

NGO comments on Draft Screening Assessment & Risk Management Scope Documents for Batch 9 Chemicals: A Response to *Canada Gazette Part I, Vol. 144, No. 12* — March 20, 2010 on Industry Challenge Chemicals of the Chemicals Management Plan

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Introduction

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. 144, No. 12 – March 20, 2010 release of the draft assessment and risk management scope documents and notice of intent to amend the Domestic Substances List to apply the Significant New Activity provision under CEPA to selected chemicals identified under the Chemicals Management Plan (CMP), Batch 9 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 otherwise unable to afford legal assistance. In addition, CELA also undertakes substantive environmental policy and legislation reform activities in the areas 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.

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 substances in Batches 1 through 8 of the Industry Challenge, including the final assessments and draft risk management options for selected chemicals in Batch 1 to 7.

For these batches, our organizations have consistently highlighted our support of specific approaches and proposals related to the risk assessment approach and results but, have taken the public comment periods as opportunities to highlight the gaps and limitations as identified in the risk based assessments and the proposed management instruments for specific chemicals. Consequently, we have developed substantial recommendations to address these gaps and limitations that decision makers should consider carefully for improving the current approach to chemicals management in Canada. These recommendations are intended to further strengthen and entrench the precautionary principle in the decision making process and promote a high level of accountability to all users, manufacturers, importers and sellers of chemicals in Canada.

Furthermore, these recommendations are designed to ensure the protection of human health and environment from toxic chemicals through a life cycle approach.

Background

In this submission, we provide commentary to the draft risk assessments for six substances and the risk management scope document for one substance. All of these substances are listed in Table 1 - (Vanadium oxide – CAS RN: 1314-62-1; Pigment Yellow 24 – CAS RN. 475-71-8; Eosine Lead Lake – CAS RN:. 1326-05-2; Pigment Red 88, - CAS RN14295-43-3; Nickel, bis[1-[4-(dimethylamino)phenyl]-2-phenyl-1,2-ethenedithiolato(2-)-S,S']- (BDN) - CAS RN 38465-55-3; and Benzoic acid, 4-[1-[(2,4-dichlorophenyl)amino]carbonyl]-3,3-dimethyl-2-oxobutoxy]-(BADAC) - CAS RN 58161-93-6).

Vanadium oxide – CAS RN: 1314-62-1 is a chemical found to be CEPA toxic according to the draft risk assessment report. However, the remaining five chemicals have been identified for notification under the Significant New Activity (SNAc) provision under section 81(3) of the *Canadian Environmental Protection Act*. For these five substances, we outline below our on-going concerns with the application of the SNAc provision. It is our perspective that the application of SNAc does not fully represent a precautionary or a preventative approach. Briefly our concerns on the SNAc provision include:

- absence of public engagement in reviewing the assessments for substances submitted through this provision;
- threshold of 100 kg for submitting under SNAc is too high and does not require accountability by all users of targeted chemicals;
- does not define these chemicals toxic under CEPA, despite evidence of the inherent hazard of these chemicals which perpetuates the on-going use of these chemicals unless evidence of harm is presented;
- inadequate framework to consider impacts to vulnerable populations (e.g. developing fetuses and children, workers, indigenous communities including Inuit communities and First Nations, people of low income and people with chemical sensitivities); and
- limited opportunity in the approach to require the submission of toxicity data on critical hazard endpoints including endocrine disruption and neurodevelopmental toxicity.

Based on the limitations noted above, we strongly urge your departments to reconsider the findings of the relevant draft screening assessments and change your decision on these substances. Despite knowledge gathered through the Industry Challenge to suggest that these substances are not in use in the Canadian market at quantities above 100 kg, we urge the government to conclude that these chemicals meet the criteria for being CEPA toxic based on the initial findings of persistence, bioaccumulation and inherent toxicity (PBiT) through the categorization process.

We want to note at this time, that the absence of specific commentary on all substances in Batch 9 should not be taken to mean that our organizations do not have questions or concerns regarding the draft assessment results and approach for those chemicals. On the contrary, we remain concerned about the status of those chemicals and urge the government to apply the strictest level of precaution in its assessment approach. Furthermore, the comments we have provided on the assessments and risk management proposals for the previous batches released under CMP contain commentaries that are also relevant for the chemicals listed in Batch 9. These comments are intended to provide your departments with a broad understanding of the public interest expectations of the government to protect Canadians and their environment from toxic chemicals. It is our view that the issues and gaps on which we continue to elaborate in these submissions have not been substantially addressed through the current government approach.

The lack of response to improve the scope of the assessment approach has resulted in very few regulatory actions aimed to eliminate chemicals of concern. In this regard, our underlying concern is the potential impacts to human health and environment that will result from permitting the on-going use, release, sale, import or disposal of these chemicals, even with limited control measures applied.

Through these submissions, our organizations want to ensure that the government utilizes the full extent of its authority under *CEPA 1999* to promote and implement the elimination or phase out of the most toxic substances found in the Canadian market. The commentary below identifies areas in the assessment report where government should strengthen its approach on the conclusion of toxicity under CEPA for chemicals selected.

Comments & Recommendations

Table 1: Final results of Categorization, Screening Level Risk Assessment (SLRA) & Risk Management Scope for selected Batch 9 substances of the Chemicals Management Plan (CMP), Challenge Program¹

Substance name (CAS RN)	Results of Categorization (S. 73)	Decisions based on draft screening level risk assessment (SLRA)	Key human health concerns	Risk management scope document & proposed measures	Uses/sources & volume (kg)
Vanadium oxide (1314-62-1)	Carcinogenicity, P (air, water, soil, sediment)	CEPA toxic	IARC Group 2B EC Category 3 mutagen Proposed EC Category 2 carcinogen Proposed EC Category 2 mutagen EC Category 3 developmental toxicity	Investigation of measures in existing emissions reduction programs to reduce emissions from combustion of certain fossil fuels; Proposal of notification - potential changes in the use pattern of vanadium oxide; Proposal that vanadium oxide be not authorized for use in natural health products; Proposal that vanadium	Manufacture of ferrovanadium alloys (major use), sulphuric acid, catalytic reduction of nitrogen oxide and sulphur emissions from power plants, burning of certain fossil fuels and emissions from oil refineries. Other minor used identified. No consumer usage identified. Incidental production 2006: between 1,000,000 – 10, 000, 000. Importation for 2006: 100, 000 – 1,000,000 Usage in Canada for 2006: 1,000,000 – 10,000,000.

¹ Environment Canada and Health Canada. Draft Screening Assessment for the Challenge Vanadium oxide Chemical Abstracts Service Registry Number 1314-62-1 (Ottawa, Canada, March 2010). See www.ec.gc.ca/substances/ese/eng/challenge/batch9/batch9_1314-62-1.cfm.

				oxide be added to the Environmental Emergency Regulations.	
Pigment Yellow 24 (475-71-8)	PBiT	*	N/A	SNAC provisions under subsection 81(3) of CEPA	Colourant in paint and textiles Usage possibly less than 100 kg.
Eosine Lead Lake (1326-05-2)	PBiT	*	N/A	SNAC provisions under subsection 81(3) of CEPA	Colourant in paints and cosmetics. Usage possibly less than 100 kg.
Pigment Red 88 (14295-43-3)	PBiT	*	N/A	SNAC provisions under subsection 81(3) of CEPA	Colourant in paints and plastics. Usage possibly less than 100 kg.
Nickel, bis[1-[4-(dimethylamino)phenyl]-2-phenyl-1,2-ethenedithiolato(2-)-	PBiT	*	N/A	SNAC provisions under subsection 81(3) of CEPA	Undisclosed business information (CBI) Usage possibly less than 100 kg.

S,S']-(BDN) (38465-55-3)					
Benzoic acid, 4-[1-[[[2,4-dichlorophenyl)amino]carbonyl]-3,3-dimethyl-2-oxobutoxy]- (BADAC) (58161-93-6)	PBiT	*	N/A	SNAC provisions under subsection 81(3) of CEPA	Photographic processing. Usage possibly less than 100 kg.

Note: P-persistence; B-bioaccumulation (Bioaccumulation Concentration or Bioaccumulation Factor); iT-Inherent toxicity); IARC – International Agency for Research on Cancer; EC – European Commission; N/A – not available; *- no conclusion based on s. 64 of CEPA but considered PBiT based on categorization

Application of Significant New Activity (SNAc) for selected chemicals under Batch 9

Below, we have provided commentary on the government's proposal to apply Significant New Activity (SNACs) on five chemicals from Batch 9:

- CAS RN: 475-71-8 Pigment Yellow 24
- CAS RN: 1326-05-2 Erosine Red Lake
- CAS RN: 14295-43-3 Pigment Red 88
- CAS RN: 38465-55-3 BDN
- CAS RN: 58161-93-6 BADAC

Based on the summary of issues related to the application of SNACs listed above, CELA and CSM have made very specific comments on the notice of intent to apply SNAc provisions to chemicals in earlier batches of chemicals² assessed under the Industry Challenge of the Chemicals Management Plan. We submitted a letter dated March 10, 2010 (attached) which outlines our concerns on the use of SNACs and other risk management activities under the CMP.

We note these concerns again:

a) Toxic under CEPA 1999: These substances should be considered toxic under CEPA based on the inherent hazard data that currently exist for these substances despite evidence that these substances may not be in current use in Canada or their usage is below the reporting threshold of 100 kg. There is also the continued absence of data on use patterns, volume, historical data and toxicity data from industry through the application of survey conducted under Section 71 of the Act. By designating these substances toxic under CEPA, a signal would be sent to any other potential users and importers that these chemicals are toxic and should not be permitted re-entry into the Canadian market based on the inherent properties of the chemicals. Government could use other available tools under CEPA to ensure that future uses of these substances are not permitted in Canada - such as adding these substances 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.

b) Reporting threshold of 100kg: Currently, facilities are required to report to the mandatory survey under section 71 of CEPA if the annual use of the chemical is 100 kg or greater. The surveys conducted cannot account for the number of possible users that fall below the 100 kg/year threshold and who are not required to report to the surveys. The aggregate use of these chemicals has not been addressed and this raises significant concerns as to the legitimacy of applying SNACs to manage these chemicals.

² See for example, CELA and CSM. "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." 2009. Accessed at http://s.cela.ca/files/661_CMP_CELA_and_CSM_batch_6_SLRA%20final.pdf.

The 100 kg threshold should be removed to ensure that all facilities respond to data requests.

c) Assessment under Schedule 6 of NSN – lacks consideration of adequate chronic toxicity and other hazard data: The application of SNAcs is inappropriate for these high priority chemicals as it does not result in a preventative approach but rather a ‘wait and see’ approach. SNAc applications 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 New Substances Notification Regulations (NSNR). The schedule outlined in the New Substances Notification Regulations is not sufficiently comprehensive with its call for toxicity data to address existing substances identified for SNAcs. The list of toxicity data is minimal as notifiers will **not** be required to submit data for chronic toxicity, endocrine disruption, or neurodevelopmental toxicity. The government should ensure that notifiers interested in re-introducing these substances or using them in quantities greater than 100 kg, are required to demonstrate that these chemicals do not result in such health or environmental impacts. Even at a low volume usage, it is our view that revisions to the New Substances program are necessary to more appropriately accommodate the future assessment of chemicals that are listed under the DSL and found to meet the criteria outlined for categorization. The level of accountability for users, importers and manufacturers to provide data for assessment should be at the highest level before due consideration of use is given by government on these substances. This should include requiring data that are not currently required under the proposed Schedule.

e) Lack of public comment under SNAc process/New Substances Program: Finally, we have an on-going concern that the application of SNAcs on these substances and other substances will mean that the public will not have opportunities to respond to the findings of assessments conducted on these chemicals. The New Substances Program, which was not necessarily designed to address existing substances, does not include a public comment review of assessments completed under the New Substances Notification Regulations. In promoting transparency in the decision making process, the SNAc provision for these chemicals may be inappropriate. The public should have access to the assessment results and be able to provide response to assessments conducted on chemicals, regardless if they are new or already in use, in Canada. It was noted in the Risk Management Workshop held in October 2009, that guidance on how SNAcs are applied in the CMP framework would be released. To date, this document has not been released nor has there been any further development to address the shortfall of the approach. Substantial discussion on this matter is warranted, particularly as SNAcs have been applied to a number of the high priority chemicals under the Industry Challenge.

Vanadium oxide - CAS RN: 1314-62-1

Vanadium oxide, otherwise referred to as vanadium pentoxide, is a naturally occurring substance. However, our comments on the draft assessment results will focus on the impact of anthropogenic sources of this substance as these sources represent the most significant source for concern and the name vanadium oxide will be used.

The major anthropogenic source of vanadium oxide which results from the burning of fossil fuels and emissions from oil refineries, produced during the catalytic processing of oil. Since vanadium is present in fossil fuels such as oil and coal, combustion of these products results in the formation of by-products which include solid residues, soot, and fly ash, with vanadium oxide. Vanadium oxide is also present in spent catalysts used in petroleum refinery processes. Metallurgy, particularly the production of ferrovandium, may also contribute to the incidental production of vanadium oxide. In addition to vanadium oxide, the combustion of fossil fuel results in the emissions of other toxic chemicals such as mercury, dioxins, furans and other heavy metals.

According to information submitted under section 71 of CEPA 1999 responses, between 1 000 000 and 10 000 000 kg of vanadium oxide were incidentally produced in Canada in the 2006 and importation activities reported a total quantity between 100 000 to 1 000 000 kg in 2006. These values indicate that these chemicals are present in Canada in significant amounts. In fact, Table 3 in the draft assessment provides evidence to demonstrate that Canada may be a significant source of vanadium oxide through its crude oil supply compared to other leading oil producing nations that includes the Middle East, Venezuela and the United States.

The screening assessment proposed that vanadium oxide meets one or more criteria under section 64 of CEPA 1999 and also meets the criteria for persistence but not the criteria for bioaccumulation potential as outlined in the *Persistence and Bioaccumulation Regulations* (Canada 2000). Vanadium oxide had been classified by the International Agency for Research on Cancer on the basis of carcinogenicity and by the European Commission on the basis of genotoxicity and developmental toxicity and has been identified by the federal government as a high priority as it is considered to pose greatest potential for exposure of individuals in Canada.

The following is a summary of the federal government's proposed risk management measures:

1. Further investigation of measures using existing programs to reduce emissions, including vanadium oxide from combustion of certain fossil fuels;
2. Notification regarding any potential changes in the use pattern;
3. No authorization for use in natural health products; and
4. Addition to the *Environmental Emergency Regulations*.

Comments and Recommendations

Based on the results of the draft assessment for vanadium oxide, the following outlines our comments and recommendations on the federal government's proposed risk management measures as highlighted in the risk scope management document for vanadium oxide.³

- **CEPA toxic**

Given the potential for carcinogenicity and genotoxicity and harm to human health at any level of exposure, vanadium oxide should be declared CEPA toxic by the federal government.

Recommendation: We support the finding that vanadium oxide is toxic under CEPA section 64.

Recommendation: Vanadium oxide should be added to Schedule 1 of CEPA.

Recommendation: Based on its inherent hazard and use pattern in Canada, the government's risk management for vanadium oxide should be a strategy that would incorporate phase out and elimination of anthropogenic sources of vanadium oxide.

- **Usage of vanadium oxide**

- We support the government's proposal that would authorize that vanadium oxide not to be exempted for use in natural health products. All chemicals used in natural health products should be subjected to evaluation for their inherent hazard properties including toxicity and impacts to health and environment. The use of chemicals found toxic under CEPA should not be used in any natural health products.
- In the draft screening assessment, data from the Drug Product Database indicated that there are two pharmaceuticals listing vanadium oxide as an active ingredient but there were no listings for the substance as an inactive ingredient. Because of the toxic properties of this substance, vanadium oxide should not be used in pharmaceutical products unless there was an extraordinary application with no safe alternatives available. Therefore, we recommend that the use of this substance in pharmaceuticals be eliminated – both as an active ingredient and as a non-active ingredient.
- The usage of vanadium oxide in pesticide applications has been inadequately dealt with in the screening assessment and the scope documents considering that the amount used by this industry amounts to 38,300 kg annually (2006 figures). This is a significant volume. It is hoped that this information would be incorporated into the final assessment. However, because of the toxicity of

³ Risk Management Scope for vanadium oxide, page 3

vanadium oxide, the government should take a more precautionary approach and phase out this substance in pesticide applications. The government's proposal fails to indicate how the *Pesticides Control Products Act* will address the finding of toxicity for this chemical. The assessment approach should be expanded to consider the impacts of pesticide products that contain this chemical.

Recommendation: We support the government's proposal to ensure that vanadium oxide is not permitted for use in natural health products, as well as in pharmaceutical products (as an active and non-active ingredient).

Recommendation: We recommend the additional actions under PCPA to prohibit the use of vanadium oxide as an active ingredient or as an inert ingredient in pesticide products.

- **Notification for potential future uses**

The government's proposed requirement of a notification for potential future uses, as also recommended for some other substances in the Industry Challenge of the Chemicals Management Plan again lacks any details. Similar to our comments from the SNAC provisions from the above comments, we are concerned that this proposal lacks the details that are required for meaningful public comments. For a substance that has such a wide usage pattern, it is essential that details on the notification system are elaborated. There are also concerns that this notification system may be very similar to the SNAC process which is elaborated on in this submission and most of our submissions in the Industry Challenge program. For this proposal, a notification application would not result in the overall use reduction of vanadium oxide.

Recommendation: We recommend that the proposal for future use notification be replaced by prohibition and phase out approach for vanadium oxide.

- **Addition to the Environmental Emergency Regulations**

- Based on the human health and environmental impacts and the possibility of increased volume usage of vanadium oxide, we support the proposal to include this substance to the *Environmental Emergency Regulations* for all facilities regardless of the threshold for use or release of vanadium oxide. Currently, the draft risk management document does not state if a threshold level would be considered for these regulations. Any proposals for these regulations should include response plans to any spills, and have a significant emphasis on how the facility would plan to promote greater accountability to protect occupational health and special consideration to the impact to public health and the environment.
- The presence of stockpiles of vanadium oxide at facility plants should provide additional justification for adding this substance to a list under the Environmental Emergency Regulations. The proposed Environmental Emergency Regulation

should provide additional consideration and details on how the regulations plan to improve containment of waste and stockpiles of vanadium oxide.

- Environmental Emergency Regulations should be connected to other aspects of action plans that would call for the elimination of this substance, including the identification of other toxic chemicals that may be produced as a result of combustion.

Recommendation: We support the addition of vanadium oxide to the Environmental Emergency Regulations for all facilities that release, use, dispose, sell or import this chemical.

Recommendation: The plans associated with these regulations should include details that integrate the other elements that will achieve the elimination of this toxic chemical.

- **Long range transport**

In the draft screening document for vanadium oxide, there was a mention of the concentration of atmospheric vanadium oxide in remote areas worldwide. However, it does not appear that long range transport of this substances and its possible impact on northern or remote communities was addressed. It is hoped that the government would rectify this oversight and address this issue in the final assessment of vanadium oxide.

Recommendation: The government should address the gap in the assessment report related to the discussion on long range transport potential and its impact on the northern communities. The government should include details to on the impacts of vanadium oxide in the northern ecosystem and affected communities.

- **Data gaps**

The draft screening document for vanadium oxide has many data gaps. We have also identified areas in the assessment that require data clarification as these are considered essential elements for the assessment of this chemical:

- The assessment currently has limited human epidemiological and chronic toxicity (human) data. It is uncertain how these data were treated in the assessment. Because of the properties of vanadium oxide, these areas require investigation;
- With respect to human exposure via food and environmental media, while individual exposures are meaningful, the cumulative exposures present a more realistic situation and should be considered in this assessment;
- While we urge the need to investigate cumulative exposures, we also urge the consideration of the synergistic effects of chemicals. We have on-going concerns of the synergy between exposures to vanadium and brominated flame retardants. This area warrants further investigation, particularly since some brominated flame retardants have been found to be toxic under CEPA due to their persistence, bioaccumulation and inherent toxicity. There may be other

brominated flame retardants that have yet to undergo assessment and such consideration may highlight the potential impacts of these chemicals to human health and the environment;

- Accurate release information for industrial releases of vanadium oxide from industrial processes is lacking and should be monitored. Currently, this chemical is not included for reporting under the National Pollutant Release Inventory (NPRI). Like other chemicals found to be toxic under CEPA through the Industry Challenge, these chemicals should be added for reporting under NPRI immediately;
- Apart from vanadium oxide (vanadium pentoxide), there are other forms of vanadium released in some industrial process, the exact nature of which health and environmental impacts are very uncertain. The assessments conducted under the Industry Challenge of the CMP have focused on a chemical by chemical approach with an exception of a few classes of chemicals (e.g., siloxanes, pigments). The government should consider taking a class approach for these chemicals. All compounds containing vanadium oxide should be identified and considered in this process;
- The range of toxicity data for all chemicals include vanadium oxide should include the submission of endocrine disruption potential and neurodevelopmental toxicity. Such data are not explicitly requested in the scope of the surveys conducted under section 71 for chemicals targeted under the Industry Challenge nor it is required under the voluntary questionnaire.
- There was no substantial information provided on safe alternatives to vanadium oxide. Adequate safe alternatives may include change in processes or a change in chemicals. For energy production particularly as it relates to use of coal and crude oil for energy production, two significant sources of vanadium oxide, the consideration of safer alternative energy sources would facilitate the goal of elimination for this chemical. The absence of such information increases the challenge of committing to a phase out strategy for these toxic chemicals.

Recommendation: We urge the government to address the various data gaps that exist in the assessment of vanadium oxide to ensure full consideration of issues such as cumulative and synergistic impacts with other chemicals, and to adopt a class approach through the inclusion of other vanadium compounds that may be in use in Canada.

Recommendation: The NPRI should be strengthened to include all CEPA toxic chemicals such as vanadium oxide.

Recommendation: Identify and assess alternatives to vanadium oxide in various applications. This information should be included in the assessment report as well as in the draft risk management document.

- **Vulnerable populations**

While inhabitants of northern or remote communities may be considered vulnerable with respect to chemicals that are capable of long range transport and harm to the environment and human health, other vulnerable communities should have been considered in the scope of the screening approach. The assessment report provides data on potential exposure to babies and children as well as presentation of epidemiology of occupational exposure but other vulnerable populations that should be considered in the screening assessment include pregnant women, people with chemical sensitivities, people of low income and indigenous communities, with emphasis on those that are in close proximity to facilities that use, release or dispose of vanadium oxide. Although some data has been presented on potential exposure to vulnerable population, there were no substantial proposals made to address these potential exposure routes for children or workers.

For those vulnerable populations that have not been addressed in the scope of the assessment, further efforts should be made to determine the impacts to these populations. If this information is not available through the surveys conducted, it is appropriate to identify this as a gap in the assessment and to fill in these data gaps using its tools under CEPA to its fullest extent.

Recommendation: Additional consideration should be given to the impacts and toxicity of these chemicals to all vulnerable subpopulations such as northern communities, indigenous groups, workers, pregnant women, children, babies, and people with sensitivities. This information should be used to develop and implement measures to specifically address impacts to vulnerable populations.

- **Existing policy and program initiatives to address vanadium oxide are inadequate**

The federal government plans to further investigate current measures using existing programs to reduce emissions of chemicals, including vanadium oxide from combustion of certain fossil fuels. The exact nature of this investigation was not revealed. The federal government expects that their actions and those of the provinces in their work to meet the Canada-Wide Standards (CWS) for particulate matter (PM) and ozone will result in a reduction of metal emissions, including vanadium oxide as PM, by 2010. It is our view, that this approach will not sufficiently address the concerns associated with vanadium oxide use, release, and disposal.

At present in some provinces, there are a few environmental regulations in place that aim at reducing particulate matter emissions - including emissions of heavy metals that would achieve the guidelines outlined under the CWS process. These regulations are far from stringent and do not go far enough to achieve pollution prevention and source reduction. Therefore, it is our view that the 2010 guidelines for PM and ozone are inadequate. Hence, it is considered inappropriate to rely on such standards to address vanadium oxide.

This view is further supported when one considers the emissions from coal-fired electrical power generation plants. This sector has been identified as being responsible for a significant portion of mercury emissions as well as other metal emissions. These plants continue to be a significant source of mercury despite the presence of the CWS. In this regard, the CWS guidelines would be equally ineffective in addressing the emissions of vanadium oxide from these plants. The identification of vanadium oxide from this sector provides additional evidence to support the need for eventual phase out of coal-fired electrical power generation plants with safer alternative forms of power generation. This approach would not only eliminate one of the largest emitters of mercury but would also reduce the emissions of other metals, including vanadium oxide.

Recommendation: The government should take regulatory actions on vanadium oxide that extend beyond existing guidelines and standards such as those outlined under the Canada-Wide Standard process. These CWS guidelines do not specifically aim for the prevention or elimination of vanadium oxide from anthropogenic sources.

Recommendation: The government should promote the phase out coal fired power plants and increase its support for the development and use of alternative energy production (excluding nuclear power) in its strategy to phase out strategy for vanadium oxide.

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ATTACHMENT

March 10, 2010

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Original transmitted by email

Dear Margaret and Karen:

Re: Risk Management under the CMP

This letter addresses the concerns of several environmental non-governmental organizations [ENGOS] dedicated to the protection of human health and the environment about the risk management activities proposed to date by Environment Canada and Health Canada under the Chemicals Management Plan (CMP). We appreciate having been invited to participate in the Risk Management Workshop held in Ottawa on October 29, 2009, which we found informative. However, it did not allow for discussion of several specific points of concern to ENGOS. Since many ENGOS present at the workshop have provided detailed comments on proposed risk management approaches for Batches 1-6 substances, we expected an opportunity for a substantial discussion of some of these points. Thus, this letter details our concerns and recommendations for improving risk management activities under the CMP, as well as our recommendations for future workshops and consultations on risk management work under the CMP. All are very important to us, and they are not listed in order of priority.

We base our recommendations on the following key principles outlined in the *Canadian Environmental Protection Act 1999* (CEPA):

- Pollution Prevention
- Virtual Elimination
- Precautionary principle

Risk management work is at a relatively early stage under the CMP, and there is time to refine approaches and actions in order to achieve greater transparency and a higher level of protection for the environment and human health. We hope you will give our recommendations serious consideration, and that you will be willing to engage with us about them in future consultations.

1) Little Emphasis on Pollution Prevention Strategies

In the batches that have come through to date, we see little emphasis on an overall goal of elimination of toxic chemicals. This would include a focus on reduction or elimination at source - that is, eliminating or at least reducing the importation, manufacture and use of chemicals found to be toxic under the plan, as well as products containing them. This is the only sure way of protecting human health and the environment from the harmful effects of these substances, especially in the context of uncertainty about hazard and exposure. While other mechanisms, such as end-of-pipe control measures, future use notification (please see point 2, below), addition to the Cosmetic Ingredient Hot List, monitoring and biomonitoring, may have some role to play, these alone do not adequately address the hazards and risks posed by these substances, especially in the case of carcinogenic, reproductive, developmental, endocrine disrupting or neurodevelopmental toxins. The options presented to date generally aim to maintain the status quo in the use of these substances, or to lead to slight reductions in releases to the environment. They do not address the real problem, which is the production, sale and use of toxic substances.

The federal government is committed, under CEPA, to apply several key principles when addressing toxic chemicals, including pollution prevention, virtual elimination and the use of the precautionary principle. There are several tools available to the government to manage toxic chemicals in accordance with these principles that have not been used in developing the risk management measures proposed to date, including pollution prevention plans to identify opportunities for source elimination of chemicals, identifying safe substitutes, and removing inefficiencies in industrial processes. The federal government made a clear commitment to pollution prevention in its management of toxic chemicals through its federal pollution prevention strategy, released in 1995.⁴ This strategy has been disregarded in the CMP to date. In the Industry Challenge, we have seen very few pollution prevention proposals, with the exception of those proposed for bisphenol A and TDI and the addition of several toxic chemicals to the Cosmetic Ingredients Hotlist, a non-regulatory measure whose efficacy in protecting human health is not clear.

In the presentations made at the October 29, 2009 workshop, we gained very little insight into the triggers necessary for Environment Canada (EC) and Health Canada (HC) to propose reduction and elimination strategies. We understand the criteria necessary for virtual elimination under CEPA, but many other actions that would promote reduction and phase-out could be taken that would result in real benefits for human health and the environment, such as expanded use of the *Prohibition of Specific Toxic Chemicals Regulations*, and other mandatory pollution prevention efforts that have not been employed under the CMP. One example would be to amend the list chemicals for prohibition under the Prohibition of Specific Toxic Chemicals Regulations to include Bisphenol A, which has been targeted for specific regulatory actions (e.g. ban of BPA in baby bottles, regulation to establish maximum concentration limit) but is used in a wide range of consumer products, has many industrial applications and has been detected in the environment.

⁴ Environment Canada, *Pollution Prevention: A Federal Strategy for Action*. 1995.

Furthermore, the recent grant of \$9.1 million from the federal government towards the establishment of a National Centre of Excellence at Queen's University for the "development and commercialization of Green Chemistry technologies"⁵ is promising with respect to finding substitutes and alternative manufacturing processes that reduce or eliminate the use of toxic chemicals. However, there has been no substantial policy dialogue or commitment to date focused on developing safe alternatives to further pollution prevention or a federal toxic chemical substitution and green chemistry strategy linked to the CMP. We would appreciate the opportunity for a fuller discussion of this point.

Our overall concern is that to this point, very little regulatory action has been proposed for high priority substances found to be toxic, with the exception of bisphenol A. This does not provide sufficient assurance that the CMP will result in the elimination or significant reduction in manufacture, import, export, use, release, and disposal of these chemicals over time in industrial applications as well as consumer products. Looking to the future, if effective actions that are based on prevention and precaution are not undertaken in an aggressive manner for the **high priority** chemicals under the Challenge program, we question whether the challenges of managing the 2600 **medium priority** chemicals will be addressed adequately either.

Recommendation: We urge the government to shift its current approach under the CMP to pollution prevention measures that will eliminate or significantly reduce the manufacture, import, export, use, release, or disposal of toxic chemicals over time.

Recommendation: We urge the government to develop a federal toxic chemical substitution and green chemistry strategy linked to the CMP.

2) Future Use Notification

Ten high priority substances determined to be CEPA toxic in Batches 1-5 of the Challenge phase of the CMP list "future use notification" as a proposed risk management activity. (See the Appendix to the workshop presentation "Risk Management Under the Chemicals Management Plan: Presentation for Stakeholders.") It is our view that future use notification should not be considered an appropriate tool for managing chemicals found to be CEPA toxic.

a) Little information provided on future use notification:

We are concerned that this risk management tool is being proposed with little information concerning what it will involve. The absence of information on this proposal does not contribute to improved government transparency.

⁵ Queen's News Centre Press Release, "Queen's PARTEQ receives \$9.1 M for National Centre of Excellence." http://qnc.queensu.ca/story_loader.php?id=49a824b1d4eb8.

b) Absence of reduction or elimination measures for CEPA toxic chemicals.

Given what little we do know, future use notification appears to allow continued and even increased use of a toxic chemical as long as new uses are notified. Thus, it appears to retain the “status quo” or “business as usual” for CEPA toxic chemicals. Future use notification will not reduce exposure to these chemicals in Canada and it will not work toward achieving the risk management objectives outlined for them in their respective proposed risk management approach documents. For example, the *Proposed Risk Management Approach* for diethyl sulfate⁶ states:

A risk management objective is a target expected to be achieved for a given substance by the implementation of risk management regulations, instrument(s) and/or tool(s). The proposed risk management objective for diethyl sulfate is to minimize exposure to this substance.

In order to achieve the risk management objective and to work towards achieving the environmental or human health objective(s), the risk management being considered for diethyl sulfate is a requirement for notification of the federal government regarding any proposed future uses (p. 11).

It is clear that there is a gap between the proposed risk management objective (i.e. minimizing exposure to the substance) and the instrument being proposed to achieve it (i.e. the requirement for notification of proposed future uses). Future use notification will do nothing to reduce exposure to diethyl sulphate if the current level of use is not reduced or eliminated. At best, it may prevent exposure from increasing, and it will not necessarily even do that, given that no restrictions on current uses appear to be contemplated (other than addition to the Cosmetic Ingredient Hotlist in some cases).

c) Cumulative impacts of toxic chemicals continue to go unaddressed.

An on-going issue raised by public interest organizations is the lack of consideration of the cumulative and aggregate impacts of many chemicals in the Canadian market. The future use notification proposal will do little to make progress in this area. Many notification processes establish a threshold level at which notification may be required. If this is the case for future use notification, the aggregation of use amounts that fall under the threshold may constitute a significant total amount, which in turn may mean that exposure estimates are significantly too low.

The following list summarizes a few of our concerns with respect to future use notification, especially its use exclusive of any other risk management activities:

- These notifications appear to do nothing to work toward the elimination or reduction in use of the chemicals in question. It is problematic that significant

⁶ Government of Canada, *Proposed Risk Management Approach for Sulfuric Acid, Diethyl Ester (Diethyl Sulfate)*, August, 2009.
http://www.ec.gc.ca/substances/ese/eng/challenge/batch4/batch4_64-67-5_rm_en.pdf.

increases in use quantities (as opposed to new uses) do not have to be reported under this provision.

- There is no responsibility placed on industry to change processes, look for safer substitutes or report on releases, transfers or use quantities of these chemicals (unless this information is required under NPRI or DSL inventory updates).
- There are no projected reduction targets established by government.
- There is often a volume threshold below which notification is not required. This threshold, whatever it may be under future use notification regulations, adds to our concern about exposure estimates.
- Future use notification simply gives notice to manufacturers and importers that new uses may require additional review. The additional review process is unclear.
- We urge a closer consideration of the application of a prohibition or reduction strategy, especially for carcinogenic, reproductive, developmental, endocrine disruption or neurodevelopmental toxins, rather than a future use notification.
- Frequent use of future use notification is likely to discourage investigation into cumulative and synergistic effects between and among similar toxic chemicals. Future use notification simply prolongs the unsatisfactory practice of examining the effects of chemicals one at a time, because once they are notified in this way, they are off the regulatory agenda, and no further investigation or action is likely unless significant new information comes forward.
- The role of the public in the future use notification provision is undefined. Given the absence of public reporting and engagement in New Substances Program (e.g., Significant New Activity), we are concerned that the public may be similarly excluded from this process.

Given our concerns, it is our view that future use notification should not be considered an appropriate tool for managing chemicals found to be CEPA toxic, especially when it is used exclusively of any other risk management tools. A regulatory approach leading to reduction and ultimately prohibition, especially for carcinogenic, reproductive, developmental, endocrine disrupting or neurodevelopmental toxins, will ensure that these chemicals no longer pose a risk to human health and the environment in the future.

Recommendation: We urge the government to reconsider its proposed use of the future use notification process for CEPA toxic chemicals. ENGOs request an opportunity to discuss this instrument and its efficacy with departmental officials.

3) Risk Management Activities Based on Exposure, not Hazard

In our view, the risk management activities proposed to date are based too heavily on exposure assessment, and not heavily enough on hazard assessment. We recommend that substances found CEPA toxic be flagged for reduction and elimination actions.

The reason for adopting future use notification as a risk management instrument for many of the substances found to be CEPA toxic in Batches 1-5 appears to be that human and environmental exposure to the substances is “very limited” or “negligible.” In light of the facts that some of these substances are considered to pose health risks at any level of exposure, and confidence in exposure estimates is often rated as very low to low, we find this reasoning unconvincing and lacking in precaution. For example, in the case of diethyl sulfate, the proposed risk management approach document states:

On the basis of the carcinogenic potential of diethyl sulfate, for which there may be a probability of harm at any exposure level, it is concluded that diethyl sulfate is a substance that is entering or may enter the environment in a quantity or concentration or under conditions that constitute or may constitute a danger in Canada to human life or health. (4)

and

Confidence in the quantitative estimates of exposure to diethyl sulfate in environment media is considered to be very low to low, as these estimates are based on modeling. However, confidence is high that exposure of the general population to the substance is very limited, in light of the indication that it is not released to the general environment in Canada as well as its very reactive nature. (9)

Thus, diethyl sulphate was determined to be CEPA toxic on the basis that “there may be a probability of harm at any exposure level,” but the proposed risk management activity ignores that fact, and appears to support the status quo or even increased use (and thus increased exposure), as long as future new uses are notified (please see point 2, above). Probability of harm at any exposure level does not appear to be taken into consideration to any great extent.

Furthermore, the frequent use of future use notification, on the basis of an exclusive focus on exposure, simply papers over important data gaps regarding toxicity, and is likely to offer very little protection to the environment and human health. In these cases, the government’s ability to seek available, or new toxicity information from industry through its authority under CEPA has been under-utilized. The options exist to add these chemicals to the Priority Substances List for further assessment (section 76), or to institute another section 71 survey (including section 71(1)(c)) to require that industry supply information required for better informed decisions concerning protective and preventative measures. In these situations, the precautionary principle should be applied.

Recommendations: We recommend that:

- ***Section 71 be used to its full extent to generate data:***
 - ***Additional data should be generated to determine the cumulative and synergistic effects of chemicals with similar structure and/or effects, and mixtures containing these chemicals;***
 - ***Additional data should be gathered for toxicity hazard endpoints such as endocrine disruption, chronic toxicity, developmental and neurodevelopmental toxicity, even if it means the generation of new toxicity data.***

- *Substances found to be CEPA toxic should be flagged for elimination or phase out strategies, particularly chemicals that are found to be carcinogenic, mutagenic, endocrine disrupting or reproductive and developmental toxicants.*

4) Over-reliance on SNACs

Several ENGOs have expressed on-going concerns with the application of Significant New Activity Notices (SNACs) to chemicals listed on the Domestic Substances List. See, for example, our letter of February 2007, reproduced below in Appendix A, expressing our concern when the first 148 high priority substances were identified for SNAC notices. Prior to the release of the CMP, the original intention was to apply SNACs to substances considered “new” to Canada and subject to the New Substances Notification Regulation. Under the CMP, we have noticed a continuing trend toward issuing SNACs to high hazard – low volume “existing” substances without designating them as CEPA toxic. We continue to have concerns with this process, including the following;

- a) The issuance of a SNAC does not necessarily mean that the chemical is not in use in Canada. The threshold for reporting use is set at 100 kg. There may be uses of these chemicals below the reporting thresholds. This means that SNACs are inadequate to fully protect human health and the environment.
- b) SNACs will require the further assessment of chemicals under the New Substances Program. The results of these assessments may not necessarily result in applying elimination or reduction strategies on these substances, regardless of the initial data gathered through the categorization process.
- c) Failure to designate a substance CEPA toxic means that no government action is required to develop management measures on these chemicals unless the SNAC provisions are completed and a finding of toxicity is made under CEPA. This also means that there is no incentive to discover and test safe alternatives for this chemical at this particular time to prevent its use in Canada in the future.
- d) The New Substances Program under which the SNAC notices will be implemented lacks a public engagement component for reviewing results of the assessment.
- e) The SNAC provision was originally designed to address substances “new” to Canada and assessed under the New Substances Program. This provision was not designed to address existing substances on chemicals listed under the Domestic Substances List.
- f) The data collected under Schedule 6 of the New Substances Notification Regulations will not address all the existing data gaps for substances on the DSL. Industry will not be required to submit data on vulnerable populations such as

infants and children, workers and aboriginal communities, or on chronic toxicity, endocrine disruption potential, and neurotoxicity, or on cumulative and synergistic impacts.

g) We note that under the CMP, SNACs have been proposed for approximately 159 substances (148 from the top 500 high priority chemicals and 11 chemicals from Batches 1-5).⁷ It is our view that it is more protective and precautionary for the government to list all of these chemicals as CEPA toxic and to propose to add them to CEPA's Prohibition of Specific Toxic Chemicals Regulations, 2000.

h) There has been very limited public policy debate on the advisability of applying SNAC notices to existing substances under the CMP, despite efforts by ENGOs to raise this important policy issue in submissions on the various batches. As the government prepares to release its guidance document on the SNAC program, it remains unclear if this document is to initiate policy discussions between government and stakeholders.

Recommendation: We urge the government to designate as CEPA toxic chemicals that are not in use, manufactured or imported into Canada, but have been found to meet the hazard criteria for designation as toxic under CEPA. These CEPA toxic chemicals should be added to Schedule 1 of CEPA.

Recommendation: We urge the government to list these toxic chemicals on the Prohibition of Certain Toxic Chemicals Regulations under CEPA to ensure that future manufacture, import, or use of these chemicals are prevented.

Recommendation: The government should initiate a comprehensive policy dialogue to assess the applicability of SNACs to existing substances under the CMP, beginning with the release of a guidance document.

5) Consideration of Many Vulnerable Populations Still Lacking in Government's Management Approaches

The typical risk management approach document to date makes slight reference to vulnerable populations, focusing only on children's exposure. Quoting again from the Risk Management Approach document for diethyl sulfate:

The Government of Canada considered, where available, risk assessment information relevant to *children's exposure* to this substance. As part of the Challenge, the Government asked industry and interested stakeholders to submit any information on the substance that may be used to inform risk assessment, risk management and product stewardship. In particular, stakeholders were asked through a *questionnaire* if any of the products containing the substance were *intended* for use by

⁷ SNAC proposed for: 148 high priority chemicals plus CAS No. 70161-19-2 and 83006-67-1 (Batch 2); CAS No. 4395-65-7, 60352-98-9 and 74336-60-0 (Batch 3); CAS No. 1154-59-2, 1176-74-5, 64325-78-6, 68443-10-7 and 70776-86-2 (Batch 4), and Disperse Orange 5 (CAS No. 6232- 56-0) (Batch 5).

children. Given the information received, it is proposed that no risk management actions to specifically protect children are required for this substance at this time. (10: italics added)

There are several problems with this approach.

- a) Even if a product is not intended for use by children, children may use it or be otherwise exposed to it. The assessment process does not take this possibility into consideration.
- b) The questionnaire is voluntary: there is no requirement to respond to it.
- c) The scope of the questions in the questionnaire is too narrow. The question asks only “if any of the products containing the substance were intended for use by children.” The questions should require the submission of other information such as toxicity data and the potential exposure of children throughout the life cycle of the chemical.
- d) Risk management activities should be prompted principally by hazard, as is the case in most jurisdictions, rather than exposure data.

As important as these points about risk to children are, the question of other vulnerable populations, including workers, people with chemical sensitivities, aboriginal communities and people of low income should also be covered in the surveys conducted by government. These vulnerable populations are not addressed at all in the risk management approach documents to date. There should be special consideration of these vulnerable communities in the management strategies.

We recognize that the government faces a serious challenge in this area: the lack of focus on these vulnerable populations in the CMP assessment framework means that the evidence on which to base a more comprehensive approach to protecting vulnerable populations is not gathered. This could be overcome if the scope of the questions asked under the section 71 survey were broadened to focus on the full list of vulnerable populations and included hazard as well as exposure data, and if the assessment process were expanded to take into account the unique attributes of these subpopulations.

Recommendation: We recommend that the Industry Challenge of the Chemicals Management Plan be re-examined and revised in light of the lack of attention paid to vulnerable populations to date. Indeed, this shift should be required when data gathering for medium priority chemicals get underway.

6) Petroleum Sector Stream – promoting greater transparency, accountability and public engagement

The lack of information and public engagement in the work being undertaken on high priority chemicals in the Petroleum Sector Stream is a very problematic issue for ENGOs. The information we have been given about progress made on the assessment and management of these chemicals has been limited to updates.

a) The Chemical Substances website contains limited information on the Petroleum Sector Stream

There is very little information on the Chemical Substances website about the assessment and risk management of the approximately 160 high priority chemicals to be handled in the petroleum sector stream. For example, the website does not describe the process in any detail or provide timelines for the release of assessments and risk management documents.

b) Updates provided at the Stakeholder Advisory Council limited

The presentation on the petroleum sector stream at the Stakeholder Advisory Council meeting of June 18, 2009 was helpful, but at that time we were told that the first set of assessments would come out in December 2009, and that they would cover 55 chemicals. This information still is not on the website, and even after the Stakeholder Advisory Council meeting of January 29, 2010, we do not have a firm date as to when these assessments will be published.

c) Expected public comment period on draft assessments does not adequately consider other CMP implementation response periods

It is very difficult for interested parties to plan their time to engage in the petroleum sector stream assessment and management process when so little information about it is available. Furthermore, we are told that the petroleum sector substances will be addressed in the same timeframe as the Challenge substances. If this is the case, a very large number of assessments and risk management documents will be released over a very short period of time. Even if efficiencies are found for grouping chemicals in assessments, any member of the public who plans to review and respond to these assessments will have to consider a very large amount of material in a very short time. The public will have very limited opportunity to engage effectively in this context.

d) Release of the petroleum sector stream assessment and risk management documents not integrated with the release of batches in the Challenge process

Members of the public may be faced with entirely too many documents at any one time to deal with them adequately in the time allotted. Since all chemicals under the Industry Challenge and the Petroleum Sector Stream are high priority chemicals, there is an expectation that the results and progress made on all of these chemicals should be made publicly available, and involve comprehensive public engagement.

Recommendation: We recommend that the work plan for the Petroleum Sector Stream chemicals be placed on the Chemical Substances website with a schedule and timelines for the release of assessments and risk management documents for the various groupings of these substances.

Recommendation: We urge the government to initiate additional discussions to address how interested parties can be given a reasonable length of time to review and respond to government proposals on high priority chemicals in the Petroleum Sector stream.

7) Socio-economic Considerations in Risk Management Approach Documents

Each Risk Management Approach document contains a section titled “Socio-economic Considerations.” These sections are possibly the weakest and least transparent in these documents to date. We request a dialogue with Environment Canada and Health Canada on this serious matter.

Some of the risk management approach documents for the early batches included very sketchy cost estimates to industry and the public of taking selected risk management steps, while no information has been provided on social and economic benefits from taking those risk management steps. For example, the Risk Management Approach for bisphenol A (BPA)⁸ claims that “socio-economic factors have been considered in the selection process for a regulation and/or instrument respecting preventive or control actions, and in the development of the risk management objective(s).” The economic information given was limited to sales figures for polycarbonate baby bottles, labour statistics for employment in baby bottle manufacturing, and the retail price of some BPA-free baby bottles (pp. 11-12). There was also mention of other industries that may be impacted by the proposed management actions, but no information or estimates. No social analysis whatsoever is provided in the document. For example, the document does not provide any insight into the potential cost savings to the health care system or the benefits to the environment as a result of taking the proposed actions. It is our view that socio-economic analysis requires substantial discussion of the full range of factors related to social, economic and environmental impacts and how such considerations contribute to the decision-making process. At the moment, interested members of the public have very little information about how government officials took socio-economic factors into account and how data was collected and assessed in the selection process for management instruments for BPA.

The majority of risk management approach documents in Batches 1-5 contain even less information in the “Socio-economic Considerations” sections than was the case for BPA. For example, the risk management approach document for diethyl sulfate simply states, “Socio-economic factors have been considered in the selection process for a regulation and/or instrument respecting preventive or control actions, and in the development of the risk management objective(s)” (p. 10). No information is provided as to what factors were considered and what the outcome of that consideration was. Given that cost-benefit analysis is meant to play a role in the choice of management instruments,⁹ this lack of

⁸ Government of Canada, *Proposed Risk Management Approach for Phenol, 4,4’-(1-methylethylidene) bis (Bisphenol A)* October, 2008. http://www.ec.gc.ca/substances/ese/eng/challenge/batch2/batch2_80-05-7_rm_en.pdf.

⁹ See Treasury Board Secretariat, *Assessing, Selecting, and Implementing Instruments for Government Action*, 2007; and Treasury Board Secretariat, *Canadian Cost-Benefit Analysis Guide: Regulatory Proposals*, 2007.

information shows lack of transparency in the decision-making process of government officials. Without knowing how the government analyzed and compared the costs and benefits of a variety of potential risk management actions for each toxic chemical, it is very challenging, if not impossible, for the public to respond to this important aspect of decision-making.

We understand the need to prioritize actions on toxic chemicals to focus on those activities that will make best use of the limited resources of Health Canada and Environment Canada. However, the public should have access to the information on which government decision makers base their decisions and the right to comment on its adequacy.

Recommendation: We urge the government to initiate a dialogue with the public on gaining access to the information used in socio-economic analyses of proposed risk management activities and commenting on its adequacy.

Recommendation: The public engagement process should be revised to provide the public enough information and time to comment effectively on the results of the government's cost-benefit analyses.

8) Risk Management Training Workshop

As noted in the introduction to this letter, we appreciate the opportunity to have participated in the Risk Management workshop held in October 2009. We understand that this meeting was a first attempt to discuss risk management activities under the CMP. The documents and presentations made were relevant and useful. However, participants had very little time to fully engage and provide government with insights and levels of expectations for actions to be taken on CEPA toxic chemicals.

We would like to emphasize the need for more focused discussions on specific management activities such as pollution prevention strategies, the use of non-regulatory tools to reduce or eliminate the manufacture and use of toxic chemicals in Canada, and addressing the needs of vulnerable populations. Planning for such discussions should include ENGO input into the scope and development of agenda items and allocation of time for discussion. This level of dialogue is critical given that the CEPA timeframe provides the government two years to develop its management options. We would appreciate the opportunity to engage in such discussions as specific risk management options are being developed, rather than provide input when decisions on management options have been released for the public comment period.

Recommendations: We urge the government to engage in a two way dialogue on proposed risk management activities to ensure public engagement throughout the risk management timeframe.

We end our letter with a recommendation for the government to make full use of the precautionary principle in the current situation. In this letter, our organizations have raised very serious concerns regarding the proposed management approach to chemicals under the Industry Challenge. In part, our comments reflect our concerns with the approach taken by government to screening risk assessments and the failure of government to require industry to supply much needed information on high priority chemicals. Many data gaps remain on many of these high priority chemicals, particularly with respect to hazard, exposure scenarios and use applications. Since 1999, sufficient time has elapsed for industry to have supplied such information, had they been required to do so. Absence of such information should not prevent the government from taking measures to fully protect Canadians from these chemicals. The Canadian government has the opportunity now to apply the precautionary principle in the absence of full scientific evidence. In the current situation, and until data gaps are filled, this is the only way to fully protect the environment and human health from the harmful effects of toxic substances.

Yours truly,



For the following signatories

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APPENDIX A

**ENGO letter on Significant New Activity dated
February 14, 2007**

February 14, 2007

Director
Existing Substances Division
Environment Canada
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(fax) 819-953-4936
(email)

Sent via email and regular mail

**Re: *Canada Gazette*, Part 1, Vol. 140, No. 49, December 9, 2006
Notice of intent to amend the *Domestic Substances List* to apply the Significant New
Activity provisions under subsection 81(3) of the
Canadian Environmental Protection Act, 1999 to 148 substances**

Environment Canada's Use of SNACs

On December 9, 2006, Environment Canada posted a notice in the *Canada Gazette* indicating its intention to amend the Domestic Substances List (DSL) by applying the Significant New Activity (SNAC) provisions under subsection 81(3) to 148 substances. The proposal to limit the use of these substances through restrictive SNACs is pragmatic in light of the fact that the government does not currently have the ability to delete these substances from the DSL. However, since the review of the *Canadian Environmental Protection Act, 1999* (CEPA '99) is now underway, the government should seek an amendment which would allow substances to be deleted from the DSL in these and other appropriate circumstances.

Following categorization, an industry survey under section 71, and a draft screening assessment under section 74, these substances are believed to be:

- Persistent, Bioaccumulative, and inherently Toxic (PBiT), and
- *Not* presently imported or manufactured in Canada in quantities above 100 kg per year, and therefore not considered to be CEPA-toxic under section 64 due to the lack of Canadian exposure.

The conclusion that these substances are not being imported or manufactured in quantities above 100 kg / year derives primarily from the results of an industry survey which was published in the *Canada Gazette* on March 4, 2006. In that survey, industry stakeholders were asked to indicate whether they manufactured or imported the substances in quantities more than 100 kg during the 2005 calendar year. While the intention of the survey was to identify those substances which are no longer in Canadian commerce (i.e. the 148 substances now subject to the SNAC notice), the survey had a

number of limitations.¹⁰ These limitations create the possibility that substances manufactured or imported in some year other than 2005, or in amounts smaller than 100 kg, continue to pose a hazard in Canada.

The SNAc proposal would require industry to reassess these substances under the New Substances Notification Regulations (NSNR) before undertaking any significant new use. The NSNR process is only triggered once the quantity of the substance reaches 100 kg / year, and the SNAc notice defines “significant new activity” as any activity involving more than 100 kg of the substance in a calendar year. This is problematic for two reasons. First, as noted above, such activities could already be occurring, and government would not be aware of them based on its 2006 survey results. It is unclear whether existing / ongoing uses not captured by the survey would be considered significant “new” uses and subject to the NSNR. Second, the threshold of 100 kg could still allow for damage to be done by these hazardous substances. The reasons for this could include their persistence in the environment, synergistic effects with other DSL substances, or potential for long range transport, to name a few.

There are other problematic aspects of the NSNR approach which should be modified with respect to these 148 substances. For instance, there is a lack of adequate and effective public transparency in the NSNR assessment process. Under that process, the Minister is required to post a notice in the *Canada Gazette* upon adding a substance to the DSL or the NDSL, granting a waiver, or imposing a condition, prohibition, or SNAc restriction. However, the public is not informed of new notifications, nor is the public typically given the opportunity to comment on draft risk assessment reports before final decisions are made.

Given the hazardous properties of these 148 substances, we urge the government to improve upon the NSNR process by imposing stricter transparency requirements through the Chemicals Management Plan. The public is entitled to be informed of, and comment upon, any proposed commercial use of these substances.

The SNAc notice goes on to indicate that, prior to the commencement of the proposed new activity, notifiers should submit the NSNR information requirements contained in:

- Schedule 4,
- Item 8 of Schedule 5, and
- Item 11 of Schedule 6.

Schedule 4 is the basic, minimal data set which is required of new substances which are being notified at the lowest volume trigger. The Schedule includes primarily identification information, and does not require the production of any test data (beyond

¹⁰ Note: early in 2006, NGOs voiced a number of concerns regarding the structure of the survey. Most notably, the survey failed to capture companies that used the substances in 2004 or previously, or planned to use the substances in 2006 or subsequently, or used the substances in amounts under 100kg. See J. Ginsburg and F. de Leon, “Letter to Environment Canada regarding a Domestic Substances List (DSL) categorization survey” (16 March 2006), online: <cela.ca/uploads/f8e04c51a8e04041f6f7faa046b03a7c/537EC_surveys.pdf>.

that which is already in the possession of the manufacturer or importer). Item 8 of Schedule 5 and Item 11 of Schedule 6 relate only to exposure information. Accordingly, should industry seek to (re)introduce the substances onto the market at quantities above 100 kg, they could be allowed to do so without submitting any test data whatsoever.

Government has indicated that “[c]onsidering the hazardous profile of these substances, there is limited possibility that they would be reintroduced.”¹¹ However, given the fact that 1) government conducted its categorization and screening assessment without requiring any new test data, and 2) these substances are already believed to be highly hazardous, there should be no opportunity for continued use without industry demonstrating through scientific testing that the substances are safe. This would require proponents to provide, at a minimum, substantive testing data equivalent to the most rigorous data schedule provided under the NSNR, including:

- Data from one repeated-dose mammalian toxicity test, of at least 28 days duration, which test is selected on the basis of the most significant route of potential human exposure;
- Mutagenicity data obtained from an *in vitro* test, with and without metabolic activation, for chromosomal aberrations in mammalian cells; and
- For chemicals having a water solubility of greater than or equal to 200 µg/L, adsorption-desorption screening test data, the hydrolysis rate as a function of pH and, if known, an identification of the products of the hydrolysis.

Further, we would augment the NSNR test schedules by requiring companies notifying these substances under the NSNR to also submit data on chronic toxicity, endocrine toxicity, neurodevelopmental toxicity, as well as information regarding safer alternatives. Additionally, the government should provide explicit guidance on how the precautionary principle will be applied to regulatory decisions affecting these substances, in light of their hazardous characteristics identified through the categorization process.

Recommendation: The Government of Canada should seek an amendment to CEPA ‘99 which would allow substances that are no longer in Canadian commerce to be deleted from the DSL.

Recommendation: Any existing or ongoing uses of the 148 substances which were not captured by the 2006 survey should be considered “new” and subject to the NSNR requirements. Before and until such time as they have received approval under the NSNR, government should impose mandatory risk management measures to eliminate these uses from the Canadian market.

Recommendation: The Government of Canada should establish a process to enhance public transparency and participation in any notification to the NSNR involving these 148 substances. The public should be informed of any notifications

¹¹ Government of Canada, “Provisions for Significant New Activities and Outcome from DSL Categorization” (Presentation at the Chemicals Management Plan: Technical Briefing, Ottawa, 15 December 2006).

and have the opportunity to comment on draft assessments before final decisions are made regarding the use of these substances at any quantity.

Recommendation: Given the hazardous properties of these substances, the SNAc notice should define *any* activity involving these substances to be new, not merely those activities in excess of 100 kg / year.

Recommendation: These 148 substances should not be approved for import, manufacture, or use unless industry can demonstrate their safety through scientific testing. At a minimum, industry should be required to submit testing data equivalent to the highest schedule for non-NDSL substances under the NSNR. Additionally, notifiers should be required to submit data on chronic toxicity, endocrine toxicity, neurodevelopmental toxicity, as well as information regarding safer alternatives.

Health Canada's Use of SNAcs

The Government of Canada has indicated that in early 2007, Health Canada will apply the SNAc provisions to certain substances that have inherently hazardous properties for humans. We have yet to see the details of this proposal, however, the comments provided above may also be relevant to Health Canada's process. We look forward to providing additional comments once further information becomes publicly available.

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