A Response to the Proposed Risk Management Approach for Chemicals Management Plan Industry Challenge Batch 3 Substances Published in *Canada Gazette* Part I, Vol. 143, No. 10 — March 7, 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. 10— March 7, 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 assessments and draft risk management options for Batch1, 2 and Bisphenol A (under Batch 2 of the Industry Challenge). Our organizations have expressed some support for proposed assessment results and have elaborated on the gaps and limitations for some aspects of proposed management instruments for specific chemicals. Consequently, we have developed appropriate substantial recommendations to address these gaps and limitations.

We provide more in depth commentary on the four substances in Batch 3 considered toxic under CEPA 1999. For the remainder of the substances in Batch 3, we have provided more general comments. However, the general comments presented below may be considered as examples of the range of concerns we have on the final decisions made by the government on substances assessed to date. They also demonstrate the level of protection that should be required 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 substances in the Canadian market.

In this submission, our organizations continue to highlight concerns 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 3 substances.

2.0 Draft Screening Level Risk Assessment Report –overarching issues & recommendations

Analogues

There was extensive use of analogues to assess the environmental and health effects of pigments/dyes in Batch 3. This practice concerns us and we have raised our objections to it in several of our joint CMP Challenge submissions to the government as well as in multi-stakeholder discussions focused on the implementation of the CMP.

In the April 23rd 2009 meeting with Health Canada and Environment Canada, which focused on issues related to risk based assessments, the use of analogues to complete assessments was identified as a common practice. This is particularly so, when there is a lack of sufficient, definite physical and chemical information on a substance. In these situations there is a heavy reliance on analogues to complete risk assessments. Other issues identified at the meeting were about the *way* analogues are used. The use of multiple analogues for determining the properties of one substance, and the use of analogues that are also being assessed under the Challenge Program seem particularly problematic.

Furthermore, we continue to be concerned about the use of analogues to complete assessments for high priority chemicals. First, we question why the government does not use its authority under CEPA, section 71, to require industry to generate basic toxicity data for each substance. This process would only require a slight refinement of the questions outlined in the Chemical Challenge. We see the lack of very basic physical and chemical data on substances that have been in use for many decades as a problem to be addressed.

The current practice for screening level risk assessment has been to rely on analogues rather than to require the generation of much needed physical, chemical and toxicity data specific to these chemicals. Second, we question who supplies the listing of analogues. It is quite disconcerting that the government assessors have not identified the list of analogues that should have been under consideration for making decisions during categorization and again during the completion of the draft assessments on these chemicals.

Finally, the government's timing for considering new analogues is also questionable. The above issues continue to be relevant in the context of the assessments being undertaken under the CMP. The assessment process mentioned above has lead the assessors to change some key decisions about several high priority chemicals at the

stage of final assessments, particularly those found to be persistent, bioaccumulative and inherently toxic.

We do not oppose the use of analogues to fill in key data gaps that exist for chemicals. However, it is of critical importance to note that the Industry Challenge was intended to fill in these data gaps. A reliance on analogues may be a hindrance to the production/generation of critical toxicity data for these chemicals – data that theoretically should be available. The long term implications of reliance on analogues for some key pieces of data are yet unclear. However, if the Industry Challenge was designed to create greater accountability by chemical users, this goal would be better met if the government required chemical users to generate new data would have been evident.

One area where we have seen some improvements in the quality of the assessment reports is in the use of tables to identify the analogues under consideration, highlighting their structures and structural differences. We appreciate this change, since the listing of analogues, their structures and structural differences clearly identified in table format is much more informative.

We maintain that the quality of the SLRA is reduced when the approach to and use of analogues are not explained explicitly. There needs to be more transparency in the SLRA. We would like to understand the rationale behind the use of several analogues to determine the physical and chemical properties of one substance – the reasons behind such choices are not always readily apparent. It is crucial to know on what properties the assessors base their choices for analogues. Knowing this information would allow us to better define or qualify why one analogue is chosen over another, and why certain analogues are used to fill data gaps for specific substances under assessment. Since there are many physical and chemical differences between the analogues, it is important to understand what characteristics they share, or don't share, with the chemical under assessment. Also, the physical and chemical properties found in analogues will impact on the decisions assessors take regarding the substance for which the analogues are standing in.

Recommendation: **The quality of the SLRA should be improved as it is critical for the decision making process that an adequate and transparent rationale for the choices of analogues specific to any physical or chemical property be provided.**

Recommendation: As part of the Challenge Program, the use of section 71 should be enhanced to ensure that industry provides the necessary data on the physical and chemical properties of chemicals. An adequate communications framework with affected industry will be required to communicate that information gaps such as physical and chemical properties are not acceptable and that all attempts should be made to supply this data.

Recommendation: The SLRA reports should disclose full sources for all analogues used to complete the assessments.

Safe substitution

Four substances were designated as being CEPA toxic in Batch 3 with alternatives being mentioned for three of the substances. For more details, please see tables 2, 3 and 5. The concept of finding and using alternatives is to eliminate the hazard of the original chemical being substituted. Replacement with another toxic substance or technique resulting in human exposure to these or other toxic substances is counterproductive. For some of the alternatives or technologies identified for the four CEPA toxic chemicals, it is ironic that the substitutes and techniques being considered for these substances do not have reduced toxicity.

It is our view that chemicals demonstrating specific human health effects such as carcinogenicity, reproductive and developmental toxicity, etc, should be phased-out. The appropriate government response to protect public health should be a commitment to phase out and eliminate such toxic substances. A commitment to elimination should rely on safe substitution for these toxic substances. This commitment is an integral part of the precautionary and protective approach to chemicals management.

To reiterate the comment that we have made in several of our submissions – substitutions or alternatives must be safe demonstrating no hazardous effects to human health to the environment. To ensure that this is achieved, an assessment of these alternatives should also be undertaken under CEPA 1999. To date, the CMP process has not effectively addressed the safety of alternatives and a listing of possible safe alternatives is generally not available. There is concern that these elements, considered fundamental to the development of protective management strategies, are lacking. As the CMP progresses, we think the need to identify alternatives and call for substitution should become greater priority for the government. The development of management measures will rely on this information. Moreover, this shift in focus sends an important signal to chemical users that a change in chemical use may be needed for specific toxic chemicals.

The process of reviewing an alternative should include a review of toxicity data (both acute and chronic), pertinent to both human health and the environment. We must keep in mind that the safety of alternatives is as important as taking action on the substances they are intended to replace. Finally, the screening of safe alternatives should incorporate an effective public engagement component so as to promote full transparency.

Recommendation: For Batch 3 substances identified as CEPA toxic with health implications such as human carcinogenic potential, reproductive and developmental toxicity, we urge the government to aim for an elimination of these substances through the substitution of safe alternatives for these chemicals.

Recommendation: Furthermore, such a process will require the identification, assessment , and implementation of safe alternatives. This process should be considered an imperative component of the Challenge Program and one that will support an elimination strategy for these toxic substances.

Recommendation: In support of these efforts, we urge the government to establish a multi-stakeholder task force on alternatives assessment. The proposed taskforce should promote transparency and open discussion on the need for safe, government assessed alternatives under CEPA 1999.

Vulnerable populations

The assessments completed under the CMP, including Batch 3, 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 using toxic chemicals, and aboriginal communities) have not been considered in the assessment process. Even when information is provided on children's exposure to chemicals, the approach to address children as a vulnerable subpopulation has not been consistently applied to all substances. For example, if products containing specific chemicals are not intended for children, no additional information is gathered to consider exposure to children.

The consideration of impacts to subpopulations listed above should be an integral part of the assessments. For example, the impacts of cancer causing chemicals to specific vulnerable subpopulations mentioned above should be carefully reviewed as one needs to consider other socio-economic factors that may be interacting with their ability to cope with such exposures.

Similarly, for some vulnerable subpopulations, such as the aboriginal communities who may be living in close proximity to some sources of cancer causing substances or other toxins – harmful to environmental or human health – careful and direct consideration should be given to these communities in the assessment process. Once a high priority substance is found not to meet the criteria for B or iT, even if it had originally been identified as PBiT as a result of categorization, it is given no such consideration as to its impacts on aboriginal communities. Nevertheless, exposure to these substances could result in significant health implications for members of such communities and this needs to be taken into consideration.

Consideration of worker exposure to chemicals assessed under CEPA is generally absent from the reports. In contrast, other jurisdictions have included workers' exposures in their assessment processes. In Australia, the National Industrial Chemical Notification and Assessment Scheme (NICNAS) includes consideration of occupational health. This is lacking in CEPA 1999 but we recognize that it is addressed by the Canadian provinces and territories. Workers who are exposed to toxic substances on a daily basis should be considered a vulnerable subpopulation. In their process to determine the toxicity of chemicals and develop measures to manage toxic chemicals, federal and provincial authorities generally do not fully acknowledge the problem of workers becoming increasingly sensitive to workplace chemicals, While this is not a situation unique to Canada this gap should be rectified. CEPA 1999 does not have any provisions to address workers as a special subpopulation with unique chemical exposures. Therefore, assessments should be strengthened to acknowledge workers' exposures to provide a more accurate picture of exposure routes and subsequent

health outcomes for these subpopulations. In particular, it is increasingly important to take actions to fully protect workers who have become very sensitive to low levels of exposure to workplace chemicals.

Recommendation: The screening assessment reports under Batch 3 should be strengthened in their approach to include impacts to vulnerable subpopulations that include people of low income, workers using toxic substances in the workplace, people with chemical sensitivities and aboriginal communities.

Human health

Based on the draft assessment completed on 19 substances in Batch 3 of the Industry Challenge of the Chemicals Management Plan, only 4 chemicals were found to be CEPA toxic and were therefore identified as human health priorities (see Table 1 for the listing of these substances). The proposed risk management strategies for these substances could have been more extensive in scope, considering the government's findings of their carcinogenicity and reproductive toxicity. The lack of details on the management for these chemicals is unacceptable. Although extensive details on the proposed measures are not required at this stage, we expect to see this information in the near future.

It would be appropriate for the government to recommend more stringent and appropriate precautionary measures that focus on the elimination and phase out of these toxic substances in Canada. The proposal to add these chemicals to Schedule 1 of CEPA (Toxic Substances List) will provide the necessary first step in these efforts. This listing would trigger the need to develop management measures for these substances.

We have a growing concern (for this batch and previous batches of chemicals assessed under the Chemicals Management Plan) that the proposed measures to manage many of these substances will not be sufficiently protective of human health and the environment. With the current risk based approach, we are concerned that the management of these toxic chemicals would mainly take the form of control measures as opposed to the elimination of toxic sources. Due to the health impacts of the chemicals found toxic in Batch 3, this method of managing risk would not provide an adequate measure of protection to human health and the environment. It is more protective to commit to an elimination strategy for toxic chemicals that would ensure the protection of human health and the environment.

There are four solvents included in Batch 3 and are used extensively in a wide range of consumer products. Three of them are CEPA toxic. The fourth solvent, 2-EEA (2-ethoxyethanol) CAS RN 111-15-9, was categorized as toxic according to the draft assessment report but in the final assessment it has been changed to non toxic under CEPA 1999 s.64(c). The change in decision for this chemical should be questions more rigorously since this solvent has reproductive and developmental toxicity as well as hematological effects. Human exposure through the use of consumer products is expected to be low for 2-EEA. It is worth noting, however, that despite expectation for low exposure to the general population, additional considerations should be given to

vulnerable subpopulations such as those with chemical sensitivities that can be negatively affected by these low level exposures found in solvents and, in particular, chronic low level exposures.

There are additional health concerns from exposure to toxic chemicals that should be addressed by government, such as the effects to the central nervous system (CNS), liver and kidney(common in exposures to solvents), as well as possible cardiac effects. Those who are chemically sensitive are more likely to show CNS and cardiovascular effects. It has been argued that some of these effects dissipate when exposure to the toxic chemical is eliminated. However, this does not adequately address the issue of sensitivity as it relates to chemical exposure. Although these are not health endpoints currently addressed in the chemical assessments, they deserve to be investigated and acted upon by the government.

Recommendation: We do not support the government decision that CAS RN 111-15-9 is not toxic under CEPA. This decision is based on the lack of data received through the Industry Challenge and low indoor human exposure.

Recommendation: Based on its reproductive and development toxicity as well as the hematological effects of 2-EEA (CAS RN 111-15-9), it should be found toxic under CEPA 1999. Furthermore, this chemical should be listed on CEPA Toxic Substances List (Schedule 1) and appropriate management strategies should be developed.

Recommendation: We do not support the use of SNAc for CAS RN 111-15-9 based on its health impacts as a reproductive toxicant. A precautionary approach as noted above would be to add this chemical to the Toxics Substances List (Schedule 1) and seek a phase out of this chemical.

Recommendation: The screening assessments should be improved to consider more inclusive and more fully other health endpoints such as chemical sensitization, endocrine disruptions, effects to the central nervous system, etc.

Recommendation: The government should enhance communication and outreach with the public as well as authorities in occupational health, unions, etc, on the outcomes for the assessment and management of the substances in the Challenge Program.

Environmental concerns

All chemicals identified as PBiT as a result of categorization retained their persistence designation. However, the designation for bioaccumulation changed for most of the chemicals. Despite meeting the criteria of persistence, the government final assessment reports did not suggest the need for measures to reduce the use of persistent chemicals. It is our view that such measures are warranted for these chemicals despite the fact that they did not meet the criteria for B or iT.

Many of these chemicals are pigments and dyes and are used extensively in industrial and consumer product applications. Over time, these chemicals are likely to find their way into waste stream and sewer water. These facts should be taken into consideration when making a determination of toxicity and management strategies. Therefore, for substances found to be persistent only, it is appropriate for the government to propose reduction measures to ensure that the environment is protected.

Significant New Activity (SNAc) provisions were proposed for three substances that were categorized as PBiT. As mentioned in Section 5.0 of this document, the SNAc provision is considered to be insufficiently protective of the environment and human health. For any future uses of these substances, a reassessment of the substance will be undertaken through the New Substances Notification Regulations, which lacks a public comment provision. This process will not guarantee a ban on these chemicals and leaves the public and environment vulnerable to their future use. These substances should be found to be toxic under CEPA based on meeting the criteria for persistence, bioaccumulation and inherent toxicity.

Recommendation: For all 14 chemicals found to be persistent based on the draft screening results, the government should undertake measures to reduce these chemicals over time. They have the potential to affect the environment since they are found in many products and may be released into the environment through their degradation.

Recommendation: Application of SNAcs for 4 substances in Batch 3 is inappropriate since this process lacks a public comment period for chemicals being assessed under the New Substances Notification Regulations. Rather, based on the PBiT designation of 3 of these substances, they should be considered toxic under CEPA and added to the CEPA Toxic Substances List (Schedule 1).

Recommendation: To prevent the re-entry of these 4 substances into Canada, they should be added to the Prohibition of Certain Toxic Substances Regulations which aims to prevent the sale, use and manufacture of these substances in the future.

Additive and cumulative effects

None of the final assessments for Batch 3 chemicals included the consideration of the additive or cumulative effects of these substances. There are similar use patterns for some of the substances and in some cases, they belong to the same general chemical family. While we recognize that some of this data may not be available, the mention of the additive or cumulative effects has been noticeably absent in all the assessments.

Human or environmental exposure to these substances does not occur in isolation. There are many chemicals that belong to the same chemical class to which people and the environment may be exposed simultaneously or which have similar toxicity impacts, such as carcinogenicity or reproductive toxicity. There is a need to at least acknowledge this significant gap in the assessments and identify possible methods or ways to address this deficiency. A more accurate and realistic picture of the impacts of these toxic chemicals on human health and the environment is justified.

Recommendation: The government's risk based approach continues to exclude the consideration of cumulative and additive effects of toxic substances. The risk based approach should be strengthened by addressing this gap.

Full life-cycle consideration

There is a need to consider the life cycle of a substance and recognize that solids and liquids may have different properties need to be treated differently. Assessments for substances in Batch 3 have not considered the full life cycle fate of these substances. For example, very little to no comments have been provided to discuss the impacts of the residues or contaminants that may be produced at different phases of production of these chemicals. Similarly, these assessments lacked discussion on degradation products and, for the volatile organic compounds listed in Batch 3, the need for elimination/reduction is necessary because they aid in the formation of ground-level ozone, a major component of 'smog'.

It is essential to include these issues in the assessment report in order to provide a complete understanding of the behaviour of these substances and therefore inform the level of management that is required for toxic chemicals. For those substances considered PBiT as a result of categorization, the issue of full life cycle consideration was not explored once it was determined that these chemicals do not meet the criteria for bioaccumulation or inherent toxicity.

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) including at the disposal phase. In our view, the absence of a full life cycle consideration affects the final decision on toxicity and therefore, the decision on any future management efforts.

Recommendation: Assessments on substances under the CMP, including assessments for Batch 3 chemicals, should take into consideration the full life cycle of a substance when making conclusions under CEPA. This would include consideration of break down products and contaminants.

3.0 Categorization and post-categorization data for substances in Batch 3

Table 1 summarizes the categorization data and post categorization for all substances in Batch 3. This includes the draft and final Screening Level Risk Assessment (SLRA) data decisions with respect to toxicity – *CEPA 1999*, Section 64 and persistence, bioaccumulation and inherent toxicity (P,B, iT as set out in the *Persistence and Bioaccumulation Regulations* (Canada 2000).

Table 1: Final Results of categorization and Screening Level Risk Assessment (SLRA) Batch 3 substances of the Chemical Management Plan (CMP) Industry Challenge

Substances (CAS RN)	Proposed results of draft SLRA* under CEPA S. 64 toxic	Results of draft 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 ---------- -- Significant New Activity provision - SNAc
Ethanol, 2-methoxy-, acetate (2-methoxyethanol acetate) **(2-MEA)** **CAS RN 110-49-6**	Toxic	• Intermediate potential for exposure to humans (IPE) • Reproductive toxicity • Developmental toxicity • Severe and irreversible teratogenic effects, with effects being observed at very low doses, often the lowest dose tested.	Not P, B	Toxic	Not P, B
Ethanol, 2-(2-methoxyethoxy) **(DEGME)** **CAS RN 111-77-3**	Toxic	• Greatest potential for exposure to humans (GPE) • Reproductive toxicity • Developmental toxicity • Hematological effects	Not P, B	Toxic	Not P, B or iT
1-Propanol, 2-methoxy **(2- methoxyproponal)** **CAS RN 1589-47-5**	Toxic	• Intermediate potential for exposure (IPE) • Developmental toxicity	Not P, B or iT	Toxic	Not P, B or iT**

Substances (CAS RN)	**Proposed results of draft SLRA* under CEPA S. 64 toxic**	**Results of draft 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 ---------- -- Significant New Activity provision - SNAc**
2-Naphthalenol, 1-[(4-methyl-2-nitrophenyl)azo] **(Pigment Red 3)** CAS RN 2425-85-6	Toxic	• Greatest potential for exposure (GPE) • Carcinogenic	P, B and iT	Toxic	P, not B
Ethanol, 2-ethoxy-, acetate (2-ethoxyethanol acetate **(2-EEA)** **CAS RN 111-15-9**	Toxic	• Greatest potential for exposure (GPE) • Reproductive toxicity • Developmental toxicity • Hematological effects	Not P,B or iT	Not toxic	Not P, B Proposed SNAc*
Benzenesulfonamide, *N*-(4-amino-9,10-dihydro-3-methoxy-9,10-dioxo-1-anthracenyl)-4-methyl-**(Disperse Red 86)** **CAS RN 81-68-5**	Not toxic	• Not a human health priority.	P, B, and iT	Not toxic	P but not B or iT
9,10-Anthracenedione, 1-hydroxy-4-[[4-[(methylsulfonyl)oxy]ph	Not toxic	• Not a human health priority	P, B and iT	Not toxic	P but not B or iT

Substances (CAS RN)	**Proposed results of draft SLRA* under CEPA S. 64 toxic**	**Results of draft 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 ---------- -- Significant New Activity provision - SNAc**
enyl]amino]- **(Disperse Violet 57)** **CAS RN 1594-08-7**					
2-Naphthalenol, 1-[(2-chloro-4-nitrophenyl)azo]- **(Pigment Red 4)** **CAS RN 2814-77-9**	Not toxic	• Not a human health priority	P, B and iT	Not toxic	P not Bor iT
2-Naphthalenol, 1-[(2,4-dinitrophenyl)azo]- **(Pigment Orange 5)** **CAS RN 3468-63-1**	Not toxic	• Not a human health priority	P, B, and iT	Not toxic	P and not B or iT
9,10-Anthracenedione, 1-amino-4-(phenylamino)- **CAS RN 4395-65**-7	Not toxic	• Not a human health priority	P, B and iT	Not toxic	P, B and iT Proposed SNAc (
2-Naphthalenol, 1-[(2-nitrophenyl)azo]- **(Pigment Orange 2)** **CAS RN 6410-09-9**	Not toxic	• Not a human health prioirty	P, B and iT	Not toxic	P, not B and iT
2-Naphthalenol, 1-[(4-					

Substances (CAS RN)	**Proposed results of draft SLRA* under CEPA S. 64 toxic**	**Results of draft 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 ---------- -- Significant New Activity provision - SNAc**
chloro-2-nitrophenyl)azo]- **(Pigment Red 6)** **CAS RN 6410-13-5**	Not toxic	• Not a human health priority	P, B and iT	Not toxic	P, not B and iT
2-Naphthalenecarboxamide, *N*-(5-chloro-2,4-dimethoxyphenyl)-4-[[5-[(diethylamino)sulfonyl]-2-methoxyphenyl]azo]-3-hydroxy- **(Pigment Red 5)** **CAS RN 6410-41-9**	Not toxic	• Not a human health priority	P , B and iT	Not toxic	P not B and iT
2-Anthracenesulfonic acid, 4,4'-[(1-methylethylidene)bis(4,1-phenyleneimino)]bis[1-amino-9,10-dihydro-9,10-dioxo-, disodium salt **(Acid Blue 127)** **CAS RN 6471-01-8**	Not toxic	• Not a human health priority	P, B and iT	Not toxic	Not P, B and iT

Substances (CAS RN)	**Proposed results of draft SLRA* under CEPA S. 64 toxic**	**Results of draft 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 ---------- -- Significant New Activity provision - SNAc**
9,10-anthracenedione, 1,8-dihydroxy-4-nitro-5-(phenylamino)- **(Disperse Blue 77)** **CAS RN 20241-76-3**	Not toxic	• Not a human health priority	P, B and iT	Not toxic	P not B and iT
Peroxide, [1,3(*or* 1,4)-phenylenebis(1-methylethylidene)]bis[(1,1-dimethylethyl) **(PBMBDP)** **CAS RN 25155-25-3**	Not toxic	• Not a human health priority	P, B and iT	Not toxic	Not P, B and iT
1-Propanaminium, 3-[[4-[(2,4-dimethylphenyl)amino]-9,10-dihydro-9,10-dioxo-1-anthracenyl]amino]-N,N,N-trimethyl-, methylsulfate **CAS RN 60352-98-9**	Not toxic	• Not a human health priority	P, B and iT	Not toxic	P, B and iT Proposed SNAc
Benzenesulfonic acid, 3-[[4-amino-9,10-dihydro-9,10-dioxo-3-[sulfo-4-(1,1,3,3-tetramethylbutyl)pheno	Not toxic	• Not a human health priority	P, B and iT	Not toxic	P not B or iT

Substances (CAS RN)	**Proposed results of draft SLRA* under CEPA S. 64 toxic**	**Results of draft 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 ---------- -- Significant New Activity provision - SNAc**
xy]-1-anthracenyl]amino]-2,4,6-trimethyl, disodium salt (**Acid Violet 48)** **CAS RN 72243-90-4**					
9,10-Anthracenedione, 1-[(5,7-dichloro-1,9-dihydro-2-methyl-9-oxopyrazolo[5,1-b]quinazolin-3-yl)azo]- **CAS RN 336-60-0**	Not toxic	• Not a human health priority	P, B and iT	Not toxic	P, B and iT Proposed SNAc

*SLRA - Screening Level Risk Assessment Reports, see: http://www.chemicalsubstanceschimiques.gc.ca/challenge-defi/batch-lot_3_e.html

4.0 Comments and recommendations specific to CEPA toxic substances in Batch 3

The four substances listed below were initially identified as having a high priority for screening assessment based on the results of these chemicals under categorization. Three of them were originally found to be CEPA toxic based on the draft SLRA. Pigment Red 3 (CAS RN 2425-85-6) was also identified as meeting the ecological categorization criteria for persistence, bioaccumulation potential, and inherent toxicity (PBiT) to non-human organisms and they are all believed to be in commerce in Canada. The tables (Tables 2-5) below highlight the final assessment decisions for each of the four substances. The tables outline the proposed risk management strategies, our brief comments and recommendations to government proposals on the four chemicals.

The chemicals are:

- Ethanol, 2-methoxy-, acetate (2-methoxyethanol acetate; 2-MEA), (CAS RN 110-49-6) (**see Table 2**)
- Ethanol, 2-(2-methoxyethoxy)- (DEGME), (CAS RN 111-77-3) (**see Table 3**)
- Ethanol, 1-Propanol, 2-methoxy- (2-methoxypropanol), (CAS RN 1589-47-5) (**see Table 4**)
- 2-Naphthalenol, 1-[(4-methyl-2-nitrophenyl)azo]- (Pigment Red 3) (CAS RN 2425-85-6) (**see Table 5**)

Ethanol, 2-methoxy-, acetate (2-methoxyethanol acetate; 2-MEA), (CAS RN 110-49-6)

We provide our brief comments and recommendations on specific proposals to manage 2-MEA in Table 2.

Table 2: 2-methoxyethanol acetate (CAS RN 110-49-6): Comments and recommendations to specific management proposals

Specific sections of Risk management scope document for 2-methoxyethanol acetate (2-MEA)	Proposed government measures & other existing measures	CELA & CSM Comments	Recommendations
Section 7.1 Alternative Chemicals or Substitutes	Propylene glycol methyl ether acetate (PGMEA) CAS RN 108-65-6 - reported as a substitute for 2-MEA (EGMEA) in the production of commercial photoresist for the semiconductor industry. PGMEA has not been assessed for toxicity under section 64 of CEPA 1999.	• It is helpful to have information on alternatives included in the risk management document • To ensure that 2-MEA is not replaced with a chemical that may have hazardous properties, alternatives should have to be assessed for their safety. At present, there is no process to assess effectiveness and safety of any alternatives for 2-MEA, including PGMEA.	**Rec.: An inventory of alternatives to 2MEA should be prepared as part of the management options.** **Rec: All substitutes for 2-MEA should be effectively assessed for safety under CEPA 1999 before they are used as replacements.** **Rec: To support the efforts on alternatives, the government should establish a multi-stakeholder task force to review and assess the safety of alternatives. This task force should include participation by government, industry, environmental and health organizations, labour, and indigenious communities.**
Section 7.2 Children's exposure	Based on information received during the Industry Challenge, it is proposed that no risk management actions to specifically protect children are required for	• Despite the claims by industry that no products directed for children's use contains 2 MEA, this should not stop government from imposing regulations preventing the use of this substance in products that children with which may come into contact. • There are many consumer and cosmetic products	**Rec: The government should develop a regulation that ensures products, including cosmetic and consumer products do not contain 2-MEA. This provision will ensure children are protected from exposure to this chemical.**

Specific sections of Risk management scope document for 2-methoxyethanol acetate (2-MEA)	Proposed government measures & other existing measures	CELA & CSM Comments	Recommendations
	this substance at this time.	that children could be in contact with but are not directed for their purpose. The government does not acknowledge this information in its proposal.	
Section 8,1 Environmental or Human Health Objective	The proposed human health objective for 2-MEA is to minimize, to the extent practicable, exposure to 2-MEA, and hence minimize the risk to human health associated with this substance.	• The objectives for managing 2 MEA are not protective of human health as it focuses on a goal of minimizing the exposure to 2-MEA. This commitment is weak and is further weakened by the use of the term "to the extent practicable." It is very subjective and may not result in any change from status quo. • We would rather see a more protective objective that supports the elimination of 2-MEA because of its impacts as a reproductive toxicant. • Minimizing risk is less protective than eliminating exposure to 2-MEA.	**Rec.: We recommend that the appropriate environmental and human health objective for 2 MEA is to eliminate rather than minimize exposure to 2-MEA.** **Rec: We oppose the use of the term "to the extent practicable" in the objective section. This is too subjective and does not commit to the necessary action required to protect human health from impacts of 2-MEA.**
Section 9.1 Proposed Risk Management Instrument	Future Notification: Provision whereby any future potential changes in the use-pattern for 2-MEA do not substantially increase the potential for exposure of the general Canadian population and would require that the federal government be notified.	• Apart from notification, the purpose of the proposed provision 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 use of this pigment? • The use of a notification provision is an insufficient measure to deal with CEPA toxic substances. It represents the status quo in the use of these solvents in Canada.	**Rec: We do not support the use of future notification as a risk management measure for 2-MEA. This still allows the use of 2-MEA.**
Section 9.1 Proposed Risk Management Instrument	The Government of Canada will initiate a discussion with the importers and users to investigate possibilities	• Considering the health properties of 2-MEA, the government proposal is rather weak. The use of the word 'investigate' suggests that it is simply to explore the possibility of reduction. The government should undertake to establish a	**Rec: We support a discussion with importers and users that is based on development of an elimination strategy for 2-MEA.**

Specific sections of Risk management scope document for 2-methoxyethanol acetate (2-MEA)	Proposed government measures & other existing measures	CELA & CSM Comments	Recommendations
	for reducing or eliminating the use of 2-MEA in Canada.	purposeful discussion that will establish an elimination strategy with importers and users rather than a reduction. The protection of human health should remain the priority for government action. A focus on identification of safe alternatives would be a component of this discussion as it is suitable complement to the development of an elimination strategy.	**Rec: 2-MEA should be targeted for phase out. In achieving this goal, industry should be given clear timelines to phase out 2-MEA. Similarly, a phase in for safe alternatives should be established.** **Rec: The government should undertake to assess the safety of alternatives under considerations for 2-MEA.**
Section 9.1 Proposed Risk Management Instrument	The addition of 2-MEA to the Health Canada Cosmetic Ingredient Hotlist.	• The goal of elimination of 2-MEA can be further supported by the addition of 2-MEA to Health Canada's Cosmetic Ingredient Hotlist. However, it is unclear if the recommendation would be for prohibition or restriction. It's moiety, 2-ME, is a prohibited substance on the Cosmetic Ingredient Hotlist. A similar requirement of prohibition of 2_MEA is appropriate. • However, increased enforcement and reporting of violations by companies of this Hotlist should be undertaken. This listing should be in conjunction with the phase out of use of 2-M|EA in other consumer and industrial applications of 2-MEA.	**Rec: To promote an elimination of 2-MEA from all sources, including cosmetic products, it should be added for complete prohibition to the Cosmetic Ingredient Hotlist.** **Rec: Additional resources should be directed to the enforcement of the Cosmetic Ingredients Hotlist.**
Other	2-MEA is not currently used in food packaging in Canada but it is used as a component in the formulation of a cleaner applied on food contact surfaces which are subsequently rinsed	• With 2-MEA being used in cleaning formulations for direct food contact surfaces, the government should consider a requlation to stipulate the phase out of this solvent for this application even though the surfaces are rinsed after cleaning. • Based on the properties of 2-MEA, consideration should be given to phase out 2-MEA in cleaners in the food industry even if there is non-food contact	**Rec: Because of its toxicity, the government should develop regulations to prohibit the use of 2-MEA in food packaging materials.** **Rec: 2-MEA should also be prohibited in all other industries and as mentioned above, safe tested**

Specific sections of Risk management scope document for 2-methoxyethanol acetate (2-MEA)	Proposed government measures & other existing measures	CELA & CSM Comments	Recommendations
	with potable water, and as a cleaner on non-food contact surfaces under well-ventilated conditions in food processing plants.	and recommend safer, tested substitutes. • Regardless of ventilation and personal protective equipment, the use of 2-MEA should be phased out of the food industry as well as all other industries.	**replacements should be established with industry and government.** **Rec: The recommendation of 2-MEA to the Prohibition of Certain Toxic Substances Regulations under CEPA, should also include all industrial products – domestic, imported and exported.**

Ethanol, 2-(2-methoxyethoxy)-(DEGME), (CAS RN 111-77-3)

We provide our brief comments and recommendations on specific proposals to manage Ethanol, 2-(2-methoxyethoxy)-(DEGME), (CAS RN *111-77-3*) in Table 3.

Table 3: Ethanol, 2-(2-methoxyethoxy)- (DEGME) - CAS RN 111-77-3 - Comments and recommendations to specific sections of proposed risk management approach

Specific sections of Risk management components report – Ethanol, 2-(2-methoxyethoxy)-(DEGME)	Proposed government management measures & other considerations	CELA & CSM Comments	Recommendations
1.3 Proposed Measure	• It is proposed that DEGME will be recommended for addition to the List of Toxic Substances in Schedule 1 of CEPA 1999. • The Ministers will develop a regulation or instrument respecting preventive or control actions to protect the health of Canadians and the environment from the potential effects of exposure to this substance.	• Given the finding that DEGME is a reproductive and developmental toxicant, it is appropriate for this chemical to be listed on the Toxic Substances List (Schedule 1) of CEPA. • Since DEGME is a reproductive and developmental toxicant, this chemical should be targeted for phase out or elimination as this is considered an appropriate measure in the protection of human health and environment. The reference to instruments is vague. Instruments that do not include a regulatory backstop, namely phase out, may not provide protective measures. • The draft management document notes that this chemical is used extensively in industrial applications and consumer products, including pesticide products for use in the pulp and paper industry, as a solvent in floor finishes, cleaners and degreasers, paints and paint removers and in some hairsprays, skin creams and cleansers, and fragrances, etc. This chemical is imported into Canada in high volumes. Given this	**Rec: We support the addition of DEGME on the Toxic Substances List (Schedule 1) of CEPA.** **Rec: The government should aim for the phase out and ultimate elimination of DEGME in industrial applications, consumer products and cosmetics, based on evidence of its developmental, reproductive and hematological effects on humans.**

Specific sections of Risk management components report – Ethanol, 2-(2-methoxyethoxy)- (DEGME)	Proposed government management measures & other considerations	CELA & CSM Comments	Recommendations
		information on current uses and the evidence of health impacts of this chemical, promoting an elimination strategy for this chemical is warranted. • Section 6.1 of the draft management document demonstrates that control measures in Canada to date on DEGME are not protective of human health. Without evidence that there will be a reduction in industrial usage, an approach that only focuses on controlling and reducing the chemical will not ensure adequate protection of human health. Lacking is the provision of appropriate triggers to identify and develop alternatives that do not exhibit the same hazardous properties as DEGME.	
7.1 Alternative Chemicals or Substitutes	Through Section 71, no information on alternatives was received. **Consumer products:** From the paints and coatings industry: 2-butoxyethanol (CAS RN 111-76-2) (2-BE) is used as a substitute for DEGME in this industry. 2-BE is CEPA toxic (to human health) and is listed on Schedule 1 of CEPA 1999. It is currently controlled for	• The issue of safe alternatives continues to be a significant gap in the draft risk management scope documents for chemicals addressed through the Chemicals Management Process. • There is some evidence from the paints and coatings industry that 2-butoxyethanol, otherwise referred to as 2-BE, is being used as a substitute for DEGME. Considering the toxicity data for both these solvents, the risks to human health and the restrictions for indoor use of 2-BE, this alternative should not be considered a safe alternative for DEGME. For both the environment and public health, alternatives are meant to be a safer choice. • The commentary provided in the draft management document highlights that DEGME is limited in use and restricted in consumer products in the EU. The move away from this chemical should be considered a good	**Rec; The government should improve the data collection process undertaken through section 71 of CEPA to ensure that industry or other stakeholders in the supply chain provide information on all available alternatives to chemicals such as DEGME.** **Rec: The government should undertake a process to identify and assess the effectiveness and safety of alternatives that exist for any alternatives to DEGME. All alternatives should be assessed by the government under CEPA 1999**

Specific sections of Risk management components report – Ethanol, 2-(2-methoxyethoxy)- (DEGME)	Proposed government management measures & other considerations	CELA & CSM Comments	Recommendations
	indoor usage in consumer products. DEGME is rarely used in consumer products in the EU and if so, it is restricted to 0.1% DEGME. **Other uses:** DEGME is listed as an alternative to 2-methyoxyethanol (2-ME) in the Regulatory Impact Analysis Statement for the *Regulations Amending the Prohibition of Certain Toxic Substances Regulations,* with specific uses: fuel additives / decontamination agents, chemical intermediates and industrial processing agents / analytical solvents. 2-ME is toxic and listed on Schedule 1 of CEPA 1999 and is on Schedule 2 of the *Prohibition of Certain Toxic Substances Regulations, 2003.*	trigger to invest further resources to identify and implement the use of safe alternatives. Furthermore, the use pattern for DEGME in the EU could be used to leverage a similar change in Canada which would support the elimination of DEGME from consumer products in Canada. Further investigation should be undertaken to determine whether a reproductive and developmental toxicant should even be permitted in consumer products at any level. For DEGME, a phase out would be more appropriate than a reduction or restriction in use. • DEGME was listed as an alternative for 2-ME (2-methoxyethanol) for some industrial applications (i.e. jet fuel additive). Without more specifics about the applications and the levels of chemicals used in these applications, we are concerned that inadequate attention is being directed to the development of safe alternatives that do not exhibit these hazardous properties. The replacement of a toxic chemical with another toxic chemical is not appropriate. • The CMP process has not effectively addressed the safety of alternatives at present. We are concerned with the lack of discussion in the government's document for assessing the safety of alternatives for the purpose of developing protective management options. As the CMP progresses, the notion of alternatives should take a greater priority for government since the development of management measures will rely on this information.	**in an open and transparent process.**
7.2 Alternative	No information provided	• Similar to section 7.2, it is critical that government	**Rec: This section should be**

Specific sections of Risk management components report – Ethanol, 2-(2-methoxyethoxy)-(DEGME)	**Proposed government management measures & other considerations**	**CELA & CSM Comments**	**Recommendations**
Technologies and/or Techniques	by industry	undertakes a process to identify and provide information on any technology or techniques that can be used to replace DEGME. This section should include sources of information that are not only industry based but could include community based information on relevancy of the use of this substance in society.	**enhanced and incorporate information from other sources such as indigenous communities.**
7,4 Children's exposure	Given the information received, it is proposed that no risk management actions to specifically protect children are required for this substance at this time.	• We question the government's position that "no risk management actions specifically protect children's health are required for this substance." Given the significant list of consumer products that include DEGME as an ingredient, the government should take preventative measures to protect children from unintentional exposure to these chemicals. There are no consumer products using this chemical that are specifically targeted for children; however, exposure could result when children spend time in a room where cleaners, floor finishes, or paint removers that contain this substance have been used. Further, exposure may also result when children come into contact with cosmetic products that contain this substance. By prohibiting the use of DEGME in consumer products, significant progress towards the protection of human health will be gained. • See general comments on vulnerable subpopulations for further comments and recommendations.	**Same as recommendation made in response to section 1.3, above**
8.1 Environmental or Human Health Objective	The proposed human health objective for DEGME is to reduce exposure of the general population to DEGME to levels that are	• The human health objective for DEGME should be an aim to eliminate exposure to DEGME. There should be a specific focus on the protection of children's health and the health of other vulnerable populations including pregnant women, individuals with chemical sensitivities and workers who are exposed to this substance in the	**Rec: The outlined human health objective should be strengthened by eliminating exposure to DEGME. Furthermore, this statement could also make special reference to the need to protect other vulnerable**

Specific sections of Risk management components report – Ethanol, 2-(2-methoxyethoxy)-(DEGME)	**Proposed government management measures & other considerations**	**CELA & CSM Comments**	**Recommendations**
	adequately protective of human health.	workplace.	**populations from exposure to DEGME.**
8.2 Risk Management Objective	The proposed risk management objective for DEGME is to ensure that the concentrations of DEGME in cosmetics and consumer products do not exceed levels that are adequately protective of human health.	The focus on the concentration of DEGME in cosmetic and consumer products is very troubling for several reasons: • This suggests that the government's focus on DEGME will only address cosmetic and consumer products and will not include measures on the industrial use of DEGME. • This means that government action will only focus on concern control measures rather than prohibit the use of DEGME. To fully protect human health, the government measures should focus on prohibiting or preventing the use of DEGME at the onset of the process, whether it is used in cosmetics or in industrial applications. • It is assumed that there are safe human exposure levels for this chemical. In fact, humans are exposed to a variety of other chemicals that are not fully accounted for in safe level assessments. In the process of considering safe levels of human exposure to a specific chemical, it becomes very problematic to ignore the possibility of the additive and cumulative effects from other toxic exposures. These effects are not considered in such assessments. Establishing a safe human exposure becomes a subjective exercise that partially relies on the confidence level for the collected data and several other factors. It is also affected by the lack of consideration of important contributing factors such as cumulative impacts of other toxic chemicals.	**Rec: We object to the current risk management objectives for DEGME as they do not fully protect human health from exposure to DEGME. These objectives focus on concentration levels for cosmetic and consumer products rather than the outright prohibition of this substance in industrial applications and consumer products.**
9.1.1 Cosmetics	Screening assessment	• The draft risk management document lacks details in its	**Rec: In support of an elimination**

Specific sections of Risk management components report – Ethanol, 2-(2-methoxyethoxy)-(DEGME)	Proposed government management measures & other considerations	CELA & CSM Comments	Recommendations
	indicates that the margins for dermal exposure to cosmetics may not be adequately protective of human health. Management of DEGME in cosmetics can be achieved through the addition of DEGME to the Health Canada Cosmetic Ingredient Hotlist.	proposal to list DEGME on the Cosmetic Ingredient Hotlist. It fails to indicate if the listing of DEGME to the Hotlist list will result in a restriction or prohibition of this substance. Such detail is critical as it demonstrates whether the government is taking steps towards eliminating this chemical. • If limiting the concentration of DEGME in cosmetics is the main intent, this would not be viewed as an adequate measure to control human exposure through dermal and inhalation pathways. Based on the toxicological data, and lack of data, for this substance, it is hoped that the government's actions will be precautionary and protective of human health. Uncertainty regarding DEGME's health effects should be taken as a reason to prohibit its use rather than simply reduce it.	**strategy for DEGME, the elimination of this substance in cosmetics and personal care products would be essential. Therefore, DEGME should be listed as a prohibited substance on the Cosmetic Ingredient Hotlist.** **Rec: The government should develop additional regulations that support an elimination strategy on industrial sources of DEGME.** **Rec: To facilitate or achieve the elimination DEGME in all applications including cosmetics, this substance should be added to the Prohibition of Certain Toxic Substances Regulations under CEPA thereby prohibiting the use, sale, import and manufacture of DEGME. This would include imported and domestically manufactured cosmetic and personal care products that contain DEGME.**
9.1.2 Consumer products	In the final screening assessment report and again in the draft risk management approach document, it was noted	• The government has sufficient evidence to demonstrate DEGME's impacts to human health. There is no need to further characterize exposure potential - reducing the degree of uncertainty for exposure can be achieved by the elimination of DEGME in consumer products. A	**See recommendations outlined in response to sections 1.3; 7.1 and 9.1.1 in Table 3.** **Rec: The elimination strategy**

Specific sections of Risk management components report – Ethanol, 2-(2-methoxyethoxy)-(DEGME)	**Proposed government management measures & other considerations**	**CELA & CSM Comments**	**Recommendations**
	that the margins for dermal exposure to a number of consumer products may not be adequately protective of human health. Products include: • paint, paint remover • floor cleaner, floor polish, floor sealer • sealant/caulking Health Canada intends to investigate whether action under the *Hazardous Products Act* is required for these products. The government will further characterize the exposure potential in order to reduce the uncertainty in the exposure estimates.	timeline for work on exposure potential was not given but such an undertaking will mean continued exposure to DEGME. Based on the EU data, the use of DEGME is limited in consumer products in the EU and its phase out in consumer products is quite feasible. • There may be applications which currently do not have safe available alternatives. For these applications, the government should undertake a process to discuss the relevancy of the application to public safety and the assessment of available alternatives for DEGME. • Currently, the government proposes to investigate whether action under the *Hazardous Products Act* is required. We would argue that the *Hazardous Products Act* has not been an effective legislation to protect human health from exposure to toxic chemicals found in products (e.g. lead in children's jewelry). Failure to act under the *Hazardous Products Act* should not prevent the government from prohibiting this substance from consumer products through the use of CEPA 1999. The government must commit to definite action to remove this substance from consumer products within a given timeframe. A focus on use regulations to establish maximum allowable concentrations is inadequate for protecting human health.	**should ensure that DEGME is prohibited from consumer products that are produced in, imported to, or sold in Canada. Any action to be undertaken under the *Hazardous Products Act* should also reflect this goal.**
9.1.3 Jet Fuel Additive	DEGME is used as a jet fuel additive—in particular as a de-icing agent. As it is consumed in	• Given the final assessment findings for DEGME, the government should investigate the technical feasibility of alternatives to DEGME as an additive in jet fuel. The government reports do not discuss the by-products of combustion which often include the formation or release	**Rec: The government should not exclude taking action to eliminate DEGME as a jet fuel additive. On the contrary, action should focus on an investigation of safe**

Specific sections of Risk management components report – Ethanol, 2-(2-methoxyethoxy)-(DEGME)	Proposed government management measures & other considerations	CELA & CSM Comments	Recommendations
	combustion reactions in jet engines and as any release of remaining DEGME would be highly dispersive, this is not a significant source of human exposure. Risk management of DEGME in jet fuel is therefore not required.	of other toxic chemicals such as dioxins and furans, heavy metals, and other air pollutants. These toxic chemicals have been known to cause a wide range of health and environmental impacts that have not been addressed in the draft management report. The suggestion that this chemical does not have any residual impacts from its use as a jet fuel additive is inappropriate and narrow in scope.	**alternatives to DEGME in its use as a jet fuel additive.**
9.1.4 Pest Control Products	DEGME is used as a formulant in pest control products. It is predominantly used in the pulp and paper industry with very low concentrations of DEGME in the final paper products. DEGME is also used as a formulant in four antifouling paint products with concentrations in these products less than 0.02%. Based on the required use of personal protective equipment	• The government should consider phasing out the use of DEGME as a formulant in pest control products for the pulp and paper industry, and in anti-fouling paint products. DEGME is not considered an 'active' ingredient, and this may facilitate the process of identifying and implementing safe, functional substitutes for DEGME in these applications. Also, for its application in the pulp and paper industries, the phrase 'very low concentrations' needs to be specified and clarified. • The levels of DEGME may be low only in the final products. There may be occupational exposure levels that are higher throughout various stages in the processing and manufacturing processes of DEGME. Ventilation is mandatory for workers' safety but the use of personal protective equipment (PPE) can be lax in some facilities. For this reason, manufacturers should make it a priority to identify and implement alternatives for chemicals found to be reproductively and developmentally toxic. The use of PPE is not a sufficient basis to permit the use of toxic substances in	**See recommendations noted in response to sections 1.3; 7.1; 7.2 in table 3** **Rec: We recommend the phase out and eventual elimination of DEGME as a formulant in pest control products and anti-fouling paint products.**

Specific sections of Risk management components report – Ethanol, 2-(2-methoxyethoxy)-(DEGME)	Proposed government management measures & other considerations	CELA & CSM Comments	Recommendations
	for pulp and paper applications and the low concentrations of DEGME for other uses, human exposure to DEGME from pest control products is expected to be minimized.	the workplace, particularly when safe, effective alternatives may be available. Therefore, when a safer alternative can be substituted, it should be utilized.	
9.1.5 Food Packaging	DEGME uses – • Solvent in the manufacture of inks and can-end coatings used in food contact applications. • Cleaners in the food industry wherein surfaces with direct food contact are rinsed with potable water. Non-food contact surfaces - cleaning is done under well-ventilated conditions. From the two uses, population exposure is expected to be negligible. To ensure that residual	• Direct food packing materials should be free of all toxic substances. Manufacturing processes need to be reviewed to ensure that no volatile organic compounds (VOCs), such as DEGME are detected in the end products of food packaging. The complete release of VOCs should minimize direct food contact with toxic substances. • DEGME usage in food packaging should be a cause for concern. There are no guarantees that human health is fully protected from the impacts of DEGME used in food packaging. • The draft document does not provide adequate proposals for addressing DEGME in food packaging. While there is some benefit from requesting low residual levels of DEGME for new submissions for food packaging with direct food contact, the government's proposal, is in effect concluding that low residual levels in contact with food may be acceptable. Such a proposal cannot be supported as it perpetuates the use of DEGME in food packaging, which we do not think is acceptable. Rather than focusing on data outlining residual levels of DEGME in food packaging, the	**Rec: In support of an elimination strategy for DEGME, we recommend that DEGME be phased out from all direct food contact packaging materials – existing and new.** **Rec: Any substitute for DEGME should be assessed and approved by the government as non toxic for human health and the environment.** **Rec: Cleaners containing DEGME used in the food industry should be phased out over a specified period of time. As recommended above, only safe, government assessed substitutes should be used as replacements.**

Specific sections of Risk management components report – Ethanol, 2-(2-methoxyethoxy)-(DEGME)	Proposed government management measures & other considerations	CELA & CSM Comments	Recommendations
	levels in food packaging applications remain low, data will be requested on residual levels of DEGME for new submissions for food packaging with direct food contact.	government should focus on collecting information on available alternatives to DEGME for food packaging. Furthermore, the document lacks information specifying levels of toxic substances permitted in direct-contact food packaging. This data could have been supplied by the food packaging industry – it should be part of their quality control data. • The food industry should strive towards the use of safer substances in their cleaners regardless of the fact that surfaces with direct food contact are rinsed with potable water. One would question if there is always strict adherence to the mechanisms in place to ensure the complete removal of these cleaners. • While there are provincial and federal regulations in place to ensure that cleaning is undertaken under well ventilated conditions, the reality may be otherwise. Based on the human health effects of this solvent, industry should move towards a safe, government tested non-toxic replacement.	

Ethanol, 1-Propanol, 2-methoxy- (2-methoxypropanol), (CAS RN 1589-47-5)

We provide our brief comments and recommendations on specific proposals to manage Ethanol, 1-Propanol, 2-methoxy- (2-methoxypropanol), (CAS RN 1589-47-5) in Table 4.

Table 4: Ethanol, 1-Propanol, 2-methoxy- (2-methoxypropanol), (CAS RN 1589-47-5) - Comments and recommendations to specific sections of proposed risk management approach

Specific sections of Risk management components report – Ethanol, 1-Propanol, 2-methoxy- (2-methoxypropanol)	**Proposed government management measures & other considerations**	**CELA & CSM Comments**	**Recommendations**
Section 1.3 – Proposed Measures	The Ministers have proposed to recommend the addition of 2-methoxypropanol to the List of Toxic Substances in Schedule 1 of CEPA 1999. As a result, the Ministers will develop a regulation or instrument respecting preventive or control actions to protect the health of Canadians and the environment from the potential effects of exposure to this substance.	The designation of CEPA toxic for Ethanol, 1-Propanol, 2-methoxy- (2-methoxypropanol is appropriate based on its developmental toxicity. The listing of this chemical to the Toxics Substances List (Schedule 1) of CEPA 1999 will trigger the process to develop management strategies which are urgently required on this substance.	**Rec: We support the listing of** 2-**methoxypropanol to the Toxics Substances List (Schedule 1) of CEPA.** **Rec: Since 2-methoxypropanol is a developmental toxicant, regulatory action for the elimination of 2-methoxypropanol is appropriate. This action should require additional regulations as there will be a need for a phase out use of PGME to prevent the source of contamination by 2-methoxypropanol.**
7.1 Alternative Chemicals or	2-methoxypropanol is produced	• While there are some alternatives for PGME for specific applications, there are concerns from the	**Rec: The draft risk management approach should include a detailed**

Substitutes	unintentionally and is an unwanted contaminant in PGME (propylene glycol monomethyl ether). Therefore, it is more appropriate to address the exposure to PGME as opposed to 2-methoxypropanol. In effect, can the residues be reduced or eliminated or are there safe substitutes.	coatings industry due to the cost and inadequate performance of these alternatives. This should not hinder the research needed to find a new replacement or to attempt to significantly reduce the residual concentration of 2-methoxypropanol in PGME. • PGME is used as an intermediate in the manufacture of a commonly used solvent in the coatings industry – propylene glycol monomethyl ether acetate (PGMEA or PMA), which can also have residual 2-methoxypropanol but a range has not been indicated. • It should also be noted that the 'P' series glycol ethers and acetates were initially intended to replace the 'E' series of these solvents because of toxicity concerns related to the 'E' series glycol ethers and their acetates.[1] However, in switching to the 'P' series of these solvents there are still toxicity concerns related mainly to the residual 2-methoxypropanol. For this reason, it is essential that safe alternatives are appropriately identified for the purpose of eliminating **2-methoxypropanol contamination** and assessed for safety.)	**section outlining all alternatives to PGME and PMA because of the presence of the residue, 2-methoxypropanol.** **Rec: All alternatives to PGME and PGMEA solvents which could contain residual 2-methyoxypropanol, should be assessed for toxicity under CEPA 1999. If these alternatives do not exhibit hazardous properties like 2-methoxypropanol, then they should be recommended to replace PGME and PGMEA.** **Rec: Based on evidence demonstrating that PGME is a source for 2-methoxypropanol contamination, it would be appropriate to require a priority assessment of this chemical. Should this chemical be found to be hazardous to human health or to the environment, a complete phase out may be necessary. In the meantime, a prohibition of this chemical is appropriate to prevent the release of 2-methoxypropanol as a residue.**
7.2 Alternative Technologies and/or Techniques	Industrial technologies to reduce the quantities of 2-methoxypropanol in PGME exist. For consumer products in the EU, the maximum concentration of 2-methoxypropanol is	• It is helpful to see information collected on alternative technologies and techniques. However, the draft management approach document provides very few details on the technology. At present, the available technology achieves a reduction in levels of 2-methoxypropanol in PGME to meet the following directives: Directive 76/769/EEC and Directive 88/379/EEC. To fully address the impacts	**Rec: Similar to the approach required to assess the safety of alternatives, it is important to undertake an assessment of available alternative technologies and techniques to ensure that they do not produce other toxic chemicals or pose a hazard to the environment or health.**

[1] See - htpp://www.dow.com/productsafety/pdfs/233-00408_pma.pdf
http://www.intox.org/databank/documents/chemical/prpglmea/cie175.htm

	0.5%.	posed by 2-methoxypropanol as a contaminant, improvements to this technology will be required. • This approach should be required where the use of PGME cannot be phased out and safe alternatives to PGME are not feasible at this time. Industry should review their processing techniques in light of the current technology in the EU to reduce residual 2-methoxypropanol in PGME. By addressing the residual 2-methoxypropanol in PGME, the residue in propylene glycol monomethyl ether acetate would also be reduced. • The draft management approach document does not fully explain the extent to which PGMEA is used in consumer products or in industrial applications. This gap makes it difficult to determine to quantify the levels of residual 2-methoxypropanol for these products or applications.	**Rec: For all other applications, we recommend that there be a phase out of PGME and PGMEA which, in effect, would result in a phase out of 2-methoxypropanol.** **Rec: Information on the use patterns of PGMEA should be included in the risk assessment document.**
7.4 Children's Exposure	It is proposed that no risk management actions to specifically protect children are required for this substance at this time	• Despite the lack of information received during the Industry Challenge, the extensive use of PGME in cosmetic and consumer products warrant additional action to protect children from exposure to these chemicals. Children may come in contact with nail polish, nail enamel, nail polish remover, hair conditioner and hair spray. These are only a few consumer products containing PGME. The report fails to acknowledge that children may use these products or be in the same area where these products are in use (e.g., nail salons, homes, etc.) despite the fact that these products are not designed for their use. It is important to acknowledge that children's health is uniquely vulnerable to toxic chemicals exposure. The lack of acknowledgement of this information will create a significant gap in the proposed management approach for 2-methoxypropanol and PGME. • Other vulnerable populations should also be considered in the management approach to these chemicals, including people of low income, people with chemical sensitivities, workers (particularly in	**Rec: Additional regulatory action to protect children from exposure to 2-methoxypropanol is warranted because the number of consumer products that may contain PGME and possibly PGMEA is extensive**. **Rec: The management proposals should also recognize and take action to protect other vulnerable populations such as people of low income, workers, people with chemical sensitivities and aboriginal communities.**

		nail salon operations, industrial settings) and aboriginal communities. Exposures to toxic chemicals for these groups have not been covered in assessments or the development of management strategies. Please see section 2.0 for further comments and recommendations	
8.1 Human Health Objective	The proposed human health objective for 2-methoxypropanol is to reduce exposure of the general population to 2-methoxypropanol to levels that are adequately protective of human health.	• The human health objectives for developing management measures for 2- methoxypropanol are inadequate since this substance has been identified as a developmental toxicant. Given the extensive use of PGME, which contains 2 methoxypropanol as a contaminant, in consumer and cosmetic products, a goal of eliminating exposure to this substance is appropriate. • It is possible that PGMEA is also in some consumer products and may contain the contaminant 2-methoxypropanol. As mentioned above, the goal of eliminating exposure to this substance is appropriate.	**Rec: The human health objective for 2-methoxypropanol should be strengthened to aim for the elimination of human exposure to this substance.**
8.2 Risk Management Objective	The proposed risk management objective for 2-methoxypropanol is to ensure that the concentrations of 2-methoxypropanol in cosmetics and consumer products do not exceed levels that are adequately protective of human health.	The proposed risk management objective focuses on establishing a concentration level that protects human health. This objective is considered weak for several reasons: • The focus on concentration of this chemical will result only in controlling its use rather than eliminating it. • Establishing a concentration that is considered protective will depend on the available technology and to some degree, require negotiation between industry and decision makers to establish an acceptable level. • Since this chemical is a developmental toxicant and there are many aspects of the exposure routes that the assessment have not been able to determine, a protective approach for managing 2-methoxypropanol would be to aim to phase out its usage in cosmetic and consumer products. Because it is a residue, this suggests that a phase	**Rec: The risk management objectives should be strengthened to focus on the elimination of 2-methoxypropanol, PGME and PGMEA in consumer and cosmetic products. Such an objective would be protective of human health.**

		out of PGME and PGMEA use in cosmetic and consumer products.	
9.1.1 Cosmetics	Screening assessment report indicates that exposure levels may not be adequately protective of human health. 2-methoxypropanol, as a residue from PGME can be found in: • Nail enamel, nail polish remover • Hair conditioner • Hair dye, hair spray • False eyelash adhesive, false eyelash solvent remover. The government's risk management proposal is the addition of 2-methoxypropanol to the Health Canada Cosmetic Ingredient Hotlist. PGME will be prohibited from cosmetics if it contains 2-methoxypropanol concentrations of greater than 0.5%.	• Based on the development toxicity of this chemical, we do not support the listing of PGME containing residual 2-methoxypropanol to the Cosmetic Ingredient Hotlist at a maximum of 0.5% concentration. The government needs to take a more precautionary stand which should focus on adding PGME and 2-methoxypropanol on the list of prohibited substances to prohibit ANY solvent containing this residue, regardless of the concentration. This action would be more appropriate in keeping with adequate protection of human health.	**Rec: We recommend that 2-methoxypropanol and PGME be added to the Cosmetic Ingredient Hotlist as a prohibited substance in cosmetics and personal care products. Therefore, all solvents containing any residual 2-methoxypropanol would be prohibited from use in cosmetics and personal care products.** **Rec: To facilitate or achieve the elimination 2-methoxypropanol in cosmetics and personal care products, 2-methoxypropanol and PGME should be added to the Prohibition of Certain Toxic Substances Regulations under CEPA. This addition would aim to prohibit the use, sale, import and manufacture of all substances containing 2-methoxypropanol in imported, exported and domestically manufactured cosmetic and personal care products.**
9.1.2 Consumer Products Including Paints and Coatings	Screening assessment indicates that the margins for inhalation exposure to certain consumer products may not be adequately protective of human	• Although the risk assessment document indicates that additional work is required to characterize the exposure potential to 2-methoxypropanol, there is sufficient evidence to indicate that more protective action for this chemical is urgently needed. To take protective action, there is no need to characterize exposure potential. Reducing the degree of	**Rec: Given the toxic designation of 2-methoxypropanol, we recommend that this substance be phased out or eliminated from consumer products.** **See recommendations in response to section 7.1; 7.2; 8.1, and 8.2 of Table 4**

	health. Products include: • paint remover • polyurethane varnish • concrete floor primer Health Canada will investigate whether action under the *Hazardous Products Act* is required with regard to these products. The initial step will involve further characterization of their exposure potential to reduce the uncertainty in the exposure estimates.	uncertainty for exposure can be achieved by the elimination of solvents containing the residue 2-methoxypropanol in consumer products. Where safe replacements are not technically feasible, any solvent containing the residue 2-methoxypropanol should have restricted levels of residue content. The focus on determining what is an adequate level of exposure to this chemical is not a protective or a precautionary approach. • However, when alternatives have to be used for solvents containing residual 2-methoxypropanol, there must evidence that these alternatives have been assessed by the government for their safety. • There has been very little evidence that the *Hazardous Products Act* can adequately protect human health from toxic chemicals found in consumer products (i.e., lead in children's jewelry). The elimination of toxic chemicals in consumer products is essential if the government is to protect human health from this and other harmful chemicals. While investigation to act under the *Hazardous Products Act* is appropriate, this should not be the only legislation applied by the government to ensure that consumer products do not contain 2-methoxypropanol. The basis for investigation should be for the purpose of removing substances (solvents) containing this residue from consumer products within a given timeframe. • The use of regulations to establish maximum allowable concentrations (rather than elimination) would not result in adequate protection to human health.	**Rec: The government should use available federal legislation including CEPA 1999 and the *Hazardous Products Act* to ensure prohibition of 2-methoxypropanol in all consumer products. Such action should ensure no import, export, manufacture or sale of any product containing this substance be permitted.**
9.1.3 Food Packaging	2-methoxypropanol may be present as an impurity in solvents used in the manufacture of • inks • lined varnishes and coatings (interior	• We are not in agreement with the government's risk management proposal, which requests data on residual levels of 2-methoxypropanol for new food packaging submissions with direct food contact. The focus of government to ensure that residual levels in food packaging applications remain low fails significantly in its effort to protect the public. There are concerns as to how a 'low' safe level for	**Rec: We recommend the phase out and eventual elimination of any solvents containing the residue 2-methoxypropanol for the purpose of all direct food packaging materials, including industrial coatings – new and existing.**

	and exterior) in paperboard and plastic food packaging applications. These solvents are not expected to be present in the finished food packaging materials. PGME usage: • Cleaners in the food industry; • Manufacture of PMA – propylene glycol monomethyl acetate with 2-Methyoxypropanol as an impurity; • Industrial coatings that are in contact with dry food products; Human exposure to 2-Methoxypropanol from these above sources is considered to be negligible. To ensure that residual levels in food packaging applications remain low, data will be requested on residual levels of 2-methoxypropanol for submissions regarding new food packaging	2-methoxypropanol will be characterized. Given the extensive exposure of the public to other existing toxic chemicals from cosmetic and consumer products, the additional exposure to 2-methoxypropanol from food packaging is unnecessary. As a result, an approach that utilizes safer substances would be more logical. • The food industry should strive towards the use of safer substances in their cleaners regardless of the fact that surfaces with direct food contact are rinsed with potable water. One would question if there is always strict adherence to the mechanisms in place to ensure the complete removal of these cleaners. • While there are provincial and federal regulations in place to ensure that cleaning in done under well ventilated conditions, the reality is otherwise. Based on the human health effects of 2-methoxypropanol, industry should move towards a safe, government assessed alternative to replace PGME in the food industry. • The technology is available to reduce the concentration of 2-methoxypropanol in PGME. Similarly, there should be available technology in the manufacture of PMA to reduce the concentration of 2-methoxypropanol. • In some applications, industrial coatings used for direct dry food contact can be significantly higher in film thickness as compared to those in the lining of cans. Therefore, the release of entrapped solvents in the applied film will be much slower and more so, if heat is not applied to accelerate the drying process of the film. This has the potential to raise levels of exposure through dry food packaging. Therefore, in an attempt to minimize the release of toxic substances in contact with dry food products, consideration should be given to the use of safer alternative solvents for these applications.	**See recommendations in response to section 7.1; 7.2;, 8.1 and 8.2 of table 4.** **Rec: Like other consumer products, all cleaners containing solvents with 2-methoxypropanol as a residue, particularly those used in the food industry should be phased out over a specified period of time.**

	intended for direct food contact.		
9.1.4 Pest Control Products	2-methoxypropanol can be present in pest control products in Canada because of the formulant PGME. Concentrations of 2-methoxypropanol in pest control products are allowed a maximum of 0.4% which the government considers a negligible source of human exposure. Therefore, risk management is not required.	• The draft management document does not provide sufficient details on the evaluation PGME and residual 2-methoxypropanol in pest control products under the Pest Control Product Act. The current maximum level of 0.4% for 2-methoxypropanol has not been reviewed fully. Therefore, it would be difficult to support the proposal that no management of this chemical is necessary for pesticide control products. While it is considered a negligible source of human exposure, some of these products are classified as consumer products. PGME is used as a formulant, which may provide easier opportunities for a phase out and subsequent substitution. If considered appropriate, the elimination of residual 2-methoxypropanol in pest control products would be possible. • Simply relying on the current use of PGME with reduced residual 2-methoyxpropanol would not be considered an appropriate risk management option for pest control products. More action is required to eliminate the source of 2-methoxypropanol. • More protective actions would include addressing agricultural pest control products which are used in larger quantities as well as products designed for general consumers. This would require considering levels of exposure to the applicant as well as to those in the immediate environs. While personal protective equipment is recommended under these application conditions, that is not always the case.	**Rec: We recommend the phase out and eventual elimination of residue 2-Methoxypropanol in pest control products. This would, in effect, mean the replacement of formulant PGME.** **Rec: If alternatives have to be used for PGME, they should be government assessed and proven to be safe for this application.** **Rec: Additional attention to phase out residue 2-methoxypropanol in any other pest control products for agricultural purpose is warranted and should be undertaken.**

2-Naphthalenol, 1-[(4-methyl-2-nitrophenyl)azo]- (Pigment Red 3) (CAS RN 2425-85-6)

We provide our brief comments and recommendations on specific proposals to manage 2-Naphthalenol, 1-[(4-methyl-2-nitrophenyl)azo]- (Pigment Red 3) (CAS RN 2425-85-6) in Table 5.

Table 5: 2-Naphthalenol, 1-[(4-methyl-2-nitrophenyl)azo]- (Pigment Red 3) (CAS RN 2425-85-6) – Comments and recommendations to specific sections of proposed management risk approach

Specific sections of Risk management components report – **2-Naphthalenol, 1-[(4-methyl-2-nitrophenyl)azo]-** **Pigment Red 3**	**Proposed government measures** **&** **other existing measures**	**CELA & CSM - comments**	**Recommendations**
Section 1.3 Proposed Measure	Ministers proposed to recommend the addition of Pigment Red 3 to the List of Toxic Substances in Schedule 1 of CEPA 1999. As a result, the Ministers will develop a regulation or instrument respecting preventive or control actions to protect the health of Canadians and the environment from the potential deleterious effects of exposure to this substance	• Based on the carcinogenicity of Pigment Red 3, it is appropriate to list this chemical on the Toxic Substances List (Schedule 1) of CEPA. Furthermore, to ensure that human health is protected from the impacts of this substance, a preventive approach is essential.	**Rec: We support the addition of Pigment Red 3 to the Toxic Substances List (Schedule 1) of CEPA 1999.** **Rec: To protect human health from this carcinogenic chemical, a goal of elimination of Pigment Red 3 should be established.**
3.2 Children's Exposure	No proposals	• The draft management document indicated that this pigment is used in consumer paints not intended for use by children. Furthermore, additional	**Rec: In addition to ensuring products intended for children do not include Pigment Red 3,**

		information gathered by Health Canada indicates that 'Pigment Red 3 is not currently being used in a popular brand of crayons sold in North America'. However, it also noted that this chemical is used in a product (soap) that is specifically intended for use by children. The information suggest that children are exposed to this chemical through selected products, therefore it is necessary to take additional action to ensure that products that are imported into Canada are addressed fully. To this end, a regulation to prohibit the use of this pigment in all domestic products and consumer products imported into Canada is necessary.. • Despite the knowledge that various products with this pigment are not intended for children, the report fails to acknowledge that some consumer products that may contain this pigment can still result in exposure to children through various routes, such as paints, chewing of plastics, or from imported products that may contain this pigment.	**additional government action is required to ensure that all consumer products, including those that are imported into Canada, do not contain Pigment Red 3.**
7.1 Alternative Chemicals or Substitutes	Substitutes have not undergone an assessment to determine whether they meet the criteria under section 64 of CEPA 1999. For safety marking paints, Pigment 104 (containing lead and chromate) is being considered as an alternative. The government is reviewing Pigment Red 104 and is currently	• As noted with the previous draft management approach for other toxic substances assessed under the Chemicals Management Plan, alternatives for toxic chemicals should not exhibit hazardous properties. It is counterproductive to attempt to replace one toxic substance with another substance containing chemicals such as lead chromate, even if the latter is silica encapsulated. This type of substitution defeats attempts to reduce the use of substances that are known to be toxic to human health and the environment. • The focus should be the elimination of exposure to these chemicals through the use of safer alternatives. This focus recognizes that compromises – not to public safety and health – may have to be investigated. • The listing of alternatives should be an integral part of the proposed risk management. For the most part, this has been noticeably absent in the	**Rec: We do not support the use of the alternative identified for Red Pigment 3 in the draft management document because it is carcinogenic.** **Rec: The government should assess the safety of suggested alternatives to ensure that they are not toxic to the environment or human health.** **Rec: The government should direct more resources and efforts to identify safe alternatives for substances like Red Pigment 3. The formation of a multi-stakeholder task force on**

	developing risk management options to reduce human exposure to Pigment Red 104 and encourage the use of alternative pigments.	proposed risk management documents.	**alternatives assessment lead by government could move this forward.**
7.2 Alternative Technologies and/or Techniques	No proposals outlined	• Information on alternative technologies and/or techniques was not available in the draft management approach document. This section could possibly include technologies or techniques that do not involve the use of Pigment Red 3 but could be pertinent to it. This information should be supplied by industry.	**Rec: Additional efforts should be undertaken to identify technologies or techniques that do not rely on Pigment Red 3 but provide similar functions as Pigment Red 3.** **Rec: Similar to the recommendations made on alternatives above, alternative technology or techniques should be assessed to ensure that they do not result in the production, release or use of toxic chemicals. Assessing the safety of alternate technology or techniques should be undertaken by government.**
9.1.1 Pigment, Paint and Plastics Sectors	The Government will investigate whether action under the *Hazardous Products Act* is required with regard to consumer exposures from use of paints containing Pigment Red 3. The initial step will involve further characterization of the exposure potential to reduce the uncertainty in the	• Since Pigment Red 3 is a carcinogenic substance, this toxic chemical should not be used in consumer products. The government's proposal to characterize exposure potential for the purpose of reducing the degree of uncertainty for exposure should not stop the government from taking protective action to eliminate this chemical. Focusing on reducing the degree of uncertainty will result in the continual exposure of the general population to Pigment Red 3 in consumer products in the interim. • As noted with comments for other toxic chemicals (2- MEA, 2-methoxypropanol) in Batch 3**,** the use of	**Rec: We recommend the phase out of Pigment Red 3 from all consumer products including plastics, paints and coatings. Any substitution for this pigment must be safe to human health and the environment. See above for comments and recommendations on alternatives.** **Rec: The government should establish a multi-stakeholder task force to assess alternatives to**

	exposure estimates.	the *Hazardous Product Act* to phase out toxic chemicals in consumer products in the past has not been effective. If the government further investigates action on Pigment Red 3 using the *Hazardous Products Act*, it is appropriate that the government make a commitment to eliminate this chemical to ensure protection to human health. • As noted previously, children's exposures to this pigment have not been fully acknowledged. For example, one way children may be exposed is through the use of plastics (hand to mouth activities may include chewing on plastics). Such exposure routes have not been addressed but should be considered. • Similarly, the issues of waste management and full life cycle management for Red Pigment 3 have not been addressed either. The volume of this substance used in Canada is high enough to warrant such consideration in its proposed risk management. The exclusion of these points results in a weaker and narrower scope for reduction.	**Pigment Red 3.** **Rec: As noted previously, additional action to protect children is required. In particular, prevention of children's exposures to this pigment from plastics and other consumer paints should be addressed in the proposed risk strategies for this pigment.** **Rec: Additional action to eliminate the use Pigment Red 3 in consumer products should be undertaken using *Hazardous Product Act,* and CEPA 1999. Such action should ensure that there is no import, export, manufacture or sale of any product containing Pigment Red 3.** **Rec: As an interim measure to the phase out of Pigment Red 3, adequate labels to warn consumers of this chemical's carcinogenicity should be used on industrial or consumer products.** **Rec: Full life cycle management, including waste management, should be included as priorities under the proposed risk management plan. For details, see the 'General Comments".**
9.1.2 Industrial Use Sector	All industrial chemical uses are governed	• Red Pigment 3 should not be considered an essential pigment for some industrial uses	**Rec: See the section on**

	under federal, provincial or territorial health and safety regulations and all workplace chemicals must comply with the *Controlled Products Regulations.* There is appropriate labeling to indicate the presence of hazardous materials and appropriate worker training to handle these substances.	particularly because this pigment is carcinogenic. While regulations are in place to protect the health of the worker, there are gaps in the current assessment process and the proposed draft management documents that do not fully acknowledge exposure to vulnerable populations such as workers. Lack of full consideration of exposure to workers to this pigment and other toxic chemicals, put workers' health at risk. Again, there needs to be a commitment by government to identify and support the development of safe alternatives for this pigment and other toxic chemicals in the workplace. • Although hazard labeling exists in Canada, further improvements to labeling requirements should be undertaken. Improvements include the need to strengthen material safety data sheets as they are not universal in content and format. Additional toxicity data may be required in some cases.	**alternatives for comments.** **Rec: A more universal approach for reporting on material safety data sheets so that there could be improved hazard information.** **Rec: Additional focus on exposure to workers from these toxic chemicals should be included in the development of management measures for these chemicals.**
9.1.3 Cosmetics Sector	Pigment Red 3 was found to be in two soap products notified in Canada, one intended specifically for use by children. The government will take action to manage Pigment Red 3 in cosmetic products by the addition of the pigment to the Health Canada Cosmetic Ingredient Hotlist.	• While section 3.1 on children's exposure focused on the prohibition of Pigment Red 3 in paints and crayons, the presence of this pigment in soaps used by children is of significant concern, Because of its carcinogenicity, the management of Pigment Red 3 should take the form of full prohibition of this chemical in all consumer products. The addition of this chemical to the Cosmetic Ingredient Hotlist may be able to achieve this goal. However, the draft management document that outlines a proposal to add Pigment Red 3 to the Cosmetic Ingredient Hotlist list is vague since it does not specify restriction or prohibition. To decrease the uncertainty or ambiguity, there must be specific mention as to how a substance would be managed when added to the Hotlist (i.e. prohibition or restriction). It is our proposal that the listing of Pigment Red 3 should be full prohibition. • If limiting the concentration of Pigment Red 3 in cosmetics is the intent, we consider this proposal not	**Rec: To achieve a prohibition of Pigment Red 3 in cosmetic products, we support the addition of Red Pigment 3 to the Cosmetic Ingredient Hotlist. This listing should be a full prohibition of Pigment Red 3 in cosmetics and personal care products.** **Rec: To further support the effort to prohibit the use of Pigment Red 3, we recommend that Red Pigment 3 be added to the Prohibition of Certain Toxic Substances Regulations under CEPA which will prevent the sale, use and manufacture of this substance in cosmetics and personal care products in the future. This prohibition should**

		protective of human health. Since this pigment has been listed as a carcinogen, it has no place being an ingredient in cosmetics	**also apply to products that are imported into Canada.**
9.1.4 Pest Control Products Sector	Pigment Red 3 is used in two anti-fouling paints at a concentration of <1.0% - governed by the *Pest Control Products Act* (PMRA 2007).	• It is not certain what type of risk management is being proposed for the use of Pigment Red 3 in anti-fouling paints. It is also unclear if this pigment assumes the role of a formulant in these products. These specifics should be outlined in the risk management document so that appropriate comments could be made regarding the risk management proposals.	**Rec: The proposed risk management documents should be more specific as to the type of risk management options available. For a substance that has been listed as a carcinogen, the lack of details on its use and function appears to indicate less than stringent management by the government.** **Rec: We recommend that Pigment Red 3 be replaced with a safer, government assessed pigment for anti-fouling industrial paints.**

5.0 Substances considered PBiT (based on categorization) recommended for SNAc provisions

Issues

Three substances listed in Table 1 and also listed below were categorized as PBiT. However, based on the results of government surveys conducted in 2005 and 2007, it was determined there was no industrial activity (import or manufacture) for these substances above the reporting threshold of 100 kg. For this reason, the proposed conclusion of the draft SLRA on these chemicals is to apply the Significant New Activity provisions under subsection 81(3) of the Act.

For Batch 3 substance with CAS RN 111-15-9, the proposed conclusion of the draft screening assessment is that the substance does not meet the criteria set out in section 64 of CEPA 1999. This substance has been classified by the European Commission on the basis of reproductive and developmental toxicity but there are concerns that any new activities for the substance which have not been identified or assessed under CEPA 1999 could lead to the substance meeting the criteria set out in section 64 of the Act. Therefore, the government has recommended that CAS RN 111-15-9 be subjected to a SNAc provision under subsection 81(3) of the Act. This will ensure that any new manufacture or use of the substance is notified and will undergo ecological and human health risk assessment as specified in section 83 of the Act, prior to the substance being introduced into Canada.

A Notice of intent to amend the DSL under subsection 87(3) of CEPA 1999 to indicate that subsection 81(3) of the Act applies to CAS RN 111-15-9 was published in the *Canada Gazette* Vol. 143, No. 10 on March 7, 2009.

The following are the substances recommended for SNAc provisions:

- 9,10-Anthracenedione, 1-amino-4-(phenylamino)- **CAS RN 4395-65**-7
- 1-Propanaminium, 3-[[4-[(2,4-dimethylphenyl)amino]-9,10-dihydro-9,10-dioxo-1-anthracenyl]amino]-N,N,N-trimethyl-, methylsulfate - **CAS RN 60352-98-9**
- 9,10-Anthracenedione, 1-[(5,7-dichloro-1,9-dihydro-2-methyl-9-oxopyrazolo[5,1-b]quinazolin-3-yl)azo]- **CAS RN 336-60-0**
- ethanol, 2-ethoxy-, acetate (2-ethoxyethanol acetate; 2-EEA) – **CAS RN 111-15-9**

The following are our concerns with the government's proposal to apply SNAcs:

a) Inadequacy of SNAc provision and CEPA toxic designation: There are three substances that were categorized as PBiT and one as CEPA toxic. For these substances evidence gathered from industry indicated that they were not in use in Canada in 2005 and 2007 according to response to the Section 71 survey. It is our view that these chemicals should not be permitted re-entry into the Canadian market based on their hazardous properties. Government could use tools under

CEPA to ensure that future use of these substances is not permitted in Canada. One way to achieve this may be to designate them CEPA toxic and add them to the *Prohibition of Certain Toxic Substances Regulation*. The application of SNAc provisions as proposed by government has limits and could not guarantee that these substances would be prohibited from future use in Canada. Since these substances are also classified as PBiT substances, they should be assessed with increased rigour than currently required for substances notified under these provisions. This would require revisions to the New Substances Notification Regulations (also see (c), below).

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

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

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

Recommendations

Recommendation: All four chemicals (3 PBiTs -CAS RN 4395-65-7; **CAS RN 60352-98-9; CAS RN 336-60-0; and human health priority chemical** CAS RN 111-15-9) **should be declared CEPA toxic. These chemicals should be added to the Toxic Substances List (Schedule 1) of CEPA.**

Recommendation: To prevent future re-entry of these chemicals into Canada, these four chemicals (3 PBiTs -CAS RN 4395-65-7; CAS RN 60352-98-9; CAS RN

336-60-0; and one human health priority chemical (CAS RN 111-15-9) should be added to the Prohibition of Certain Toxic Substances Regulations. This would ensure that no future use, manufacture, import or sale of these substances would be permitted in Canada. This response would be in keeping with the precautionary principle.

Recommendation: The application of SNAc provisions for these substances is not appropriate. Substances with CAS RNs: 4395-65-7, 60352-98-9 and 336-60-0 should not be flagged for SNAc provisions since the data required by government under the New Substances Notification Regulations (NSN) Schedule 6 is limiting. Substances assessed under the NSN do not include a public comment period on subsequent assessments conducted using SNAcs. Given that these substances have been identified through the initial categorization as being PBiT, it is imperative to retain an opportunity for the public to comment on future assessment of these chemicals.

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