A Response to the Proposed Screening Level Risk Assessments and Proposed Risk Management Scope Documents for Chemicals Management Plan Industry Challenge Batch 5 Substances Published in *Canada Gazette* Part I, Vol. 143, No. 8 — February 21, 2009

Submitted to:
George Enei
Science and Risk Assessment Directorate

Margaret Kenny
Chemical Sectors Director
Environment Canada

Karen Lloyd
Safe Environments Programme
Health Canada

at
Executive Director
Existing Substances Division
Gatineau, Quebec K1A 0H3
Existing.Substances.Existantes@ec.gc.ca

Prepared by:
Chemical Sensitivities Manitoba
and
Canadian Environmental Law Association

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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. 8 — February 21, 2009 release of the draft decisions from screening assessment reports for selected substances identified under the Chemicals Management Plan (CMP), Batch 5 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.

In this submission, we have not provided commentary on all draft screening assessment reports undertaken on substances in Batch 5. The absence of such commentary does not mean that we do not have any comments related to the draft assessment results. The comments presented below may be considered as examples of the range of concerns we have on these chemicals.

Given the importance of the work completed under the categorization process to identify chemicals for further attention, we want to ensure that the assessments undertaken at this stage fully implement the precautionary principle and that in the decision making process, we are ensured the protection of human health and the environment. In addition, our organizations want to ensure that the government utilizes the full extent of its authority to promote and implement the elimination or phase out of the most toxic chemicals in the Canadian market.

Draft Screening Level Risk Assessment Reports – Overall findings

The draft screening assessments decisions on the 17 of 19 Batch 5 substances highlight troubling trends for priority substances undergoing screening under the Chemicals Management Plan (CMP) (see Appendix). In particular, 12 chemicals found to be persistent, bioaccumulative and inherently toxic (PBiT) as a result of categorization are now considered not bioaccumulative or inherently toxic to the aquatic environment based on the draft screening assessment. The decisions on B and iT for these 12 chemicals have changed since categorization. These results concern us. We consider the screening assessment process too limited in its scope and the resulting decisions do not appear to apply the precautionary principle fully and effectively.

The decisions made in these assessments relied on the use of other pigments as analogues rather than experimental data for the targeted chemicals. In our view, this extensive use of analogues to determine the toxicity for these substances is not fully justified. It is also unclear from the draft assessment reports whether the analogues used to make decisions reduced the level of uncertainties in the data as compared to the data used to make the categorization decision (i.e. QSARs or other modelling data).

It is our view that the quality of the surveys conducted under the Industry Challenge need to be improved significantly. If improvements to the surveys are undertaken, it would impact on the quality of the assessment results and decrease the uncertainty of the data. Such revisions should include a requirement that the chemical user submit all data in their possession, particularly on their hazardous properties about a targeted chemical or seek to fill data gaps with a requirement that they generate new data about the targeted chemical. The requirement for new data would replace the reliance on analogue data to complete assessment. The current approach is not fully protective of human health and the environment as it does not accurately provide the significant data that are deficient for these chemicals.

In fact, several health and environmental organizations submitted a substantive letter to the Ministers of Health and Environment outlining the need to require that all toxicity data be submitted to complete these assessments. This letter was dated February 13, 2009. This letter highlighted the substantive gap that exists in the current risk based assessment approach as utilized in the Chemicals Management Plan. This letter has not resulted in any subsequent discussion with the government nor any noticeable changes in the government's approach to data collection. It is important to highlight these gaps as it has a profound impact on the quality of protection provided to human health and the environment. NGOs consider this type of communication essential to fill in data gaps. NGOs continue to highlight similar gaps as the government continues its work under the CMP.

Up to the present, the draft decisions, particularly for Batch 4 and now Batch 5, have lead to a dramatically high number of high priority chemicals, as identified through categorization, to be identified now as not being toxic under CEPA. We are extremely

concerned that the decisions made in these recent screening assessments undermine the value of the results collected through the categorization process on 23,000 chemicals. The government has had seven years to make its decisions on persistence, bioaccumulation and toxicity. Similarly, users and manufacturers have had the same opportunity to provide the necessary data needed to demonstrate the safety of their chemicals mainly through a voluntary process. However, the list of references for some of these assessments outline that information used in the screening assessments are at least 10 years old and are now being introduced as 'new' information in the assessment. This, coupled with the drastic changes from the categorization results and the high degree of uncertainty identified in assessments (as they are associated with the use of analogues such as Dispersed Blue 79, Disperse Orange 30 to determine B or iT) is very disconcerting.

Furthermore, such a disturbing trend in the decisions made on high priority chemicals does not provide any level of confidence that chemicals listed in the high or medium priority categories of CMP, will eventually result in a finding of CEPA toxic. As demonstrated in these assessments, the threshold established under CEPA for toxicity is extremely high. The level of uncertainty attached to the data for assessment of these chemicals must significantly decrease before the chemical will be considered toxic. Therefore, not many chemicals have been able to meet this threshold. This appears to be somewhat contradictory to what is required for a precautionary approach.

RECOMMENDATION: We question the quality and scope of the screening assessments conducted on chemicals covered under Batch 5. The reliance on analogues to determine bioaccumulation and inherent toxicity for 12 of the 13 chemicals considered PBiT under categorization should be rejected. Rather, a call for experimental data for these pigments should be required.

Human Health Priorities

Based on the draft assessment completed on 19 chemicals in Batch 5 of the Industry Challenge of the Chemicals Management Plan, only 2 chemicals were found to be toxic under CEPA. The two chemicals found to be toxic under CEPA were identified as human health priorities: 2-Propenamide (acrylamide) (CAS RN 79-06-1) and Ethanol, 2-chloro-, phosphate (3:1) [TCEP] (CAS RN 115-96-8). The proposed risk management strategies on these chemicals are very narrow in scope despite the government finding of carcinogenicity and reproductive toxicity. For these chemicals, it would be appropriate for the government to take 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 on these substances. The lack of details on the management of these cancer causing and reproductive toxins is unacceptable - the draft screening assessment reports provide practically no details on the measures under consideration for these two substances.

We have a growing concern (for this batch and previous batches of chemicals assessed under the Chemicals Management Plan) that proposed measures to manage many of these substances will not be sufficiently protective of human health and the environment. We recognize that the government approach is based on managing risk. With risk based approach, we are concerned that management of toxic chemicals would result consideration of control measures based on source of exposure. For toxic chemicals identified through the CMP, managing risk is will not provide adequate measure of protection to human health and the environment. It is more protective to commit to an elimination strategy for toxic chemicals to ensure the protection of human health and the environment.

For the 6 human health priorities, 4 of the chemicals were not found toxic under CEPA. Therefore, no management measures are proposed. For one of the human health priorities, 2-Chloroacetamide (CAS RN 79-07-2), where no relevant data was received through the Industry Challenge, the government proposed to conclude that this chemical does not meet the criteria of toxic under CEPA but its inherent toxicity to human health remains unchanged.

Since 2003, this chemical has been targeted for re-evaluation by the Pest Management Registry Agency. A Significant New Activity (SNAc) has now been proposed for this chemical. Despite evidence gathered by the government through the Industry Challenge of one non-pesticidal use of this chemical, the government deems it unnecessary to ensure its full and complete removal in Canada. However, based on the evidence gathered showing reproductive toxicity from exposure to this chemical, the government has sufficient grounds to take protective action on this chemical on this time.

Relying on the re-evaluation process on the pesticidal use of this chemical or the use of the SNAc provision does not represent a protective or a precautionary measure. For any future uses of this chemical, another assessment will be undertaken through the New Substances Notification Regulations, which lacks a public comment provision. This process will not guarantee a ban on this chemical and therefore leaves the public vulnerable to future use.

RECOMMENDATION: Based on its reproductive toxicity, 2-Chloroacetamide (CAS RN 79-07-2) should be found to be toxic under CEPA 1999 despite the limited data received through the Industry Challenge. Furthermore, this chemical should be listed on CEPA Toxic Substances List (Schedule 1) and appropriate management strategies should be developed.

RECOMMENDATION: Based on it reproductive toxicity, 2-Chloroacetamide (CAS RN 79-07-2) should be added to the *Prohibition of Certain Toxic Substances Regulations* to ensure that the future sale, use, manufacture or import of this chemical is not permitted in Canada. This approach is more protective of human health than the current approach to apply SNAc.

RECOMMENDATION: We do not support the use of SNAc for 2-Chloroacetamide (CAS RN 79-07-2) as it does not ensure the full protection of the public. Furthermore, an assessment of this chemical under the New Substances Notification Regulations will not include input from the public on assessment results.

Environmental Priorities

All chemicals identified as PBiT as a result of categorization retained their persistence designation. Despite meeting the criteria of persistence, the government draft screening reports did not include any measures for reducing the use of persistent chemicals. It is our view that such measures are warranted for these chemicals despite their not meeting the criteria of B or iT. Many of these chemicals are pigments and dyes. They are used extensively in industrial and consumer product applications. Over time, these chemicals will likely breakdown and affect the environment. Like other azo dyes these chemicals are expected 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. Furthermore, for these persistent chemicals the absence of experimental data to determine bioaccumulation or toxicity means that the uncertainty on these chemicals toxicity remains high. Therefore, for substances found to be persistent only, it is appropriate for government to propose reduction measures for persistent chemicals to ensure that the environment is protected.

For one chemical, Ethanol, 2-[[4-[(2,6-dichloro-4-nitrophenyl)azo]phenyl]methylamino]- , (Disperse Orange 5) (CAS RN 6232-56-0), which was found to be a persistent, bioaccumulative and inherently toxic chemical through categorization, no additional data was generated through the Industry Challenge. The categorization decision for Disperse Orange 5 remained unchanged and the chemical does not meet the criteria of toxic under CEPA 1999. With a lack of new data arising from the Industry Challenge and based on its PBiT properties, the government has decided that action on this chemical is needed for future uses. Therefore, a Significant New Activity (SNAc) was proposed for this chemical.

As noted with 2-Chloroacetamide (CAS RN 79-07-2), a SNAc provision does not represent a protective or a precautionary measure. For any future uses of this chemical, a reassessment of the chemical will be undertaken through the New Substances Notification Regulations, which lacks a public comment provision. This process will not guarantee a ban on this chemical and leaves the public and environment vulnerable to its future use. This chemical should be found to be toxic under CEPA based on meeting the criteria for persistence, bioaccumulation and inherent toxicity.

RECOMMENDATION: We do not support the proposed assessment decisions on the 12 chemicals identified as high priority to the environment (PBiT chemicals) through categorization. The draft assessment decisions on these chemicals were

based on various analogues in the azo dye family to make a determination on bioaccumulation and inherent toxicity to the aquatic environment.

RECOMMENDATION: For all 12 chemicals found to be persistent based on the draft screening results, the government should undertake measures to reduce these chemicals over time. This should be done because they have the potential to affect the environment; such chemicals are found in many products and may be released in the environment through their degradation.

RECOMMENDATION: For Disperse Orange 5 (CAS RN 6232-56-0) a conclusion of toxic under CEPA is appropriate despite the lack of additional data provided during the Industry Challenge.

RECOMMENDATION: Application of SNAc for Disperse Orange 5 (CAS RN 6232-56-0) 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 this chemical, it should be considered toxic under CEPA and added to CEPA Toxic Substances List (Schedule 1). To prevent the re-entry of this chemical into Canada, this chemical should be added to the Prohibition of Certain Toxic Substances Regulations which aims to prevent the sale, use and manufacture of this chemical in the future.

Overarching Issues

CELA and CSM are noting the following comments. These comments have been noted for other substances assessed under the Industry Challenge as well as Batch 5 chemicals.

Carcinogens: Under Batch 5, there were 6 chemicals that were identified as human health priorities through categorization. Three chemicals (e.g. 2-Propenamide (acrylamide),]- (CAS RN 79-06-1); Ethanol, 2-chloro-, phosphate (3:1) [TCEP] (CAS RN 115-96-8); and Tributyl Phosphate (CAS RN 126-73-8) were identified by international agencies as carcinogenic. However, through the draft assessment only two chemicals (e.g., 2-Propenamide (acrylamide),]- (CAS RN 79-06-1); Ethanol, 2-chloro-, phosphate (3:1) [TCEP] (CAS RN 115-96-8); were found to be toxic. We maintain that any substance found to be carcinogenic or having the potential to be carcinogenic should be phased out or eliminated by the government.

For acrylamide, the government proposal includes a listing to CEPA Toxic Substances List (Schedule 1), DSL inventory update, research and monitoring and possible regulation or instrument. The draft risk management scope document does not outline the government's objectives with its proposed measures. These proposals do not focus on elimination measures but rather a reduction measure. It will focus on taking action under the *Food and Drug Act* to address sources of acrylamide from certain foods. The absence of measures directed at industrial sources of acrylamide is a significant gap in the draft assessment report and should be addressed. The proposed approach should

include prevent acrylamide exposure from all sources to adequately protect human health (see below for additional comments on acrylamide).

RECOMMENDATION: The management strategies for the two carcinogens identified as CEPA toxic should be strengthened with a goal of elimination.

Reproductive toxicants

Of the 6 health priorities, three chemicals (Formamide (CAS RN 75-12-70; Acetamide, N,N-dimethyl- (CAS RN 127-19-5); and 2-Chloroacetamide (CAS RN 79-07-2)) were found to have reproductive toxicity. Based on the draft assessment results, none of these chemicals met the criteria of toxicity under CEPA. However, due to information gathered through the Industry Challenge, one of the chemicals, 2-Chloroacetamide (CAS RN 79-07-2) was proposed for Significant New Activity (SNAc).

Formamide (CAS RN 75-12-70), which is used in the art and craft sector, has been identified by the European Commission as a class 2 reproductive and developmental toxicant with specific concerns related to the impact to the unborn child. These chemicals are known to be used in felt tip markers and pens, which are sold in European markets.

The current conclusions on health impacts and CEPA toxicity for this chemical should be questioned. The assumptions by assessors on the use and extent of exposure from these chemicals are narrow in scope. The draft report on this chemical clearly notes that there is "potential dermal exposure to formamide resulting from exposure to formamide-containing inks, the extent of availability of formamide-containing pens/markers in Canada is unknown." It is this particular source stream that should be emphasized not downplayed when it comes to the safety of the public. The last few years should demonstrate the challenge faced by Canada in protecting the public from products that contain toxic chemicals such as lead. The US National Toxicological Program (NTP) and the European Commission data adequately demonstrated the hazards associated with formamide. The conclusions under CEPA that formamide is not toxic were purely based on the assumption that exposure to Canadians would be limited. Given the lack of regulations in place in Canada to ensure the borders do not permit the entry of products that may contain formamide, the conclusions that Canadians' health is fully protected from this chemical are fully justified. The assessment should be revised to adequately take into account the potential impacts of this chemical to human health and the potential of products containing this chemical to enter the Canadian market.

RECOMMENDATION: Based on US NTP and European Commission data on formamide, the draft assessment process has not provided sufficient evidence to demonstrate the safety of formamide. This chemical should be found to be toxic under CEPA based on its reproductive toxicity.

RECOMMENDATION: Chemicals that have reproductive and development toxicity should be targeted for elimination to ensure the protection of human health. This action should include the prohibition of use, sale and import of this chemical in Canada including products that may contain formamide.

Full life-cycle consideration: While there has been some progress in acknowledging the need to consider the life cycle of a substance, government assessments could be improved in this area. A complete investigation and consideration of the full life cycle of a substance is necessary to make decisions on the impact of its toxicity to the environment and human health. None of the draft screening assessments for Batch 5 chemicals included consideration of 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 or metabolites. Nevertheless, it is essential to include these issues in the assessment report in order to provide a complete understanding of the behaviour of these chemicals.

For those chemicals 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. The government has not committed to take action on chemicals that are found to be only persistent.

It is critical that the government improves its assessment process to account for exposure and fate of a substance throughout its life cycle (e.g., breakdown products, metabolites) including at the disposal phase. In our view, the absence of a full life cycle consideration affects the final decision on toxicity and therefore the decision on any future management effort.

RECOMMENDATION: Assessments on chemicals under CMP, including assessments for Batch 5 chemicals, should take into consideration the full life cycle of chemical in making its conclusion under CEPA. This would include consideration of break down products, contaminants and metabolites.

Vulnerable populations: The assessments completed under the CMP to date have included information on exposure of substances for some vulnerable subpopulations such as children. However, other vulnerable subpopulations (e.g., people with chemical sensitivities, people of low income, workers, and aboriginal communities) are not considered in the assessment process and the approach to address vulnerable populations has not been consistently applied to all substances. This is the case with Batch 5 substances.

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 their 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 5 should be strengthened in their approach to include impacts to vulnerable subpopulations that include people of low income, workers, people with chemical sensitivities and aboriginal communities.

Lack of Cumulative and Synergistic Effects: None of the draft assessments for Batch 5 chemicals included the consideration of cumulative and synergistic effects of chemicals. The quality of the assessment results would be significantly strengthened with the inclusion of these considerations. Exposure to chemicals does not occur in isolation. In fact, 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. These interactions have not been acknowledged. The risk based approach undertaken under CMP continues to disregard important interactions that may occur between chemicals. Significant attention to this gap should be undertaken to provide a more accurate picture of the impacts these toxic chemicals have on human health and the environment.

RECOMMENDATION: The government's risk based approach continues to exclude the consideration of cumulative and synergistic effects of chemicals. The risk based approach should be strengthened by addressing this gap.

Safe substitution: Since there were only two chemicals identified as toxic under CEPA, the issue of safe alternatives was absent in most draft screening assessment reports. The draft Risk Management Scope document for Ethanol, 2-chloro-, phosphate (3:1) [TCEP] (CAS RN 115-96-8) does note that a final decision on CEPA toxic may result in the consideration of safe alternatives for specific uses of this chemical. It is difficult to determine how easily a goal of elimination for toxic chemicals can be achieved without the appropriate political commitment, as well as some level of information that a safe alternative may exist to replace the toxic chemical.

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 would be a positive contribution to the overall assessment and management processes, particularly as the government makes a determination of toxicity on these substances. It is also necessary that a process be in place to assess or screen the safety of the substitutes under CEPA.

This process should include a review of toxicity data (both acute and chronic), pertinent to both human health and the environment. The safety of alternatives is equally 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: The finding of toxicity for any chemical that has a health impact such as carcinogenicity (i.e., Ethanol, 2-chloro-, phosphate (3:1) [TCEP] CAS RN: 115-96-8) should require the identification and implementation of safe alternatives. This requirement would promote and facilitate the elimination of these toxic substances.

Additional comments on Selected Chemicals

1) *2-Propenamide (acrylamide),] (CAS RN 79-06-1)*.

Acrylamide is used mainly in the manufacture of various polymers, which in turn are used as binding, thickening, or flocculating agents in grout, cement, sewage/waste water treatment, pesticide formulations, cosmetics, sugar manufacturing, soil erosion prevention, ore processing, food packaging, plastic products and in molecular biology laboratory applications. In Canada, polyacrylamide is used as a coagulant and flocculant for the clarification of drinking water; it is also used in potting soils and as a non-medicinal ingredient in natural health products. This chemical is also produced through chemical reaction in specific foods, such as French fries and potato chips. Therefore, the main exposure of the general population to this toxic chemical is through certain foods that are cooked at high temperatures.

The extensive use of acrylamide in industrial applications and its formation through the cooking process of specific processed foods demonstrates that Canadians' exposure to this chemical is extensive. While the draft assessment report highlights that Canadian exposure to acrylamide comes primarily through dietary sources, the industrial and consumer product uses of acrylamide should not be understated. Despite the carcinogenicity of acrylamide, the draft Risk Management Scope document for acrylamide does not include a proposal to develop an elimination strategy for this chemical. A proposed regulation or instrument is a control measure that will focus on establishing levels considered safe to human health rather than source prevention for these chemicals. Similarly, action taken under the *Food and Drug Act* will emphasize "reduction of inadvertent production of acrylamide in processed food." The proposed strategy would be insufficient for fully protecting Canadians since industrial sources of acrylamide will not be addressed. The consideration of all sources of exposure is urgently needed, rather than a focus on only the dietary route.

There are several key gaps in the draft risk management scope document for acrylamide, including the following:

- lack of information on safe alternatives,

- no details on the type of cosmetic products containing acrylamide or consumers who use these products, and
- lack of detail on whether measures to be taken will include the reduction of acrylamide in industrial uses.

RECOMMENDATION: We support the finding of toxic under CEPA for Acrylamide. This chemical should be added to Schedule 1 of CEPA.

RECOMMENDATION: Due to its carcinogencity and reproductive toxicity, the draft risk management scope document for acrylamide should be strengthened based on establishing a goal of eliminating this chemical from industrial and consumer applications. Although, the draft risk management document notes the consideration of regulations or instruments, the focus is on reduction of levels of acrylamide.

RECOMMENDATION: The use of future notification requirements for acrylamide will be an insufficient tool to protect human health. An industrial strategy to eliminate acrylamide should be a focus of the government's risk management strategy for this chemical.

2) Pigments and Azo dyes - Acetamide, N-[5-[[2-(acetyloxy)ethyl](phenylmethyl)amino]-2-[(2,4-dinitrophenyl)azo]-4-methoxyphenyl]- (CAS RN 16421-41-3)

This chemical was PBiT as a result of categorization. While there were no reported uses of this chemical in 2005 and 2006, the government received information during the Industry Challenge on the presence of analogues for this substance. With the consideration of these analogues, the government concluded that these substances were not toxic under CEPA. This approach appears to be inconsistent with other chemicals that currently appear to not be in use in Canada. For these other substances, the government applied a SNAc provision. We question the approach taken to complete the assessment on Acetamide, N-[5-[[2-(acetyloxy)ethyl](phenylmethyl)amino]-2-[(2,4-dinitrophenyl)azo]-4-methoxyphenyl]- (CAS RN 16421-41-3) given that it is not in current use. The government decision will allow future use of this chemical in Canada without additional oversight despite the use of analogues to determine toxicity.

Like other pigments assessed under Batch 5, the government has relied on the use of analogues to conclude that this substance and other pigments are not toxic under CEPA. The reliance on the use patterns of disperse azo dyes in these situations may be in keeping with the precautionary principle. Furthermore, it deters the generation of much needed experimental data from industry if and when the targeted chemical is used again in Canada. There are significant uncertainties in the quality of data for many of these pigment chemicals and relying on data from other pigments for chemicals that are not current used in Canada appears to build on the level of uncertainty around these chemicals. Should the chemical come into use in Canada beyond 2006, the government

has an obligation to review new data attached to this chemical. At the moment, the proposed conclusion suggests that the government is not required to update toxicity data on this chemical. This is a significant gap that needs to be addressed.

As noted in the commentary of full life cycle assessment, the draft assessment on Acetamide, N-[5-[[2-(acetyloxy)ethyl](phenylmethyl)amino]-2-[(2,4-dinitrophenyl)azo]-4-methoxyphenyl]- wit CAS RN 16421-41-3.does not take into account the impacts from pigments after it has been disposed in landfills. These substances are used in various consumer products that find their way into landfills or though industrial applications may be discharged to sewage treatment systems as effluents. Assessors assume that all sewage treatment systems have the capacity to treat or capture pigments before effluent waste is discharged to the receiving environment. However, sewage treatment plants cannot guarantee such screening.

Similarly, the assessment also fails to account for the break down products of these chemicals once they have been discharged to landfills as part of consumer products.

RECOMMENDATIONS: The government should not consider the use of analogues to complete the assessment of Acetamide, N-[5-[[2-(acetyloxy)ethyl](phenylmethyl)amino]-2-[(2,4-dinitrophenyl)azo]-4-methoxyphenyl]- (CAS RN 16421-41-3) based on the data that this chemical is not in use in Canada. Any future use of this chemical should require the submission of new toxicity data to demonstrate its safety.

RECOMMENDATIONS: The assessments should be revised to account for the environment and health impacts from break down products of pigments once they are disposed of in landfills.

For more information, contact:

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

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

Summary of Draft SLRA Results for Batch 5 chemicals under the Chemicals Management Plan Industry Challenge

Chemical Name	CAS Registry No.	Result from Categorization (Environmental or Human Health Priority)	Results from Categorization on Persistence (P), Bioaccumulative (B), inherently toxic (iT) to environment or health, Potential for Exposure	Draft Screening Level Risk Assessment Results under CEPA s. 64 (toxic/not toxic)	Persistent, Bioaccumulative, inherently toxic or Health impact based on Draft SLRA	Proposed Management Strategy
Ethanol, 2-[[4-[(2,6-dichloro-4-nitrophenyl)azo]phenyl] methylamino]- , (Disperse Orange 5),	6232-56-0	Environmental	PBiT	Not toxic	P, B, iT	SNAc
Formamide	75-12-7	Health	• Intermediate potential for exposure • classified by the European Commission on the basis of reproductive and developmental toxicity.	Not Toxic		
2-Propenamide (acrylamide),]-,	79-06-1	Health	• greatest potential for exposure to individuals in Canada • carcinogenicity, • genotoxicity and • reproductive toxicity	toxic	Carcinogenicity	• DSL inventory update • Research and monitoring to validate assumptions

Chemical Name	**CAS Registry No.**	**Result from Categorization (Environmental or Human Health Priority)**	**Results from Categorization on Persistence (P), Bioaccumulative (B), inherently toxic (iT) to environment or health, Potential for Exposure**	**Draft Screening Level Risk Assessment Results under CEPA s. 64 (toxic/not toxic)**	**Persistent, Bioaccumulative, inherently toxic or Health impact based on Draft SLRA**	**Proposed Management Strategy**
						• Add to CEPA schedule 1 • Propose regulation or instrument respecting preventative or control actions focused on reducing exposure of human population to sources in processed foods • Investigate utility of a future use notification requirement
2-Chloroacetamide	79-07-2	health	• classification as a reproductive toxicant by the European Commission, • IPE	Not toxic	Hazardous properties retained	SNAc
Ethanol, 2-chloro-, phosphate (3:1) [TCEP],	115-96-8	Health	• IPE • classified by the European Commission on the	toxic	P Also carcinogenicity and impaired fertility	• Add to CEPA Schedule 1 • Investigate the

Chemical Name	**CAS Registry No.**	**Result from Categorization (Environmental or Human Health Priority)**	**Results from Categorization on Persistence (P), Bioaccumulative (B), inherently toxic (iT) to environment or health, Potential for Exposure**	**Draft Screening Level Risk Assessment Results under CEPA s. 64 (toxic/not toxic)**	**Persistent, Bioaccumulative, inherently toxic or Health impact based on Draft SLRA**	**Proposed Management Strategy**
			basis of carcinogenicity • P			potential options within the various use patterns for replacement of TCEP with an alternative.
Tributyl Phosphate	126-73-8	Health	• IPE • classified by the European Commission on the basis of carcinogenicity.	Not Toxic		
Acetamide, N,N-dimethyl-	127-19-5	Health	• IPE • classified by the European Commission on the basis of developmental toxicity.	Not Toxic		
Propanenitrile, 3-[[2-(acetyloxy)ethyl][4-[(2,6-dichloro-4-nitrophenyl)azo]phenyl]amino]- (Disperse Orange 30)	5261-31-4	Environmental	PBiT	Not toxic	P Not B* or iT*	DSL inventory update
Acetamide, N-[5-[bis[2-(acetyloxy)ethyl]amino]-2-[(2-bromo-4,6-dinitrophenyl)azo]-4-ethoxyphenyl]-	12239-34-8	Environmental	PBiT	Not toxic	P Not B* or iT*	DSL inventory update

Chemical Name	**CAS Registry No.**	**Result from Categorization (Environmental or Human Health Priority)**	**Results from Categorization on Persistence (P), Bioaccumulative (B), inherently toxic (iT) to environment or health, Potential for Exposure**	**Draft Screening Level Risk Assessment Results under CEPA s. 64 (toxic/not toxic)**	**Persistent, Bioaccumulative, inherently toxic or Health impact based on Draft SLRA**	**Proposed Management Strategy**
(Disperse Blue 79)						
Acetamide, N-[5-[[2-(acetyloxy)ethyl](phenylmethyl)amino]-2-[(2-chloro-4,6-dinitrophenyl)azo]-4-methoxyphenyl]-[ANAM]	16421-40-2	Environmental	PBiT	Not Toxic	P Not B* or iT*	
Acetamide, N-[5-[[2-(acetyloxy)ethyl](phenylmethyl)amino]-2-[(2,4-dinitrophenyl)azo]-4-methoxyphenyl]-	16421-41-3	Environmental	PBiT	Not toxic	P Not B*or iT*	Update of DSL inventory
Ethanol, 2,2'-[[4-[(2-bromo-6-chloro-4-nitrophenyl)azo]-3-chlorophenyl]imino]bis-(Disperse Brown 1:1)	17464-91-4	Environmental	PBiT	Not Toxic	P Not B* or iT*	DSL inventory update initiative
Ethanol, 2,2'-[[3-chloro-4-[(2,6-dichloro-4-nitrophenyl)azo]phenyl]imino]bis- (Disperse Brown 1)	23355-64-8	Environmental	PBiT	Not Toxic	P Not B* or iT*	DSL inventory update initiative
Propanamide, N-[5-[bis[2-(acetyloxy)ethyl]amino]-2-[(2-chloro-4-nitrophenyl)azo]phenyl]- (Disperse Red 167)	26850-12-4	Environmental	PBiT	Not Toxic	P Not B* or iT * concentrations.)	DSL inventory update initiative

Chemical Name	**CAS Registry No.**	**Result from Categorization (Environmental or Human Health Priority)**	**Results from Categorization on Persistence (P), Bioaccumulative (B), inherently toxic (iT) to environment or health, Potential for Exposure**	**Draft Screening Level Risk Assessment Results under CEPA s. 64 (toxic/not toxic)**	**Persistent, Bioaccumulative, inherently toxic or Health impact based on Draft SLRA**	**Proposed Management Strategy**
Benzamide, N-[5-[bis[2-(acetyloxy)ethyl]amino]-2-[(4-nitrophenyl)azo]phenyl] -	29765-00-2	Environmental	PBiT	Not Toxic	P Not B or iT*	DSL inventory update initiative
Acetamide, N-[2-[(2-bromo-4,6-dinitrophenyl)azo]-5-(diethylamino)phenyl]-	52697-38-8	Environmental	PBiT	Not Toxic	P Not B* or iT*	DSL inventory update initiative
Propanenitrile, 3-[[4-[(2,6-dibromo-4-nitrophenyl)azo]phenyl] ethylamino]- (Disperse Orange 61)	55281-26-0	environmental	PBiT	Not Toxic	P Not B* and iT*	DSL inventory update initiative
Ethanol, 2,2'-[[4-[(2,6-dibromo-4-nitrophenyl)azo]phenyl]imino]bis-, diacetate (ester)	55619-18-6	environmental	PBiT	Not Toxic	P Not B* or iT*	DSL inventory update initiative
Benzenamine, 4-[(2,6-dichloro-4-nitrophenyl)azo]-N-(4-nitrophenyl)-	72927-94-7	Environmental	PBiT	Not Toxic	P	DSL inventory update initiative

* decisions for B and iT changed based on experimental data from analogues

Source: Draft Screening Assessment Reports and Draft Risk Management Scope Document for the Challenge Chemicals under the Chemicals Management Plan, see - http://www.chemicalsubstanceschimiques.gc.ca/challenge-defi/batch-lot_5_e.html