following comments and recommendations to demonstrate its continued interest in the government's efforts under the Chemicals Management Plan to address the 4,300 substances identified through categorization as of September 2006. The comments are in response to the Canada Gazette Vol. 142, No. 3 — January 19, 2008 as it relates to 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
- Naphthalenecarboxamide, N-[4-(acetylamino)phenyl]-4-[[5-(aminocarbonyl)-2-chlorophenyl]azo]-3-hydroxy- (Pigment Orange 38), CAS no. 12236-64-5
- Benzenesulfonic acid, 4-[[3-[[2-hydroxy-3-[[(4-methoxyphenyl)amino]carbonyl]-1-naphthalenyl]azo]-4-methylbenzoyl]amino]-, calcium salt (2:1) (Pigment Red 247:1), CAS No. 43035-18-3
- Naphthalenecarboxamide, 4-[[5-[[[4-(aminocarbonyl)phenyl] amino]carbonyl]-2-methoxyphenyl]azo]-N-(5-chloro-2,4-dimethoxyphenyl)-3-hydroxy- (Pigment Red 187), CAS No. 59487-23-9

General Comments on Results of Screening Level Risk Assessment for Batch 1 substances

Based on the screening assessments completed on Batch 1 substances identified under the chemicals Management Plan's Industry Challenge, CELA supports the government's proposal to list the following substances as toxic under section 64 of CEPA. Furthermore, CELA supports the government's proposal to add the following substances to Schedule 1 (Toxics Substances List) of CEPA:

- *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

Recommendation: Based on the results of the Screening Level Risk Assessments (SLRA) completed on Batch 1 substances under the Industry Challenge, CELA supports the conclusion of toxic under CEPA section 64 and the addition of the following substances to Schedule 1 (Toxic Substances List) of CEPA: *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); and 1,4-Benzenediol (1,4-benzenediol)(CAS No. 123-31-9).*

The SLRAs completed on the following substances confirmed that these substances are persistent, bioaccumulative and inherently toxic substances which meet the criteria of the

Persistence and Bioaccumulation Regulations under CEPA. Therefore, under this regulation appropriate action would be virtual elimination with regard to 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

Recommendation: CELA supports the government's proposal for virtual elimination of Peroxide, (1,1,4,4-tetramethyl-1,4-butanediyl)bis[(1,1-dimethylethyl)] (DMHBP) (CAS no. 78-63-70); 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). Actions taken in regard to these substances should include the prohibition of use, sale, manufacture, export, import and disposal.

The following substances were found to be high priority for human health, based on their high potential for exposure and determination of high hazard for carcinogenicity or genotoxicity: 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 SLRA results provide adequate rationale and supporting data to demonstrate the need for immediate government action to reduce and eliminate these substances from industrial and consumer products. Furthermore, the following substances are considered carcinogens according to the California Proposition 65: Benzene, 1,3-diisocyanatomethyl- (TDI mixed isomers) (CAS no. 26471-62-5), Naphthalene (CAS no. 91-20-3) and 1,2-Benzenediol (1,2-benzenediol) (CAS No. 120-80-9) as carcinogens (see - http://www.oehha.org/prop65/prop65_list/files/singlelist09-28-07.xls.)

In addition, the U.S. Scorecard web site (see - http://www.scorecard.org/chemical-profiles/) identifies that many of these substances have other health effects that require important consideration in the scope of the SLRAs. For example:

- Oxirane, methyl- (Methyloxirane) (CAS no. 75-56-9), which is a recognized carcinogen and is suspected of being a developmental toxicant, gastrointestinal or liver toxicant, immunotoxicant, neurotoxicant, reproductive toxicant, respiratory toxicant, and skin or sense organ toxicant.

- Oxirane, ethyl-, (ethyloxirane) (CAS no. 106-88-7), which is suspected of being a carcinogen, cardiovascular or blood toxicant, gastrointestinal or liver toxicant, respiratory toxicant, and kidney or sense organ toxicant.
- Benzene, 1,3-diisocyanatomethyl- (TDI mixed isomers) (CAS no. 26471-62-5), which is a recognized carcinogen, and is suspected to be a cardiovascular or blood toxicant, gastrointestinal or liver toxicant, neurotoxicant, respiratory toxicant and skin or sense organ toxicant.
- Benzene, 2,4-diisocyanato-1-methyl- (2,4-TDI)(CAS No. 584-84-9) is a recognized carcinogen, and is suspected to be a cardiovascular or blood toxicant, gastrointestinal or liver toxicant, immunotoxicant, neurotoxicant, respiratory toxicant, skin or sense organ toxicant.
- Benzene, 1,3-diisocyanato-2-methyl- (2,6-TDI) (CAS no. 91-08-7) is a recognized carcinogen, and is suspected of being a cardiovascular or blood toxicant, gastrointestinal or liver toxicant, immunotoxicant, respiratory toxicant, and skin or sense organ toxicant.
- Naphthalene (CAS no. 91-20-3) is a recognized carcinogen, and is suspected of being a cardiovascular or blood toxicant, developmental toxicant, gastrointestinal or liver toxicant, neurotoxicant, respiratory toxicant, and skin or sense organ toxicant.
- 1,2-Benzenediol (1,2-benzenediol) (CAS no. 120-80-9) is a recognized carcinogen and suspected cardiovascular or blood toxicant, gastrointestinal or liver toxicant, immunotoxicant, neurotoxicant, skin or sense organ toxicant.
- 1,4-Benzenediol (1,4-benzenediol) (CAS No. 123-31-9) is suspected of being a carcinogen, cardiovascular or blood toxicant, gastrointestinal or liver toxicant, immunotoxicant, neurotoxicant, reproductive toxicant, respiratory toxicant, or skin or sense organ toxicant.

The range of potential health effects that may be associated with these substances requires careful consideration by the assessors, as these additional health endpoints should also inform the development of management response. Many of the substances have a wide range of uses for industrial applications and consumer products.

In general, any substance identified as a mutagen or a cancer causing substance in the SLRAs should be targeted for phase out or prohibition of its use, manufacture, sale, import, export and disposal. Furthermore, particular attention to a prohibition of these toxic substances should made explicit for consumer products including personal care products and those used in food or in food packaging.

Recommendation: CELA recommends the government develops regulations under CEPA targeting 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). These regulations should

prohibit and phase out the use of these substances for industrial applications, consumer products, personal care products and food products.

Recommendation: To support this goal, the government should initiate a process to identify safer alternatives, assess the toxicity of these alternatives and promote the alternatives for these substances in industrial, and consumer products. An action plan for each substance is required to outline a process to conduct an assessment on alternatives, and set out reduction targets to achieve prohibition or phase out.

Recommendation: For those substances, such as but not limited to CAS no. 75-56-9, which may be used in food products as additives or fumigants, the results of the SLRA should be used to trigger action for prohibition or similar management response under CEPA and other applicable statutes (e.g. Food and Drug Act, Pesticides Control Product Act, etc.) or policy initiatives (e.g. Cosmetic HotList).

Substances proposed not to meet the criteria for toxicity under s. 64 of CEPA

Based on the screening assessment results, three substances from Batch 1 substances identified as persistent, bioaccumulative and inherently toxic (PBiT) in categorization were found not to meet the criteria for toxic under CEPA section 64. The government found that these substances [i.e., Naphthalenecarboxamide, N-[4-(acetylamino)phenyl]-4-[[5-(aminocarbonyl)-2-chlorophenyl]azo]-3-hydroxy- (Pigment Orange 38)(CAS no. 12236-64-5); Benzenesulfonic acid, 4-[[3-[[2-hydroxy-3-[[(4-methoxyphenyl)amino]carbonyl]-1-naphthalenyl]azo]-4-methylbenzoyl]amino]-, calcium salt (2:1) (Pigment Red 247:1)(CAS No. 43035-18-3); and Naphthalenecarboxamide, 4-[[5-[[[4-(aminocarbonyl)phenyl] amino]carbonyl]-2-methoxyphenyl]azo]-N-(5-chloro-2,4-dimethoxyphenyl)-3-hydroxy- (Pigment Red 187)(CAS No. 59487-23-9) no longer meet the criteria for bioaccumulation, and has downgraded the aquatic toxicity level to low and medium levels. CELA respectfully submits that the government's proposal to take no further action on these substances is inadequate.

In our review of the SLRA report, we identified the following issues that require further investigation of the adequacy of the assessments completed on these substances.

Issue 1: Consideration of new experimental solubility data to challenge Bioaccumulation and Inherent toxicity information

The assessment reports for the three substances noted the use of experimental solubility data for each substance. The change in solubility data has a significant impact on the determination of bioaccumulation factor and the inherent toxicity values. It is not clear from the assessment reports what tests, if any, the government applied to validate the use of the experimental data for solubility in these assessments. Furthermore, it was also unclear from the assessments whether

the experimental results followed the OECD Good Laboratory Practices to further validate the use of experimental data.

It should also be noted that a study by Gobas et al. ((Kelly BC, Ikonomou G, Blair JD, Moriin A, and Gobas F A, 2007. Food web-specific biomagnification of persistent organic pollutants. Science. Vol 317: 236-238), noted that octanol-water partitioning cannot serve as a universal model for identifying bioaccumulative substances in wildlife and humans, and that air to lipid transfer is a an important consideration, particularly for low to moderately hydrophobic substances that bioaccumulate in food chains. It is unclear from the assessment reports whether this finding was taken into consideration when reviewing the experimental solubility data and the analogue data provided. If it has not already done so, the government ought to consider this factor in finalizing the adequacy of the data used, and therefore the use of analogues for bioaccumulation and inherent toxicity.

Issue 2: Uncertainty in the use of analogue to determine bioaccumulation and inherent toxicity to the environment

The government provided analogues to determine both bioaccumulation value and inherent toxicity to aquatic environment for the following three substances: Pigment Orange 38(CAS no. 12236-64-5); Pigment Red 247:1(CAS No. 43035-18-3); and Pigment Red 187(CAS No. 59487-23-9). CELA respectfully raises some concerns about the uncertainties associated with the use of analogues. It is our view that the assessment reports provided insufficient information on what range of analogues were under consideration, how the analogues were selected, who supplied the information for the analogues (government or industry), and what features of the analogues determined suitability. Since the use of the analogues has significant implications for the determination of toxicity under CEPA for these three substances, we question why these analogues were not considered during the categorization phase, particularly in light of the fact that industry was given seven years to submit information to governments on these substances.

For Pigment Orange 38 (i.e., CAS no 12236-64-5), the analogue selected (Analog Pigment Red 2) was half the molecular weight of the substance. The assessment report should provide an adequate explanation of what impact this difference in molecular weight would have on the behaviour of the substance.

The results of the assessments on these three pigments would have been improved significantly if the survey applied during the industry challenge required the submission from industry of experimental data for developmental or other mammalian toxicity data on these substances. This type of data may have provided additional insight on how these substances are reacting in organisms exposed to these substances.

The gaps in the assessment report on the use of analogues, combined with the absence of tests to validate the experimental data, raises some concern on the assessment conclusions for these substances.

Recommendation: Based on the concerns raised with the use of experimental solubility levels and the lack of rationale for use of analogues to determine bioaccumulation and inherent toxicity to the environment for all three substances (CAS Nos. 12236-64-5; 43035-18-3; 59487-23-9), CELA believes further investigation into the toxicity of these substances is warranted. Therefore, it is premature to conclude that the three substances do not meet the criteria outlined under section 64 of CEPA.

Recommendation: In assessments where decisions on persistence, bioaccumulation and inherent toxicity are revised, additional precaution should be applied by way of requiring explicit experimental toxicity data for developmental and mammalian toxicity.

Issue 3: Inadequate investigation of exposure levels

The Draft SLRA for CAS No. 59487-23-9 (Pigment Red 187) states that this is an organic substance that is used in Canada and elsewhere primarily as a colour pigment in plastics, inks, paints and textiles, and is also used in the food and beverage sector. Its secondary use is as an inert ingredient in pesticides. Consideration of exposure to children, via food additives and personal care products, such as products applied to the skin, should be included in the use pattern questionnaire to industry and other stakeholders interested in this substance. It is unclear whether the Assessment addressed the migration of this pigment from food containers, or the fact that its possible use as a food additive may be another direct source of exposure to children. By way of example, three synthetic azo red-dyes used as food colour additives were examined, and because they induced colon DNA damage at a very low dose, starting at 10mg/kg the authors recommended that more extensive assessment of azo additives is warranted. (Tsuda S. et al. Toxicol Sci. 2001, May; 61(1): 92-9). A second study that investigated the effects of three azo dyes on mouse embryo culture cells pre-treated for 1 hr with S9-untreated azo dyes at concentrations of 0.3, 1.0, and 5 mM, found the cell growth was slightly reduced by 5 mM Ponceau 3R. All the S9-untreated azo dyes inhibited cell growth when added to the medium during cultivation (Okawa Y. et al. Shokuhin Eiseigaku Zasshi 1989; 30(6):496-500).

Recommendation: The exposure routes and levels of exposure of children to these substances in consumer products should be required from industry and considered in these assessments.

Specific Issues on Screening Level Risk Assessments

There are a number of issues that should be considered as the government continues to conduct assessments on substances identified through categorization and the focus of the Chemicals Management Plan. Using examples from Batch 1 substances, CELA highlights the following issues as important and relevant for further consideration in reaching conclusions on toxicity under section 64 of CEPA for current and future batches of substances.

1) Use of validated surrogate or modeling data

Surrogate data will no doubt be expected during the Industry Challenge and the completion of the SLRAs. We had noted in a previous section the absence of information to verify the adequacy of experimental data for three pigments. For any experimental data submitted by industry it is critical to the decision making process to include information that will be used to identify and select appropriate analogues to determine environmental fate or impacts to human health. Furthermore, since analogue or surrogate data are expected to be used to review specific criteria (Persistence, Bioaccumulation, inherent toxicity), it is also useful to confirm that such data follows OECD Good Laboratory Practice to ensure that the data is valid for the assessments undertaken and to promote transparency in the process.

Since the use of surrogate or modeling data is expected to have a significant impact on the final outcome regarding the toxicity of the substance as well as the proposed management strategy to be developed on the substance, if applicable, it is important that the issues mentioned on the use of analogues be addressed in future assessments to reduce the uncertainty in assessment reports.

Recommendation: See previous section.

2) Consideration of hazard: toxicity to human systems including vulnerable subpopulations (e.g., children and workers)

Few of the assessments for Batch 1 substances included consideration of exposure to children's health and workers. This is a significant gap in the assessments.

We recognize that CEPA does not explicitly address occupational exposure to substances being assessed under CEPA. However, exposure routes to workers provide signals that may be valuable to estimating exposure to the general human population and possible impacts from exposure. Of particular significance to workers' exposure are dermal contact and inhalation routes of specific substances. It is valuable to the overall process to require this information, as it can better inform the type of management approach required for this substance or the sectors that may require specific attention. There were very few assessments for Batch 1 substances which utilized the use of workers' exposure information. For example, the assessment on methyloxirane (CAS no. 75-56-9) mentioned the exposure levels to workers of the substance.

Recommendation: The SLRAs should include for consideration information provided on workplace exposure, with particular focus on exposure through dermal and inhalation pathways.

3) Account for each phase of a substance's life cycle from use/manufacture of substance to end of life use (disposal methods) of products

Whether the government is conducting a SLRA or a full assessment, all assessments should provide information on the level of exposure and level of toxicity of a substance during each

phase of its life cycle, from use to market to end of life including disposal methods. For each phase of the substance's life cycle, it is important to provide information on the potential level of exposure to non-living or living organisms, and the human populations of all ages. In addition, should substances produce by-products during any aspects of the use of the substance, such information is important to the overall decision making process.

Many of the assessments for Batch 1 substances did not provide a full description of the life cycle of the substances. The following substances, DMBP (CAS no. 1068-27-5) and DBTMC (CAS no. 6731-36-8) outline that much of the substances (92.9 % by mass for DMBP and 97% by mass for DBTMC) is transformed during the industrial process and another 5% (DMBP) and 1% (DBTMC) is sent off to the waste stream. The assessment report does not elaborate on what the transformation products are for each substance, the toxicity of the transformation products, and whether the amount entering the waste stream breaks down over time and at what rate. The assessment report also does not mention what substances are released into the environment during the incineration of these substances.

Other substances identified that exposure routes may be through consumer products or at the end of the product's life as they are sent for final disposal via incineration or landfill, for example CAS Nos. 6731-36-8, 43035-18-3, and 12236-64-5 (which indicated that "90 percent of the mass of the pigment ends up in waste disposal facilities"). In these assessments, no estimates were provided to demonstrate the level of leaching of substances or the type of breakdown products that may be released through incineration.

In assessments that indicated partitioning of substances is favoured in one environmental media over another, limited data or no data was provided to demonstrate the potential impact to other organisms aside from fish, algae or daphnia. For example, CAS No. 78-63-7 would be present in soil and sediment but no data was provided to demonstrate potential impact to air breathing organisms or terrestrial animals that are found in these media.

Recommendation: Recognizing that SLRAs differ from full PSL assessments, the full life cycle of the substances should be provided and considered to identify all possible routes of exposure/impact to human health and the environment.

4) Expand industry accountability to submit toxicity data to demonstrate the safety of substances through Section 71 surveys

The SLRAs conducted for Batch 1 substances demonstrate that the government continues to focus only on the limited toxicity information that was available for the categorization process. Over the past few years, non-governmental organizations submitted several submissions outlining the need for industry to provide toxicity data that demonstrates the safety of their substances, especially to the developing systems of children. The assessment reports for Batch 1 substances do not appear to reveal new data for developmental, neurodevelopmental, chronic or endocrine disrupting toxicity. It is our view that the industry challenge is an opportunity for government to fill in data gaps on toxicity end points that were not included in the

categorization, but are very relevant to determining if there are important impacts on health and environment. Specifically, we identified the need to seek data for endocrine disruption, chronic toxicity and neurodevelopment toxicity to account for the impact to children.

The surveys applied under the Industry Challenge should be expanded to outline explicit requirement for toxicity data for the following hazardous properties: neurodevelopmental toxicity, endocrine disruptors, and chronic toxicity. Lack of data on these toxicity endpoints should require the government take this information into consideration in making a decision of toxicity under CEPA section 64.

Recommendation: The surveys under S. 71 should be expanded in their scope to require experimental mammalian toxicity data as necessary on the following toxicity endpoints: developmental toxicity, neurotoxicity, developmental neurotoxicity, endocrine disruption, and chronic toxicity to fill in data gaps that exist in regard to certain substances. More information regarding potential toxicity to children, in particular the developing fetus, should be an integral requirement of all assessments undertaken on substances.

5) Consideration of exposure to children, via consumer products, food additives, and personal care products such as products applied to the skin should be included in the assessments

The SLRAs conducted to date do not provide a consistent approach to considering the impacts on children's health. Given the unique vulnerability of children to the impacts of exposure to toxic substances, careful consideration of all exposure routes to children and to the developing fetus are integral components for all assessments, regardless of whether a given substance is identified as an ecological priority or a human health priority.

By way of example, in our review of the Batch 1 substances, the assessment completed on Methyloxirane (CAS no 75-56-9) provides estimates for adults' exposure to products containing the substances (Appendix 3). It is a glaring gap in the assessment to assume that average size adults are the only group exposed to this substance through the use of the following products: acrylic aerosol spray paint, automotive vinyl upholstery cleaners and textiles spot removers. While adults are primarily responsible for use of these products, there are short to long term exposure scenarios in which children may come into contact with products themselves post application. No data was provided (estimated or measured) to quantify the level of exposure to children from these products.

In addition, other substances such as CAS no. 12236-64-5, outlines use of these pigments in crayons and paints among its uses internationally, while CAS no. 54079-53-7 is used in the application of textiles. Other examples include DMHBP (CAS no. 78-63-7) for use in plastics and rubbers for soles of shoes, and naphthalene (CAS no. 91-20-3) which is used in blanket was products and fabric cleaners. The potential for exposure to children from these products exist and therefore to the substances mentioned. However no information was provided on estimated exposure levels to children to the substances from such products.

Recommendation: Government should include data on exposure levels to children and the developing fetus from products that contain any of the substances identified through the categorization process.

One way to ensure that data is collected on the impacts on children is to expand the survey developed under Section 71 of CEPA. The government should seek to determine toxicity and exposure data relevant to children's health, including exposure through drinking water and indoor and outdoor air.

Recommendation: The government should expand the Section 71 surveys to require data on toxicity and exposure data relevant to children's health, including exposure through drinking water and indoor and outdoor air.

6) Impact on terrestrial and aquatic species from substances available in sediment or soil

The SLRAs conducted do not provide a consistent explanation of the impacts on surrounding ecosystems from substances released to sediment or the environment. While the approach in categorization was to focus on the use of aquatic toxicity, the impacts to terrestrial species and other air breathing organisms (excluding daphnia, fish and algae) are important to consider as well. More information should be provided in the ecological assessment sections to demonstrate to what extent the terrestrial and other air breathing organisms may be impacted from the availability of substances in soil or sediment.

Recommendation: Additional information should be provided in assessment reports on the impact of substances on terrestrial species and other air breathing organisms that may be found in soil or sediment.

7) Absence of consideration of classes of substances, cumulative and synergistic impacts to health and environment

The SLRAs have done a very poor job in attempting to address substances that may belong to the same class, or considering the cumulative impacts from substances with similar chemical structures or modes of action. The approach with full PSL substances and with current SLRA reports has been on individual substances. The interactions of multiple substances in the environment are not acknowledged in these assessments.

For future Batch substances it would provide added value to the assessment results if the cumulative impacts of substances with similar structures or similar modes of action would be considered or estimated.

Recommendation: Future assessment reports should include cumulative impacts of substances being assessed under the CMP that have similar chemical structures or modes of action.

General Comments on Management Options

Please find below some additional recommendations for specific substances for Batch 1 substances.

For peroxides that have been found to be PBiT, we support a management tool to develop "regulations respecting the manner in which and conditions under which the substance or a product containing it may be imported, manufactured, processed or used; and the manner, conditions, places and method of disposal of the peroxide or a product containing it." It should be noted that regulations should aim for the phase out of these substances.

Recommendation: FOR DMHBP, DBTMC and DMBP, CELA supports a regulation that aims to phase out the use of these substances. Furthermore, the regulation should ensure that incineration is not selected as an option to address end of life products, due to the toxicity of by-products released from such an approach.

The use and release data for substances identified through categorization will be of importance in the efforts to develop a policy response to assess and manage these substances. The government has stated in its release of the Chemicals Management Plan in December 2006 the need to update the existing substances listed under the Domestic Substances List. The DSL is outdated, and will require an update to ensure that Canadians know what types of substances are in current use.

Similarly, Canadians should also be provided the information on the substances that are released and transferred from facilities in Canada. In this regard, it will be important to update the National Pollutant Release Inventory (NPRI), to reflect the results of categorization and the implementation of the CMP. Currently, the NPRI requires reporting on the following substances covered under Batch 1: 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). It is interesting to note that these substances are those which are considered human health priorities. Most of the substances that have been identified to be PBiT are note reported under the NPRI. The NPRI should be updated to reflect the decisions in the SLRAs.

Recommendation: The DSL inventory update should be undertaken as soon as possible with input from stakeholders with respect to the scope of substances it covers and the level of reporting required for these substances.

Recommendation: Substances identified through categorization should be added to the NPRI for reporting. To begin, the NPRI should be updated to add the following substances for reporting: 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); Naphthalenecarboxamide, N-[4-(acetylamino)phenyl]-4-[[5-(aminocarbonyl)-2-chlorophenyl]azo]-3-hydroxy- (Pigment Orange 38) (CAS No. 12236-64-5); Benzenesulfonic acid, 4-[[3-[[2-hydroxy-3-[[(4-methoxyphenyl)amino]carbonyl]-1-naphthalenyl]azo]-4-methylbenzoyl]amino]-, calcium salt (2:1) (Pigment Red 247:1) (CAS No. 43035-18-3); and Naphthalenecarboxamide, 4-[[5-[[[4-(aminocarbonyl)phenyl] amino]carbonyl]-2-methoxyphenyl]azo]-N-(5-chloro-2,4-dimethoxyphenyl)-3-hydroxy- (Pigment Red 187)(CAS No. 59487-23-9).

Recommendation: For substances that are PBiT substances, reporting thresholds should be lowered (e.g. dioxins and furans, mercury, lead, etc.) to capture all facilities which use and release these substances.

Recommendation: For the three pigments (CAS Nos. 12236-64-5, 43035-18-3, 59487-23-9), it is important to track releases because of these substances' extensive use in industrial applications and consumer products.

Recommendation: All substances found to result in significant health impacts should also be added onto the NPRI, with particular focus on those substances which are carcinogens, mutagens, genotoxic, developmental and reproductive toxicants, skin sensitizers, respiratory toxicant, neurodevelopmental toxicants and endocrine disrupters.

Recommendation: All substances under Batch 1 that are proposed for CEPA Schedule 1 should be required to complete pollution prevention planning.

For human health priority substances

Recommendation: Those substances found to be carcinogenic, mutagenic or genotoxic should be phased out over time. The appropriate government response should include regulations to prohibit the use, sale, manufacture, export, import and disposal of these substances. An action plan for reduction and elimination should be considered to ensure that safer alternatives are identified, assessed for their toxicity, and promoted.

Methyloxirane (Propylene Oxide) CAS No. 75-56-9

Recommendation: An appropriate management response should include the elimination of this substance over time. This goal may be reached through the development of a pollution prevention strategy that outlines timelines and targets to prohibit its use, manufacture, import, sale, and disposal, particularly as it pertains to consumer products (i.e., upholstery cleaners).

Recommendation: Additional work to determine the level of exposure to these substances from indoor air and dust is required. As a follow-up, the management response should ensure that products containing these substances are prohibited for future use.

Recommendation: The assessment results indicate that use of this substance as a fumigant on food products such as nuts may add a source of exposure for Canadians. The presence of methyloxirane on food products such as nuts should not be permitted in any level. The government should ensure that the Food and Drug Regulations prohibits the use of this substance as a food additive, without exemptions.

Recommendation: The government should commit to prohibit the use of methyloxirane in cosmetic products. This can be achieved by requiring a process to investigate safer alternatives, assess their toxicity, and promote their use in place of methyloxirane.

Naphthalene CAS No. 91-20-3

Recommendation: The government should ensure that naphthalene is prohibited in consumer products such as mothballs, room deodorizers and cleaning products.

Recommendation: The government should identify alternatives to naphthalene in its various uses, and conduct an assessment for their toxicity to ensure their safety. Finding safer alternatives will support the production of consumer products that are naphthalene-free.

Recommendation: The government should include the aggregate use and exposure to naphthalene as it prepares to conduct an assessment for petroleum uses and releases. Furthermore, this assessment should also take into consideration the cumulative impact of the other substances found in use and release of substances relevant to the petroleum sector.

Recommendation: Under the CMP, the government's management approach should require the phase out of naphthalene as a pesticide active ingredient due to its health impacts.

Ethyloxirane (Butylene Oxide) CAS No. 106-88-7

Recommendation: The government should ensure that the assessment results trigger a regulatory response under the Occupational Health and Safety Act to protect workers from exposure to Ethyloxirane (Butylene Oxide), with specific attention to inhalation of this substances.

Recommendation: Prohibit all present or future use of ethyloxirane in cosmetic and consumer products.

1,2-Benzenediol (Catechol) CAS No. 120-80-9

Recommendation: An action plan to reduce and eliminate this substance over time is appropriate. The plan should be achieved by developing a pollution prevention strategy to address the use, sale, manufacture, export, import and disposal of catechol.

Recommendation: The government should establish a process by which safer alternatives to catchecol are identified, assessed for safety, and promoted in application such as photography developing solution, adhesives, and deodourizers.

Recommendation: The government should develop a regulation to prohibit the use of catechol in consumer products to ensure that the Canadian Cosmetic Hot List is implemented to the full extent.

1,4-Benzenediol (Hydroquinone) CAS No. 123-31-9

Recommendation: The restriction on the use of 1,4-benzenediol in manicure products and skin lighteners for cosmetic use should be enforced. Alternative skin lighteners exist, though their relative safety needs to be ensured.

Recommendation: Safer alternative products and technologies for this substance, in consumer and cosmetic products as well as in the digital photography industry should be identified, assessed for their safety and, if safe, promoted. This process should be undertaken as soon as possible to inform the management process.

Recommendation: For uses in digital photography, the government should investigate the alternatives to hydroquinone containing solutions noted in http://greenphotochemistry.com/.

Recommendation: The management plan for hydroquinone should ensure that appropriate disposal methods are followed for products containing hydroquinone. This plan should not consider incineration an appropriate disposal method since other toxic by-products may be produced and released.

Toluene Diisocyanates CAS Nos. 91-08-7, 584-84-9, 26471-62-5

Recommendation: Due to the uncertainty around the level of exposure to TDI in food packaging, its use in food packaging should be prohibited.

Recommendation: The government should develop an action plan to reduce and eliminate TDI in industrial applications and consumer products. The foundation of the action plan is applying a pollution prevention strategy that may include a process to identify safer alternatives to TDI, call for a reduction of use of TDI by facilities, and monitor the release of TDI in dust as well as polyurethane household furniture.

Recommendation: The government should ensure that possible disposal methods for products containing TDI containing do not include incineration as an option.

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