A Response to the Proposed Risk Management Approach for Chemicals Management Plan Industry Challenge Batch 6 Substances Published in *Canada Gazette* Part I, Vol. 143, No. 22— May 30, 2009

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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. 22— May 30, 2009 release of the proposed risk assessment results and risk management approach reports for selected substances identified under the Chemicals Management Plan (CMP), Batch 6 of the Industry Challenge.

CELA (www.cela.ca) is a non-profit, public interest organization established in 1970 to use existing laws to protect the environment and to advocate for environmental law reform. It is also a legal aid clinic that provides legal services to citizens or citizens' groups who are unable to afford legal assistance. In addition, CELA also undertakes substantive environmental policy and legislation reform activities in the area of access to justice, pollution and health, water sustainability and land use issues since its inception. Under its pollution and health program, CELA has been actively involved in matters that promote the prevention and elimination of toxic chemicals addressed in the *Canadian Environmental Protection Act*, including the categorization process and implementation of the CMP.

Chemical Sensitivities Manitoba (CSM), a volunteer organization, was founded in 1997 by four individuals who saw the need to address the 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.

Introduction

While this submission does not include new data for substances in Batch 6 of the CMP Industry Challenge, it reiterates several important policy issues resulting from the risk based approach taken by the government. These issues continue to be relevant in the decision making process highlighted in the draft assessments results on chemicals including those in Batch 6 of the CMP Industry Challenge. We are submitting these comments for further consideration by your departments in their efforts to finalize the draft assessments for chemicals under Batch 6 and ensure that decisions support the precautionary principle in protection of human health and the environment.

Issues and recommendations

1) <u>The Availability and Quality of Data in support of the Precautionary Principle</u>

Despite the consideration of new data in the current assessment process, ***data gaps on chemicals continue to exist with the level of uncertainty increasing because there is more reliance on modeled data and analogues.***

The Industry Challenge was intended to gather information on quantity, use and toxicity data that are available to industry and other stakeholders in order to complete screening level risk assessments. We have seen the consideration of new data, with particular focus on the

identification of analogues for chemicals in Batches 1 – 5, that resulted in a change in the determination of key criteria such as bioaccumulation and inherent toxicity. The consideration of such data has resulted in many chemicals, in particular, pigments in Batches 1-5 and polysiloxanes in Batch 3, not considered to meet the criteria in accordance with the Persistence and Bioaccumulation Regulations under CEPA. We continue to see this trend for chemicals assessed under Batch 6. While we see a role for analogues and modeled data in filling in the current gaps and as a replacement for experimental data, there are long term implications that will hinder the process for better understanding these chemicals. Therefore, this practice is of significant concern for several reasons:

- Given the resources allocated to the implementation of the CMP, there will be constraints on the government's and even industry stakeholders' ability to redirect attention and resources to the generation of new toxicity data over the coming years. This will make it significantly difficult to return to the chemicals for which analogue data were considered by government in its decision making process.
- It is unclear if any new experimental toxicity data is being generated as a result of the Industry Challenge.
- The assessment reports fail to explicitly note the source of any 'new data' under consideration and if the data was submitted through the Industry Challenge survey conducted under s. 71 of CEPA. The assessment reports also fail to provide adequate justification that would explain how or why an analogue was not identified by the government during the categorization process between 1999-2006, particularly in the case of an analogue that was already listed on the Domestic Substance List (DSL);
- The reliance on analogues or modeled data does very little to encourage the use of existing acceptable testing protocols to fill in the data gaps. This may not be in keeping with the precautionary principle. New analogue data may be used to replace other modelled data identified during the categorization process. The levels of uncertainty on these chemicals are not reduced but are elevated. We have not seen any cases where new data for chemicals under the Industry Challenge was considered and contributed to support a decision of toxic under CEPA, or where it supported the values required for criteria outlined under the Persistence and Bioaccumulation Regulations.

There are thirteen pigments in Batch 6 for which analogues were applied in order to review the bioaccumulation criteria and the inherent toxicity of the chemical.

As noted previously, we recognize the role of analogues in the decision making process, particularly in the short term. The current consideration of a limited number of analogues (e.g. Disperse Orange 30, Disperse Blue 79 and Disperse Blue 79:1) to make decisions on many chemicals is viewed as problematic from a policy perspective. The apparent reliance on a few analogues and read across data to assess key criteria used in the current approach further entrenches the need to fill the data gaps we are faced with on existing chemicals in the Canadian market.

We do not consider it to be sufficiently protective of human health and the environment when

there is significant reliance on data derived from analogues for making decisions on chemical use in Canada. The decisions made in the assessment reports will have long term policy implications as the government continues with the CMP and the medium priority chemicals. Decisions made on existing chemicals and possibly decisions made under the New Substances Notification Regulations for new substances, can be affected by this reliance on analogue data.

The government should take steps to fill in the information gaps on chemicals beyond the scope of the Industry Challenge or that of the DSL Inventory Update, with particular emphasis on requirements for experimental data. In our view, a government workplan outlining these requirements is essential when applying the precautionary principle to its full extent. We feel that the current approach contradicts the foundations of the precautionary principle. Rather than taking action to protect human health and the environment from chemicals that lack scientific certainty regarding their fate, we are concerned that the government's employment of analogues is used to justify continued use of some chemicals. This results in placing the burden of proof on civil society which must then demonstrate the negative impacts of these chemicals on human health and environment in order to have them properly controlled. The absence of this evidence results in the continued use of such chemicals.

Despite the resources that may be required to generate some experimental chronic toxicity data, it is of utmost importance to the future of Canadians that steps be taken to continually fill data gaps. The effective implementation of section 71(1)(c) is one of the provisions available to government but it has not been utilized in this manner. In addition, the provisions under section 70 have not been fully enforced. The results of categorization provides adequate justification that these chemicals are suspected of meeting the criteria of toxicity under CEPA but there has been no validation that new data on these chemicals are being submitted to government in a timely manner as required under Section 70. The government should increase the level of priority given to these provisions in moving forward on the implementation of the CMP. It would demonstrate an increase level of accountability to industry and provide assurance that CEPA provisions are being followed.

RECOMMENDATION: The government should develop an effective workplan, beyond the scope of the Industry Challenge and DSL Inventory Update, to fill in the data gaps with experimental data and in particular, to require the generation of data using section 71(1)(c) and full enforcement of section 70. The workplan should ensure full accountability to chemical users, manufacturers and those responsible for disposal (complete supply chain) in filling information gaps for all chemicals covered under the CMP, including medium priority chemicals, other chemicals under the DSL and new chemicals.

2) <u>Proposed measures on selected chemicals not fully protective of human health and the environment</u>

SNAC application does not guarantee that a chemical will be prohibited in Canada

The government is proposing SNAc applications for Direct Black 38 (CAS RN 1937-37-7); and 3-chloropropene (CAS RN 107—05-1). For these two substances, evidence gathered from industry indicated that they were not in use above the threshold of 100kg in Canada in 2006

according to responses to the Section 71 surveys.

Direct Black is proposed to be persistent but not bioaccumulative. Similar azo dyes have surface chemical treatments (but are not disclosed due to confidential business information) which could be carcinogenic. According to the draft assessment report, 3-chloropropene is proposed not to be CEPA toxic but has been classified by other jurisdictions on the basis of carcinogenicity and genotoxicity. These treatments can be present as a residue or reacted state in some products.

Based on the hazardous properties and the level of uncertainty about these chemicals, it is our view that these chemicals should be considered toxic under CEPA and should not be permitted re-entry into the Canadian market. Government has various tools under CEPA to ensure that future uses of these substances are 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.*

While the intent of the SNAc provisions as proposed by government is to monitor any new use of this chemical in Canada, its application has significant limits and could not guarantee that these substances would be prohibited from future use in Canada. Since Disperse Black 38 was classified as a PBiT substance and 3-chlorpropene as not meeting the criteria of toxic under CEPA despite its hazardous properties, they should be assessed with more rigour than currently required for substances notified under the SNAc provisions. This would require revisions to the New Substances Notification Regulations.

RECOMMENDATION: We do not support the application of SNAc provisions for substances Direct Black 38 (CAS RN: 1937-37-7) and 3-chloropropene (CAS RN: 107-05-1) since data required by government under the New Substances Notification Regulations (NSN) Schedule 6 is limiting.

RECOMMENDATION: We support the conclusion of toxic under CEPA for 3-chloropropene (CAS RN 107- 05-1|). However, this chemical should be designated to Schedule 1 and consideration for listing under the Prohibition of Certain Toxic Substances and be considered as part of the management regime.

RECOMMENDATION: Substances assessed under the NSN should include a public comment period, particularly for subsequent assessments conducted using SNAcs. Based on the data for hazardous properties of these chemicals gathered through categorization, it is imperative to require a public comment period under the NSN program and in particular, to provide the public the opportunity to comment on future assessment of these chemicals.

3) Gaps and Limitations in the Screening Level Risk Assessment (SLRA)

It is our view there are significant limitations in the current screening level risk assessments. These include:

- the absence of consideration of cumulative and possible synergistic impacts of chemicals;
- the limited or absence of consideration of impacts to vulnerable populations (including children, workers, indigenous communities, people with chemical

sensitivities and people of low income),
entrenching the information gaps on chemicals by relying on available data (includes data derived from modeling, QSARs, and read across data) rather than seeking methods and opportunities to obtain some experimental data (see section in on "Availability and Quality of Data gaps in support of the Precautionary Principle");

- lack of consideration of full life cycle of the chemical
  consideration of impacts from waste stream, including recycling practices for products that may contain these chemicals;
- lack of consideration of by-products and metabolites throughout the life cycle; and
  limited or no information on available alternatives that do not possess hazardous properties.

These limitations have significant impacts on the draft assessment results on the targeted chemicals. In our previous submissions on chemicals identified in Batches 1 through 5 (draft and final assessment reports), we have outlined many of the same issues. Unfortunately, the final assessment reports for Batches 1 to 3 have not addressed the issues we have raised in this regard. We note, for example, the comments we made in previous submissions on the lack of attention given to assess the impacts of chemicals found in many consumer products that end up in landfills or those that may be targeted for incineration. We have not received any substantive responses addressing how these gaps will addressed.

These sources of chemical release (specifically incineration) may be significant sources of the chemical targeted under assessment, and a source of other toxic by-products that can often result from incineration activities; these include dioxins and furans, hexachlorobenzene, particulate matters and heavy metals. It has been noted in a public response that there are regulations regarding the releases of these chemicals during incineration yet they are said not to pose a hazard to human health or the environment. We do not support these types of comments since adequate scientific data has been collected over the years to show the scope and range of human health implications linked to these chemicals. Cancer, endocrine disruptions, reproductive and developmental, and respiratory problems have all been well documented in relation to these chemicals. There continues to be public concerns in this area. The absence of certain information provides an incomplete assessment of a chemical's impacts throughout its entire life cycle and this lack of information can affect the government's decision-making process in determining the toxicity of a chemical under section 64 of CEPA.

RECOMMENDATION: The SLRA process should be more rigorous and address the various gaps identified above to ensure that decisions are fully protective of human health and the environment.

a) Absence of consideration of cumulative or synergistic effects: This is an on-going issue of concern and has not received an adequate response by government.

On a daily basis, humans are exposed to hundreds of chemicals in products and food, through environmental exposure, in drinking water, etc. However, the risk based approach fails to

account for the potential interactions of various chemicals from these sources. Full and adequate responses to chemical use cannot be undertaken unless the approach is significantly modified to evaluate these impacts.

Similarly, on a daily basis, humans are exposed to chemicals that have known health impacts. However, the current approach does not quantify the effects of having several chemicals that have similar health impacts (e.g. cancer, endocrine disruption, reproductive and developmental problems, etc.) or that have similar modes of action. The consideration of the synergistic effects or additive effects would add a very important dimension not currently considered in the process of the risk based approach. This approach should result in a decision making process that does not assess chemicals in an isolated manner, one chemical at a time.

RECOMMENDATION: Despite the lack of data pertaining to cumulative and synergistic effects of chemicals, the SLRA process should be improved to consider the possibility of cumulative and synergistic effects of chemicals. These chemicals are generally not used in isolation; therefore their assessment should take this into account.

b) Vulnerable populations: The assessments completed under the CMP to date have included some information on exposure of substances for some vulnerable subpopulations including children. However, other vulnerable subpopulations (e.g., people with chemical sensitivities, people of low income, workers, and aboriginal communities) have not been consistently considered or addressed in the assessment process and approach. The consideration of impacts to subpopulations is a significant gap in the current approach. The impacts of cancer causing chemicals to specific vulnerable subpopulations as mentioned above should be carefully reviewed as one needs to consider other socio-economic factors that may be interacting with a subpopulation's ability to cope with such exposures.

Similarly, for some vulnerable subpopulations such as aboriginal communities - who may be living in close proximity to some sources of cancer causing substances - careful and direct consideration should be given to these communities in the assessment process, since exposure to these substances could result in significant health implications for members of such communities. For substances that were identified as PBiT as a result of categorization, no such consideration is included in the assessment once a chemical is found not to meet the criteria for B or iT.

RECOMMENDATION: The screening assessment reports under Batch 6 should be strengthened in scope to include impacts to vulnerable subpopulations that include people of low income, workers, people with chemical sensitivities and aboriginal peoples. The approach should include specific questions outlined in the Industry Challenge surveys that require stakeholders to submit data in this regard.

c) Full life cycle considerations:

i) Impacts from waste streams - The screening level risk assessments on all these chemicals lack an adequate assessment of the impacts of chemicals once the chemicals are disposed of as part of a consumer product or disposed of as industrial waste. The SLRA reports notes that leachates may result from such disposal processes. However, no data assessments of the long term impacts from this source are provided in the assessment reports. In addition, no recognition

or quantification of the by-products or metabolites (that may result from degradation or reactions from the disposal of chemicals or products that contain a chemical being assessed) is acknowledged in the assessment process. It is unknown if any of the by-products or metabolites are themselves toxic to the environment or to human health.

The waste stream provides an additional challenge not addressed in the SLRA. This is a matter of the possible exposure of toxic chemicals to workers in landfills or other waste facilities where workers may come into contact with these chemicals directly or in products that contain these chemicals. Again this is a significant gap in the SLRA.

ii) Incineration - If incineration practices are used to address these chemicals (either as part of the industrial application process or to manage/dispose of consumer products that may contain these chemicals), no data has been provided on the full scope of impacts that this may have to the environment or human health. It is well documented that incineration processes result in the production of some of most harmful chemicals to human health including dioxins and furans, heavy metals and particulate. These chemicals have been a focus of regulatory actions for management in the past. The lack of information on incineration practices hinders the complete understanding of a chemical's fate.

RECOMMENDATION: Assessments on chemicals under CMP, including assessments for Batch 6 chemicals, should take into consideration the full life cycle of chemicals in making conclusions under CEPA. This approach should include further consideration of the fate of a chemical as it enters the waste stream along with its break down products, contaminants and metabolites.

RECOMMENDATION: The SLRA process should identify and quantify the levels of chemicals that result from incineration processes, if applicable.

d) Safer alternatives: There were only two chemicals under Batch 6 identified as toxic under CEPA. The issue of safe alternatives was absent in the draft screening assessment reports for these chemicals. It is difficult to determine the barriers faced by affected industry in developing management options for CEPA toxic chemicals without such information. Further, identification of alternatives would facilitate discussions on the possible elimination of these chemicals and an appropriate transition process to identify any time limited exemptions that may be required. Finally, the availability of this information may assist and facilitate the necessary commitment by decision makers in supporting an elimination strategy in situations where safe alternatives exist.

It is our view that the identification of all possible safe alternatives should be included in all the assessment documents as this type of information can be a positive contribution to the assessment and management processes, particularly when the government makes a determination of toxicity on these substances. It is also necessary that a process be in place to assess or screen the safety of the substitutes under CEPA. This process should include the review of toxicity data (both acute and chronic), pertinent to both human health and the environment. The safety of alternatives is as important as taking action on the substance it is intended to replace. Finally, the screening of safe alternatives should incorporate an effective public engagement component so

as to promote full transparency.

RECOMMENDATION: The SLRA process should be strengthened to require the identification of safe alternatives. In particular, those chemicals that are carcinogenic, otherwise toxic, or coated with potential toxic chemical surface coatings (including dyes and pigments) should require the identification and implementation of safe alternatives. This requirement would promote and facilitate the elimination of these toxic substances.

4) <u>Proposed measures that protect human health and the environment</u>

For chemicals benzyl chloride (CAS RN 100-44-7) and DHNUP (CAS RN 68515-42-4) which have been proposed as toxic under CEPA section 64, the reliance on the risk based approach to conclude on the listing of these chemicals, has not resulted in proposed management measures that adequately protect human health and the environment from exposure to these substances. The challenge of justifying an elimination strategy - on chemicals that have been found to have impacts to human health because of their reproductive and developmental toxicity - is placed squarely on the public, due to the limitations of the screening level risk assessment. For example, the lack of data for all sources of exposure to a chemical makes it extremely difficult and nearly impossible to demonstrate the need for the elimination of these chemicals. Hence, the piece meal approach undertaken currently will result in very limited measures. We recommend that the hazards of a chemical should be considered adequate justification for its elimination. This new shift in approach would not rely on demonstrating and requiring data on exposure.

For the proposed CEPA toxic chemicals mentioned above, the scope of the risk management documents outlined a narrow scope in the proposed measurements. The goals of the risk management do not consider regulatory actions to phase out the use of these chemicals based on their impacts to human health.

The measures outlined for CEPA toxic chemicals need to be fully protective of human health. In our view, the scope of the risk management for these two chemicals is wholly inadequate.

For benzyl chloride, the levels of use of these chemicals are very high at 100,000 -1,000,000 kg imported for 2006. Since the main use of this chemical as intermediate for production of quadranary ammonium compound, there is an unfounded assumption that no additional action is required to address this use. We would offer that no evidence has been provided in the draft screening assessment report that the role as an intermediate does not produce residue or releases of these chemicals or other toxic chemicals. Some additional inventory to confirm the industrial processes do not result in residual release or contamination is necessary and appropriate in this instance. It is also unclear whether any waste from such a process is addressed.

Similarly, additional efforts should be directed to identifying other chemicals or processed that may be considered as safe alternatives to this chemical and given careful consideration in developing the management regime. Currently, the screening level risk assessment does not provide any such information that could be incorporated as appropriate management measures. Should alternatives be available, some consideration for their safety would also be required to avoid the continued use of chemicals with toxic properties.

RECOMMENDATION: We support the designation as CEPA toxic for benzyl chloride (CAS RN 100-44-7) and DHNUP (CAS RN 68515-42-4) based on their toxic properties.

RECOMMENDATION: The proposed risk management measures for these CEPA toxic chemicals are wholly inadequate because of the high volume use of these chemicals. It is appropriate to develop management regimes that include regulatory measures that promote an elimination strategy for these toxic chemicals.

RECOMMENDATION: For the proposed CEPA toxic chemicals, safe alternatives should be considered and be an integral part of the risk management scope document.

5) Emerging issues for consideration:

a) Effects of climate change: Methyl chloride (74-897-3) is a chemical that is involved in the chlorine-catalyzed destruction of stratospheric ozone. There are measures for comprehensive management of ozone-depleting substances in Canada. However, the SLRA on methyl chloride does not provide any accurate statistics on methyl chloride releases from the combustion of fossil fuels and biomass. Furthermore, the SLRA does not include levels of dispersion of methyl chloride from point sources in order to assess the impacts to people and the environment.

RECOMMENDATION: In acknowledgement of the detrimental effects of methyl chloride on stratospheric ozone, increased measures should be in place to estimate methyl chloride releases from biomass and fossil fuels. This information should be provided in the SLRA.

RECOMMENDATION: Based on its carcinogenicity, we do not support that methyl chloride does not meet the criteria of toxic under CEPA.

RECOMMENDATION: Based on the multi-functional use of methyl chloride, including its use as an intermediate for consumer and commercial products, safe alternatives for this chemical should be identified and implemented.

b) Recycling practices: We have noted extensively that toxic chemicals in the waste stream are not adequately and fully addressed in the SLRAs for chemicals identified under the Industry Challenge. By extension, we also note that recycling as part of the end of life process is not addressed in these assessments but should be given more attention. Recycling may contribute to the level of some toxic chemicals as they are released from recycling practices or reconstituted back into other products. We are stating these matters for consideration in the context of these SLRAs. We are concerned that further use of some toxic chemicals through recycling activities will result in continued exposure/impact to human health and the environment through the recycling process itself (industrial releases), as well as from the recycled products that may contain these chemicals. We are now seeing similar discussions and concerns being raised at the international level on other toxic chemicals such as the polybrominated diphenyl ethers. There is a need for focus on this matter to better understand the impacts of chemicals throughout their complete life cycle. This matter has not been discussed under the CMP process but should be considered relevant especially the discussion on by-products and life cycle considerations. Both

these items represent a significant gap in the government approach.

RECOMMENDATION: The SLRAs for chemicals targeted under the CMP including chemicals in batch 6 of the Industry Challenge should include an assessment of the contributions of recycling practices for products that contain these chemicals.

See Table 1 which summarizes the results of categorization, draft screening risk assessment decisions, risk management scope details and other pertinent information for chemicals in Batch 6 of the Industry Challenge, Chemicals Management Plan.
We have provided the table as a reference to track the final assessment results for the chemicals under Batch 6.

TABLE 1 – Summary of results for chemicals in Batch 6 of the Industry Challenge, Chemicals Management Plan

Substance **(CAS RN)**	**Results of Categorization (S. 73)**	**Decisions based on draft screening level risk assessment**	**Key human health concerns outlined in draft screening level assessment (SLRA)**	**Risk management scope document* & applicable details of proposed measures**	**Key data considerations**	**Uses and Volume (kg)**
19800-42-1 Disperse Orange 29	P, B, iT	**Does not meet the** criteria of S. 64 under CEPA 1999**.** **P but not B.**	Human health not a concern in the SLRA.	None ** **To be added to the Domestic Substances Inventory update.**	Monoazo disperse dyes used as analogues. New data from a close structural analogue - low potential to accumulate in the lipid tissues of organisms. Experimental toxicity data for chemical analogues suggest Disperse Orange 29 does not cause acute harm to aquatic organisms exposed at low concentrations.	Used as pigments, stains, dyes, inks – mainly as textile colourants. 1,000 – 10, 000 kg imported into Canada - 2005 & 2006.
85-86-9 Solvent Red 23	P, B, iT	**Does not** meet the criteria of S. 64 under CEPA 1999.	Human health not listed as a concern in the SLRA..	None** **To be added to the Domestic Substances Inventory**	Monoazo disperse dyes used as analogues. New data from a close structural	Used mainly in oils, fats and waxes, but also in alcoholic, ester and hydrocarbon solvents,

Substance **(CAS RN)**	**Results of Categorization (S. 73)**	**Decisions based on draft screening level risk assessment**	**Key human health concerns outlined in draft screening level assessment (SLRA)**	**Risk management scope document* & applicable details of proposed measures**	**Key data considerations**	**Uses and Volume (kg)**
		P but not B.		**update**	analogue - low potential to accumulate in the lipid tissues of organisms. Experimental toxicity data for chemical analogues suggest that Disperse Red 23 does not cause acute harm to aquatic organisms exposed at low concentrations.	polystyrene, cosmetics, chemical indicator, pesticide colorant. 1000 – 10, 000 kg imported into Canada - 2005 & 2006.
6250-23-3 Disperse Yellow 23	P, B, iT	**Does not** meet the criteria of S. 64 under CEPA 1999. **P but not B.**	Human health not listed as a concern in the SLRA.	None** **To be added to the Domestic Substances Inventory update.**	Monoazo disperse dyes used as analogues. New data from a close structural analogue - low potential to accumulate in the lipid tissues of organisms.	Used as pigments, stains, dyes, inks – mainly as textile colourants. No reports of usage over the reporting threshold of 100 kg.

Substance **(CAS RN)**	**Results of Categorization (S. 73)**	**Decisions based on draft screening level risk assessment**	**Key human health concerns outlined in draft screening level assessment (SLRA)**	**Risk management scope document* & applicable details of proposed measures**	**Key data considerations**	**Uses and Volume (kg)**
					Experimental toxicity data for chemical analogues suggest that Disperse Yellow 23 does not cause acute harm to aquatic organisms exposed at low concentrations	
6253-10-7 Disperse Orange 13	P, B, iT	**Does not** meet the criteria of S. 64 under CEPA 1999. **P but not B.**	Human health not listed as a concern in SLRA.	None** **To be added to the Domestic Substances Inventory update.**	Monoazo disperse dyes used as analogues. New data from a close structural analogue - low potential to accumulate in the lipid tissues of organisms. Experimental toxicity data for chemical analogues suggest that Disperse	Used as pigments, stains, dyes, inks – mainly as textile colourants. No reports of usage over the reporting threshold of 100 kg.

Substance **(CAS RN)**	**Results of Categorization (S. 73)**	**Decisions based on draft screening level risk assessment**	**Key human health concerns outlined in draft screening level assessment (SLRA)**	**Risk management scope document* & applicable details of proposed measures**	**Key data considerations**	**Uses and Volume (kg)**
					Orange 13 does not cause acute harm to aquatic organisms exposed at low concentrations.	
6300-37-4 Disperse Yellow 7	P, B, iT	**Does not** meet the criteria of S. 64 under CEPA 1999. **P but not B.**	Human health not listed as a concern in the SLRA.	None** **To be added to the Domestic Substances Inventory update.**	Monoazo disperse dyes used as analogues. New data from a close structural analogue - low potential to accumulate in the lipid tissues of organisms. Experimental toxicity data for chemical analogues suggest that Disperse Yellow 7 does not cause acute harm to aquatic organisms exposed at low concentrations.	Used as pigments, stains, dyes, inks – mainly as textile colourants. No reports of usage over the reporting threshold of 100 kg.

Substance **(CAS RN)**	**Results of Categorization (S. 73)**	**Decisions based on draft screening level risk assessment**	**Key human health concerns outlined in draft screening level assessment (SLRA)**	**Risk management scope document* & applicable details of proposed measures**	**Key data considerations**	**Uses and Volume (kg)**
21811-64-3 Disperse Yellow 68	P, B, iT	**Does not** meet the criteria of S. 64 under CEPA 1999. **P but not B.**	Human health not listed in the SLRA as a concern.	None** **To be added to the Domestic Substances Inventory update.**	Monoazo disperse dyes used as analogues. New data from a close structural analogue - low potential to accumulate in the lipid tissues of organisms. Experimental toxicity data for chemical analogues suggest that Disperse Yellow 68 does not cause acute harm to aquatic organisms exposed at low concentrations.	Used as pigments, stains, dyes, inks – mainly as textile colourants. No reports of usage over the reporting threshold of 100 kg.
93805-00-6 Phenol, 4-[[2-methoxy-4-[(2-methoxyphenyl)azo]-5-	P, B, iT	**Does not** meet the criteria of S. 64 under	Human health not listed as a concern in the SLRA.	None** **To be added to the Domestic**	Monoazo disperse dyes used as analogues.	Used as pigments, stains, dyes, inks – mainly as textile colourants.

Substance **(CAS RN)**	**Results of Categorization (S. 73)**	**Decisions based on draft screening level risk assessment**	**Key human health concerns outlined in draft screening level assessment (SLRA)**	**Risk management scope document* & applicable details of proposed measures**	**Key data considerations**	**Uses and Volume (kg)**
methylphenyl]azo]- MMMP		CEPA 1999. **P but not B.**		**Substances Inventory update.**	New data from a close structural analogue - low potential to accumulate in the lipid tissues of organisms. Experimental toxicity data for chemical analogues suggest that this disazo dye does not cause acute harm to aquatic organisms exposed at low concentrations.	No reports of usage over the reporting threshold of 100 kg.
1229-55-6 Solvent Red 1	P, B, iT	**Does not** meet criteria for S. 64 under CEPA 1999. **P but not B**	Human health concerns not listed in the SLRA.	None** **To be included in the update of the upcoming DSL.**	Close structural analogue used. No acute harm to aquatic organisms exposed to low concentrations.	Colourant dyes – possibly used in textiles, paper, fabric. No reports of usage above the reporting threshold of 100 kg in 2006.

Substance **(CAS RN)**	**Results of Categorization (S. 73)**	**Decisions based on draft screening level risk assessment**	**Key human health concerns outlined in draft screening level assessment (SLRA)**	**Risk management scope document* & applicable details of proposed measures**	**Key data considerations**	**Uses and Volume (kg)**
3118-97-6 Solvent Orange 7	P, B, iT	**Does not** meet criteria for S. 64 under CEPA 1999. **P but not B**	Human health concerns not listed in the SLRA.	None** **To be included in the update of the upcoming DSL.**	Close structural analogue used. N**o** acute harm to aquatic organisms exposed to low concentrations**.**	Colourant dyes – possibly used in textiles, paper, fabric. No reports of usage above the reporting threshold of 100 kg in 2006.
6535-42-8 Solvent Red 3	P, B, iT	**Does not** meet criteria for S. 64 under CEPA 1999. **P but not B**	Human health not listed as a concern in the SLRA.	None** **To be included in the update of the upcoming DSL.**	Close structural analogue used. N**o** acute harm to aquatic organisms exposed to low concentrations.	Colourant dyes – possibly used in textiles, paper, fabric. No reports of usage above the reporting threshold of 100 kg in 2006.
1937-37-7 Direct Black 38	P, B, iT High hazard for human health but low potential for exposure	**Does not** meet the criteria for S. 64, CEPA 1999. **P but not B**	Human health not listed as a concern in the SLRA.	None** **To be included in the upcoming DSL Inventory Update.**	Low potential for B in the lipid tissues of aquatic organisms. Anthraquinone dyes used as	Dye in the textile industry, paper, leather, plastics, inks, wood. Canada 2005 and 2006 - no reports

Substance (CAS RN)	Results of Categorization (S. 73)	Decisions based on draft screening level risk assessment	Key human health concerns outlined in draft screening level assessment (SLRA)	Risk management scope document* & applicable details of proposed measures	Key data considerations	Uses and Volume (kg)
				Proposed that Significant New Activity provision be applied	analogues – these analogues are also included in the Challenge Program. They are not azo dyes but contain the 2 sulfonic acids groups as in Direct Black 38. This dye can contain a chemical surface treatment and if so, the chemical composition is possibly confidential business information. Residues from manufacturing or storage, such as carcinogenic aromatic amines, can be present.	of using, manufacturing, or importing above the reporting threshold of 100 kg.
6358-57-2	P, B, iT	**Does not**	Human health	None**	Low potential for B	Dye in the textile

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Acid Red 111		meet the criteria for S. 64, CEPA 1999.	not a concern in the SLRA.	**To be included in the update of the upcoming DSL.**	in the lipid tissues of aquatic organisms. Anthraquinone dyes used as analogues – these analogues are also included in the Challenge Program. They are not azo dyes but contain the 2 sulfonic acids groups as in Acid Red 111. This dye can contain a chemical surface treatment and if so, the chemical composition is possibly confidential business information. Residues from manufacturing or	industry, paper, leather, plastics, inks, wood, coatings. Reported import of between 100 and 1000 kg of into Canada in 2005 and 2006

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					storage, such as carcinogenic aromatic amines, can be present. Low potential for B in the lipid tissues of aquatic organisms.	
7147-42-4 butanamide, 2,2'-[(3,3'-dimethoxy[1,1'-biphenyl]-4,4'-diyl)bis(azo)]bis[N-(2-methylphenyl)-3-oxo-(BPAOPB)	P, B, iT	**Does not** meet criteria in S. 64 CEPA 1999. P but not B	Human health not a concern in the SLRA.	None** **To be included in the update of the DSL.**	Analogues used. No acute harm to aquatic organisms.	As a colour pigment in printing inks and plastics; lesser extent in coatings. For 2006 – less than four Canadian companies reported manufacturing between 100 and 1000 kg of BPAOPB. No imports or uses were reported.
74-87-3	Toxic	**Does not** meet the	Classified by the European	None**	Information gaps as release	Chemical intermediate –

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Methane,chloro- (methyl chloride)	P not B or iT	criteria under S. 64 of CEPA 1999	Commission based on carcinogenicity.	Methyl chloride included as a chemical in the chlorine-catalysed destruction of stratospheric ozone. Measures for the comprehensive management of ozone-depleting substances are in place in Canada.	quantities of methyl chloride from combustion of fossil fuels and biomass releases are not accurately known. Modelling of the dispersion of methyl chloride from point sources to estimate exposure of people in communities has not been conducted.	uses include a solvent in the manufacture of butyl rubber, quaternary ammonium compounds. Also used as an intermediate in the manufacture of methylene chloride, a food additive approved for use as anextraction solvent, food additive methyl cellulose, hydroxypropyl methylcellulose. From the use of these materials, residues in food are considered as negligible or non-existent. Methyl chloride can be a residue in consumer products

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						but it is not intentionally added. 1,049,000 kg of methyl chloride were imported into Canada in 2006.
100-44-7 benzene, (chloromethyl)- (benzyl chloride)	Toxic	**Proposed toxic** under criteria of S. 64 of CEPA 1999	Classified by other agencies on the basis of carcinogenicity and genotoxicity	Proposal to add benzyl chloride to the Environmental Emergency (E2) Regulations under Section 200 of CEPA 1999.	Lack of data for chronic human exposure through inhalation to benzyl chloride. There is uncertainty due to the limited information on the presence or concentrations of the substance in products available in Canada, as the substance is not used directly in products. More information	In Canada - benzyl chloride is mainly used as a chemical intermediate for the synthesis of quaternary ammonium compounds, which are used primarily as hard surface sanitizers, corrosion inhibitors, fungicides in industrial cleaners and bactericides or surfactants in household and personal care

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					on concentrations in consumer products accessible in Canada would permit better characterization of risk of potential adverse health effects associated with the use of products containing benzyl chloride. In addition, there is a lack of data regarding possible emission from coal combustion.	products. Used as an intermediate in the organic synthesis of benzyl alcohol and benzyl butyl phthalate, which are used in a wide spectrum of applications, including pharmaceuticals, cosmetic formulations, flavour products, solvents, textile dyes and plasticizers in vinyl flooring and other flexible polyvinyl chloride uses, such as food packaging. 2006 in Canada - 100 000– 1 000 000 kg were imported with no companies

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						reported manufacturing in quantities greater than or equal to the threshold of 100 kg.
107-05-1 1-propene, 3-chloro- (3-chloropropene)	Toxic	**Does not** meet the criteria under S. 64 of CEPA 1999 **Not P or B.** **iT to aquatic organisms**	Classified by the European Commission and the US EPA on the basis of carcinogenicity and genotoxicity.	None** **To be subjected to the Significant New Activity**	Limited data were available to estimate exposure to 3-chloropropene in the general environment. Significant uncertainty concerning levels of residual 3-chloropropene in products used in Canada that could result in exposure of the general population.	3-chloropropene is used mainly in the production of epichlorohydrin, glycerine and quaternary ammonium compounds. It is also used as a chemical intermediate in the production of llyl compounds, cross-linking substances, pharmaceutical agents and agricultural chemicals. For 2006 in Canada – the total amount of 3-

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						chloropropene was less than the threshold of 100 kg. There was no reported manufacture or direct reported use for 2006. However, it was imported in its reacted use or as a residue in products.
117-82-8 1,2-benzenedicarboxylic acid, bis(2-methoxyethyl) ester (di(methoxyethyl)phthalate, DMEP),	Toxic	**Does not** meet the criteria under S. 64 of CEPA 1999	Classified by the European Commission on the basis of reproductive and developmental toxicity.	None **DMEP to be subjected to the Significant New Activity provisions**		Uses of DMEP in food packaging, cosmetic products or pesticide products, either as an active ingredient or as a formulant, have not been notified in Canada. DMEP can be used as a plasticizer in paints and coatings. The *Controlled*

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						Products Regulations established under the *Hazardous Products Act* require DMEP to be disclosed on the Material Safety Data Sheet that must accompany workplace chemicals when it is present at a concentration of 0.1% or greater as specified on the Ingredient Disclosure List (Canada 1988). Canada 2006 – it was not manufactured or imported in a quantity equal to or greater than the 100 kg reporting threshold.

Substance **(CAS RN)**	**Results of Categorization (S. 73)**	**Decisions based on draft screening level risk assessment**	**Key human health concerns outlined in draft screening level assessment (SLRA)**	**Risk management scope document* & applicable details of proposed measures**	**Key data considerations**	**Uses and Volume (kg)**
68515-42-4 1,2-benzenedicarboxylic acid, di-C7-11-branched and linear alkyl esters (DHNUP)	Toxic	**Proposed toxic** under criteria of S. 64 of CEPA 1999	Classified by the European Commission on the basis of reproductive and developmental toxicity. Liver toxicity.	isk management measures would focus on the handling practices of containers storing and/or transporting DHNUP.	Lack of consistent nomenclature of DHNUP makes literature searches very difficult. UVCB nature of DHNUP – difficult to estimate the exact nature of human exposure	2006 & prior – use as a plasticizer of electrical and communication wire insulation Manufactured in a quantity in the range of 100 000–1 000 000 kg in 2006. Quantity imported into Canada in the same calendar year was reported to be in the range of 10 000 000–100 000 000 kg. Manufacturing activity involving DHNUP was estimated to be completely phased out in Canada subsequent to the 2006 reporting year, whereas

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						annual importation activity was estimated to have declined by over 95%. Phaseout of DHNUP in Canada occurred largely due to the decreased availability of the upstream plasticizer alcohols required for its synthesis. It is not known if the decline in DHNUP quantities in Canadian commerce is temporary or permanent.

* Based on Draft Screening Level Risk Assessment Report prepared for chemicals identified in CMP Industry Challenge, Batch 6.

**No risk management scope documents were prepared for these substances because the proposed conclusion of the draft screening assessment reports is that they do not meet any of the criteria set out under S. 64 of CEPA 1999

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