A Response to Draft Risk Assessment Results for Chemicals Management Plan Industry Challenge Batch 4 Substances Published in *Canada Gazette* Part I, Vol. 143, No. 4 — January 24, 2009

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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. 4 — January 24, 2009 release of the draft risk assessment and management reports for substances identified under the Chemicals Management Plan (CMP), Batch 4 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.

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 and Batch 3 substances, including the final assessment and risk management for Bisphenol A (under Batch 2 of the Industry Challenge). In these comments, we have expressed concerns with regard to specific gaps in the assessment process and the preliminary proposed management measures for these substances. At the same time, our organizations have developed substantial recommendations to address these gaps and limitations. With this submission, our organizations continue to highlight some of the concerns that have been previously noted as they are also relevant to the results of the assessment of Batch 4 substances.

We are summarizing these overaching issues for your further consideration and seek written response to these concerns by your departments as they relate to Batch 4 substances.

1) *Possible cumulative and synergistic effects:* We note that the assessments conducted on Batch 4 substances have not attempted to consider the possible cumulative and synergistic effects of these substances. Also of concern, are the

combined effects of substances represented by these general chemical categories. This gap has been prevalent in many of the assessment processes conducted through Batches 1- 3. To date, there has been no evidence to indicate that the government has plans to address this significant gap. Without any attempt to consider the possible cumulative and synergistic impact of chemicals, we are concerned that government's decisions may not result in the level of regulatory response required to adequately protect human health and the environment. In situations where there are chronic exposures to some substances or if a few chemicals of the same class may be found in different proportions, in mixtures or as impurities, taking into account synergy or cumulative effects are critical in the decision making process. It is our view that the CMP offers the government an opportunity to review these limitations and challenges and act upon them. The current approach by government raises concern about the adequacy or the lack of management options for many of chemicals assessed to date.

2*) Lack of transparency:* In general, the assessment reports to date lack full transparency in several aspects of the assessment process, including the disclosure and subsequent use of information gathered on substances through the survey and questionnaire undertaken by government in the Industry Challenge. It is unclear and difficult to identify through the draft assessment reports if any new toxicity data, not previously submitted by industry during the categorization process, was received or considered by assessors. It was also difficult to determine if any new toxicity data was instrumental in the government's decision to change the categorization decision for some of the substances in this batch. For example, several substances were categorized as persistent, bioaccumulative and inherently toxic (PBiT) are now only P (e.g., 4,4'- (3H-2,1-benzoxathiol-3-ylidene)bis[2,6-dibromo-, S,S-dioxide (Bromophenol Blue), CAS RN 115-39-9; Phenol, 4,4'- (3H-2,1-benzoxathiol-3-ylidene)bis[2-bromo-6-methyl-, S,S-dioxide (Bromcresol Purple), CAS RN115-40-2;Phenol, 4,4'- (3H-2,1-benzoxathiol-3-ylidene)bis[2,5-dimethyl-, S,S-dioxide (Xylenol Blue), CAS RN 125-31-5; Phenol, 4,4- (3H-1,2-benzoxathiol-3-ylidene)bis[2,6-dibromo-3-methyl-, S,S-dioxide, monosodium salt (PBTBO) CAS RN 62625-32-5) and cannot not meet the criteria as toxic under CEPA. To improve the quality of the assessment, the government's approach should clearly articulate the new toxicity data being considered in making the decision. Furthermore, the identification and submission of additional data on specific toxicity endpoints (i.e. neurodevelopmental toxicity and endocrine disruption) could contribute to a more complete data set for the assessments. The government should address the limited transparency in this area and the absence of data as they undermine the assessment process and the proposed management decisions made by government.

3*) Full Life cycle Consideration:* While there has been some progress in acknowledging the need to consider the life cycle of a substance, government assessments require improvement 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. All assessments for Batch 4 substances have not considered the full life cycle fate of these substances. In particular, the determination of exposure levels and leaching potential of these substances and

identifying potential break down products during the disposal methods should be essential components of all assessments. In addition, there is a lack of consideration of the impacts of metabolites from these substances, which themselves may be toxic.

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, where there is a possibility of release of chemicals found in consumer product. In our view, the absence of a full life cycle consideration affects the final decision on toxicity as well as the quality of the management measures necessary to protect health and environment.

4) *Occupational exposure:* Throughout the CMP, the issue of occupational exposure has been raised on many occasions. To date, there has been very little advancement to address this gap and there has not been any apparent indication of attempts to communicate the results of the assessments and proposed risk management strategies to occupational health and safety establishments. This communication gap requires consideration by the government.

Workers are at the front line of exposure and can often provide significant information on potential impacts of occupational exposure. While we recognize that occupational health is currently not considered under CEPA, the absence of this information in assessment reports demonstrates a failure to acknowledge that some people in society have a double challenge: workplace exposure coupled with other environmental exposures to some substances. Any management strategies for these substances should take account these situations and ensure that management steps are both protective and preventative.

5) *Material Data Sheets:* Because of the potential of some substances in Batch 4 to be harmful to human health at low concentrations, under Canada's Workplace Hazardous Materials Information System (WHMIS), material safety data sheets (MSDSs) should disclose the presence of these substances regardless of concentration and , as a result, all potential health risks should also be identified in the MSDSs. Also there should be a mechanism by which industry could be required to review and modify health and environmental information on the MSDSs of substances assessed by the government in the Challenge Program. Updated MSDSs are essential tools in occupational health as well as the workplace and therefore, should reflect the most recent and updated information.

6) *Carcinogens:* Several substances in Batch 4 (and in previous batches) were identified as likely human carcinogens with possible genotoxicity and reproductive toxicity and having the potential to do harm at any level of exposure. We are of the opinion that the establishment of safe levels for human exposure to these substances cannot be accurately determined. For any substances found to be carcinogenic or having the potential to be carcinogenic, we maintain that the appropriate government approach should be to phase out or eliminate these substances. In exceptional cases where there is an essential use of a substance and where safe substitutes (see #7

below) may not currently exist, a time limited exemption to a phase out may be considered. However, this is only recommended on a case by case basis with a goal to phase out the carcinogen in a time specified period.

7) *Safe substitution:* There is an urgent need in the risk management scope documents for more consideration of safe alternatives for substances in Batch 4. Currently, the information on substitutes in these assessment reports is limited or absent. It is our view that the identification of all alternatives should be included in the assessment process. This type of information would be a positive contribution to the overall assessment process, particularly as the government makes a determination of toxicity on these substances. However, it is also necessary that in the process of identifying these substitutes, a process to assess or screen the safety of the substitutes under CEPA be also undertaken. These screening efforts for safe alternatives must include interaction between government, industry and stakeholders so that the process is transparent. The safety of alternatives is as important as taking action on the substance it is intended to replace. This process should include toxicity data (both acute and chronic), pertinent to health and environment.

8) *Vulnerable populations:* The assessments completed under the CMP to date have included information on exposure of substances to some vulnerable subpopulations such as children. Other vulnerable subpopulations are often 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 4 substances.

The impacts of exposure to substances to other vulnerable subpopulations such as aboriginal communities have generally not been considered when undertaking these assessments. For Batch 4 chemicals, substances identified as persistent, bioaccumulative and inherently toxic (e.g., BNST, CAS RN 68921-45-9) as well as for the substances (e.g. CAS RNs: 64325-78-6; 1154-59-2; 1176-74-5; 70776-86-2; 68443-10-7) that have been identified as PBiTs but are proposed for Significant New Activity no consideration of vulnerable populations has been included. From previous batches, there has been some consideration of impacts to aboriginal communities in the assessment, particularly if the substance is considered to be persistent, bioaccumulative and inherently toxic and has the capacity for long range transport with intact deposition. However, in these assessments, the commentary on impacts to this community has not been supported by sufficient scientific data but rather assumptions are made by the assessors that there is limited impacts to the groups. This is a significant gap in the approach.

An added dimension in approach is needed as vulnerable subpopulations such as aboriginal communities that may be living in close proximity to some sources of toxic substances that could result in significant health implications for members of the community. Government attention is needed to also address this gap.

Similarly, other vulnerable subpopulations should also be considered when assessments are conducted. This would include people with chemical sensitivities who

are generally affected by low level exposure to chemicals (in the environment and the workplace) and people in the low income bracket who often live in areas of high pollution. Government should expand the scope of the assessments to consider the impacts of exposure to these vulnerable subpopulations.

The quality of risk assessments conducted under the CMP may be implicated and the final decisions on these substances may differ if the above issues are addressed in a more fulsome and rigorous manner.

COMMENTS ON SPECIFIC CHEMICALS IN BATCH 4

A. Substances considered PBiT based on categorization process

The twelve substances listed below were initially identified as having a high priority for screening assessment as they were originally found to meet the ecological categorization criteria for persistence, bioaccumulation potential and inherent toxicity (PBiT) to non-human organisms and believed to in commerce in Canada. Based on the draft screening results, these substances do not satisfy the criteria for CEPA 'toxic' with the exception of Benzenamine, *N*-phenyl-, reaction products with styrene and 2,4,4-trimethylpentene (BNST) (CAS RN 68921-45-9); a decision that was made based on its human health toxicity not its ecological criteria.

Table 1 : Summary Results of Draft Screening Level Risk Assessment (SLRA) of Batch 4 Substances (Persistent, Bioaccumulative, Inherently Toxic) and Uses

Substance Name (CAS RN)	Decision based on categorization process	Results of Draft SLRA finding of toxic under CEPA Section 64	Decision based on SLRA report (Persistence, Bioaccumulation and inherently Toxic (PBiT)	Proposed Significant New Activity (SNAc)	Use data
4,4'- (3*H*-2,1-benzoxathiol-3-ylidene)bis[2,6-dibromo-, *S*,*S*-dioxide (Bromophenol Blue) **(CAS RN 115-39-9)**	PBiT	No	Only persistent	No	• Confidential business information claimed by industry • Other documented uses - protein dye, acid/base pH indicator

Phenol, 4,4'- (3H-2,1-benzoxathiol-3-ylidene)bis[2-bromo-6-methyl-, *S*,*S*-dioxide (Bromcresol Purple) **(CAS RN115-40-2)**	PBiT	No	Only persistent	No	• No use data from industry. • Other documented uses - analytical reagent, acid/base pH indicator
Phenol, 4,4'- (3*H*-2,1-benzoxathiol-3-ylidene)bis[2,5-dimethyl-, *S*,*S*-dioxide (Xylenol Blue) **(CAS RN 125-31-5)**	PBiT	No	Only persistent	No	• No data from industry. • Other documented uses - analytical reagent
Phenol, 4,4- (3*H*-1,2-benzoxathiol-3-ylidene)bis[2,6-dibromo-3-methyl-, *S,S*-dioxide, monosodium salt (PBTBO) **(CAS RN 62625-32-5)**	PBiT	No	Only persistent	No	• No data from industry. • Other documented uses - acid-base indicator and analytical reagent - microbiological, chemical and biochemical tests applications.
Adenosine, *N*-benzoyl-5 - *O*-[bis(4-methoxyphenyl)phenyl methyl]-2 -deoxy- **(CAS RN 64325-78-6)**	PBiT	No	PBiT*	**Yes**	• Based on section 71 surveys conducted (2005 data), this chemical is not in use in Canada above the reporting threshold of 100kg
Benzamide, 3,5-dichloro-N-(3,4-dichlorophenyl)-2-hydroxy- (3,3',4',5-Tetrachlorosalicylanilide) (3,3',4',5-Tetrachlorosalicylanilid	PBiT	No	PBiT*	**Yes**	• Based on section 71 surveys conducted (2005 data), this chemical is not in use

e) **(CAS RN 1154-59-2)**					in Canada above the reporting threshold of 100 kg
Benzoic acid, 2-[(3,5-dibromo-4-hydroxyphenyl)(3,5-dibromo-4-oxo-2,5-cyclohexadien-1-ylidene)methyl]-, ethyl ester **(CAS RN 1176-74-5)**	PBiT	No	PBiT*	**Yes**	• Based on section 71 surveys conducted (2005 data), this chemical is not in use in Canada above the reporting threshold of 100 kg
2-Butanone, 4-[[[1,2,3,4,4a,9,10,10a-octahydro-1,4a-dimethyl-7-(1-methylethyl)-1-phenanthrenyl]methyl](3-oxo-3-phenylpropyl)amino]-, [1R-(1α,4αβ,10aα)]- **(CAS RN 70776-86-2)**	PBiT	No	PBiT*	**Yes**	• Based on section 71 surveys conducted (2005 data), this chemical is not in use in Canada above the reporting threshold of 100 kg
Amines, C18-22-tert-alkyl, ethoxylated **(CAS RN 68443-10-7)**	PBiT	No	PBiT*	**Yes**	Based on section 71 surveys conducted (2005 data), this chemical is not in use in Canada above the reporting threshold of 100 kg
5H-Dibenz[b,f]azepine-5-propanamine, 3-chloro-10,11-dihydro-N,N-dimethyl-, monohydrochloride (clomipramine hydrochloride) (**CAS RN 17321-77-6)**	PBiT	No	Only persistent	No	• Pharmaceutical and medicinal use for humans and animals

Amines, tallow alkyl, ethoxylated, phosphates (ATAEP) **(CAS RN 68308-48-5)**	PBiT	No	Does not meet the criteria for P, B or iT	No	• Cosmetics, soaps and cleaning products
Benzenamine, *N*-phenyl-, reaction products with styrene and 2,4,4-trimethylpentene (BNST) **(CAS RN 68921-45-9)**	PBiT	Yes	PBiT	No	• Confidential business information claimed by industry. • Some other documented uses - antioxidant/corrosion inhibitor/tarnish inhibitor/scavenger/antiscaling agent; lubricating agent/lubricant ; additive/mould release agent
Amines, C18-22-tert-alkyl, (chloromethyl)phosphonates (2:1) (ATACP) **(CAS RN 79357-73-6)**	PBiT	No	Does not meet criteria for P, B or iT	No	• Confidential business information claimed by industry • Other documented uses – lubricant, additive

* These chemicals are PBiT unless new information is submitted or if the chemical is re-introduced into Canada through the SNAc provision

A. 1. Substances considered PBiT (based on categorization) recommended for SNAc provisions

Issues

Five substances listed in Table 1 and listed below were categorized as PBiT). However, based on the results of government surveys conducted in March 2006 and November 2007, it was determined there was no industrial activity (import or

manufacture) for these substances above the reporting threshold of 100 kg. The proposed conclusion of the draft SLRA on these chemicals is to apply the Significant New Activity provisions under subsection 81(3) of the Act. The following substances were recommended for SNAc provisions.

- Adenosine, N-benzoyl-5 - O-[bis(4-methoxyphenyl)phenylmethyl]-2 -deoxy- (CAS RN 64325-78-6);
- Benzamide, 3,5-dichloro-N-(3,4-dichlorophenyl)-2-hydroxy- (3,3',4',5-Tetrachlorosalicylanilide) (3,3',4',5-Tetrachlorosalicylanilide) (CAS RN 1154-59-2);
- Benzoic acid, 2-[(3,5-dibromo-4-hydroxyphenyl)(3,5-dibromo-4-oxo-2,5-cyclohexadien-1-ylidene)methyl]-, ethyl ester (CAS RN 1176-74-5);
- 2-Butanone, 4-[[[1,2,3,4,4a,9,10,10a-octahydro-1,4a-dimethyl-7-(1-methylethyl)-1-phenanthrenyl]methyl](3-oxo-3-phenylpropyl)amino]-, [1R-(1α,4αβ,10aα)]- (CAS RN 70776-86-20); and
- Amines, C18-22-tert-alkyl, ethoxylated (CAS RN 68443-10-7)

We raise the following concerns related to the government's proposal:

a) Toxic under CEPA 1999: These substances should be considered toxic under CEPA based on their properties of persistence, bioaccumulation and inherent toxicity despite the evidence gathered that these PBiT chemicals are not in use in Canada and with no other data (uses, volume, historical data) submitted by industry through the application of 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. Government could use other tools under CEPA to ensure that future use 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. Since these substances are also classified as PBiT substances, they should be assessed with increased rigour than currently required for substances notifying under these provisions. This would require revisions to the New Substances Notification Regulations (also see (c), below).

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

c) Assessment under Schedule 6 of NSN – lack consideration of adequate chronic toxicity and other hazard data: The application of SNAc is

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

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

Recommendations

Recommendation 1: Conclude the five PBiT chemicals as CEPA toxic (Schedule 1) and add to the Prohibition of Certain Toxic Substances Regulation. Despite the evidence gathered that these chemicals are not in use in Canada (above the notification trigger of 100kg) and that no other data was submitted by industry to challenge the decision that chemicals with CAS Registration Numbers - 1154-59-2, 1176-74-5, 64325-78-6, 68443-10-7 and 70776-86-2 are PBiT substances, we recommend that these substances be considered CEPA toxic and be added to the Prohibition of Certain Toxic Substances Regulations 2005. This would ensure that no future use, manufacture, import or sale of these substances be permitted in Canada. This response would be in keeping with the precautionary principle.

Recommendation 2: The application of SNAc provision not appropriate. Substances with CAS Registration Numbers: 1154-59-2, 1176-74-5, 64325-78-6, 68443-10-7 and 70776-86-2 should not be flagged for SNAc provisions since the data required by government under the New Substances Notification Regulations (NSN) Schedule 6 is limiting and substances assessed under the NSN do not include a public comment period on subsequent assessments conducted using SNAcs. Given that these substances have been identified through the initial categorization as being PBiT, it is imperative to retain an opportunity for the public to comment on future assessment of these chemicals.

A.2. Other proposed PBiT substances (based on categorization process): CAS RNs: 115-39-9, 115-40-2, 125-31-5, 17321-77-6, 68308-48-5 and 79357-73-6 (except CAS RN: 68921-45-9)

Issues

a) Lack of rationale to support draft decisions to conclude these chemicals do not meet the criteria for P, B, or iT

Initially through categorization, substances with CAS RNs: 115-39-9, 115-40-2, 125-31-5, 17321-77-6, 68308-48-5 and 79357-73-6 were all considered to be PBiT. The government's SLRA documents concluded that these chemicals no longer met one or more of the criteria for persistence, bioaccumulation and inherently toxicity. The government also concluded that these substances do not meet the criteria as outlined in section 64 of CEPA hence draft risk management documents were not done.

The reports do not explicitly document the new data that was gathered and considered by government that lead to changes in PBiT categorization for these chemicals. Nor were there any clear indications in the draft assessment reports that some of the data were industry derived.

Since there is a lack of industry data for these substances (and most in batch 4), we question the extensive use of modeling in the draft assessments to make decisions on persistence and bioaccumulation because of the uncertainties associated with the derived data. And as a result, we question the rationale applied by the government to conclude that these substances no longer meet all the criteria as PBiT substances and why the precautionary principle was not fully applied even though many substances retained their persistence designation. With the use of modeling, the change in decisions on persistence or bioaccumulation would automatically mean a change in decision on inherent toxicity of a chemical. Toxicity of the chemicals was determined based on the new data considered for persistence or bioaccumulation. This approach would mean that these substances cannot be proposed as CEPA toxic and no further action by the government will be undertaken. It is our view, that if available data was not robust enough to make PBiT determinations during the categorization process, then we question the use of modeled data and the rationale behind the changes in the decisions during the SLRA process. This approach compounds the uncertainties attached to specific data gathered through categorization with other uncertainties resulting from modeled data. The preferred approach by government is to require industry to provide experimental data demonstrating the safety of the chemical. Government should make requirement part of the Section 71 survey.

Finally, the draft decisions of SLRAs are further complicated by the claims of Confidential Business Information made by industry on several of these Batch 4

substances. There is uncertainty as to the grounds for which the government accepts the use of a substance to be confidential business information as adequate and valid under the Challenge Program.

b) Sewer treatment plants/sludge:

The draft assessment reports conducted under the CMP generally do not provide a consistent approach in addressing the discharge of effluents from sewage treatment plants, which may contain toxic chemicals. There are several concerns regarding this issue. Since many of these chemicals are released to different environmental media, there are concerns that chemical treatment by sewage treatment plants may have the potential to: discharge effluents to water bodies that may contain toxic chemicals, or produce sewage sludge that may contain toxic chemicals, which may ultimately be disposed of in landfills or used in agricultural applications. The assessment reports assumes or does not provide the adequate rationale that treatment plants are able to treat or remove all chemicals that they receive therefore producing effluent or sludge that will have no impact to the receiving environment. The level of effective removal of toxic chemicals from sewage treatment process is determined by the level and type of treatment applied. This information is often lacking in the assessment reports. From a public policy perspective, the quality of the discharge of effluent from sewage treatment plants could be improved by promoting source prevention of toxic chemicals. The assessment process should include a better analysis outlining the fate and impacts of chemicals being treated by sewer treatment plants. The enhanced consideration of this pathway will contribute to the full life cycle accounting of a chemical's fate and decision making on the toxicity of the substance.

Recommendations

Recommendation 3: Increase transparency on PBiT decisions is required. We recommend improved transparency by government on decisions of PBiT for substances and, in particular, the identification of additional data that led to the decision of PBiT changes.

Recommendation 4: Retain PBiT designation on 6 substances. In the absence of data provided by industry on PBiT substances and the uncertainties related to the modeled-derived data used in the assessment, the government should retain its original decision of PBiT for these substances (e.g. CAS RNs: 115-39-9, 115-40-2, 125-31-5, 17321-77-6, 68308-48-5 and 79357-73-6). Furthermore, these substances should be considered CEPA toxic under section 64.

Recommendation 5: Require action plans to reduce the presence of these substances. Based on the current government decision determining that these chemicals are persistent, action plans to reduce their presence is warranted. Strategies for reduction should include the development and implementation of pollution prevention plan which would include source prevention and the

identification of safe alternatives so that environmental persistence could be adequately addressed.

Recommendation 6: <u>Recognize the limitations of sewage treatment plants to remove all toxic substances.</u> The government should acknowledge that sewage treatment plants are unable to effectively remove all toxic substances. Hence, the government should apply a preventative approach to use of toxic substances.

A. 3. Benzenamine, *N*-phenyl-, reaction products with styrene and 2,4,4-trimethylpentene (BNST) (CAS RN 68921-45-9): Toxic under CEPA

<u>Issues</u>

The import and manufacture of BNST to Canada is significant. According to the draft SLRA report for BNST, between 100,001 and 1,000,000 kg of BNST were imported into Canada in 2006, and between 1,000,000 and 10,000,000 kg were manufactured in Canada in 2006. Furthermore, BNST is expected to be found in finished imported products but the government's assessment results did not provide an accurate estimate.

The data documented in the SLRA demonstrates that BNST is a high production volume (HPV) chemical, (also identified in the US Environmental Protection Agency HPV Chemical Program), and evidence demonstrates that this chemical is persistent, bioaccumulative and toxic to the aquatic environment.[1] Given the findings of the assessment, it is appropriate that the government concludes that BNST is toxic under CEPA 1999. Since this substance meets all criteria outlined under the *Persistence and Bioaccumulation Regulations*, the government's proposed strategy that "Government of Canada will follow the process specified in CEPA 1999 for substances that meet the criteria for virtual elimination" is in appropriate. However, modeled data have indicated the BNST is capable to harm aquatic substances at low levels of concentration. This information would suggest that establishing a level at which this chemical could be contained may prove difficult. To ensure protection to human health and the environment, the management of BNST may be best undertaken using a phase out approach. Therefore, the proposal by governments towards a "*prohibition through regulations of the manufacture, use, sale, offer for sale and import of BNST or a product containing it*"[2] is preferred with one qualification. The use of the prohibition is a good

[1] Based on the SLRA for BNST, releases of BNST to the environment is expected to be low with the majority of BNST (75%) being chemically transformed (into products). Approximately 19% of the BNST will be in the air as a result of product use and 3% will to go waste disposal. With a low water solubility, BNST has a tendency to partition to particles and lipids of organisms and will most probably be present in soil and sediment. BNST is expected to be persistent in water, soil and sediments and has the potential to accumulate in organisms with the potential to biomagnify in trophic food chains. Data also suggest that it is highly hazardous to aquatic organisms.

[2]Government of Canada. RISK MANAGEMENT SCOPE for Benzenamine, N-phenyl-, Reaction Products with Styrene and 2,4,4-Trimethylpentene (BNST) Chemical Abstracts Service Registry Number (CAS

strategy as long as the regulations include a prohibition of all sources of BNTS including imported products that may contain the chemical and the regulations do not provide exemptions. This would ensure that current and future uses of BNST are phased out and provides an opportunity for safe alternatives to be identified and implemented. Other proposed regulations simply establishing conditions for use of BNST would not guarantee protection to the environment to human health.

Socio-economic factors should not be the guiding force behind the government's decisions in developing the most effective measure on BNST that would protect the environment and human health. But rather, protection should take priority over economic factors. Even if government undertakes control measures for BNST that aim to simply contain the use of the chemical, the continued use of this substance may still mean environmental and human exposure in the long term. A preventative approach to end its use is the approach measure to ensure protection.

Finally, it is noted that environmental monitoring has not been undertaken for this HPV substance.

Recommendations

Recommendation 7: Designate as CEPA toxic. We support the government proposal that Benzenamine, N-phenyl-, reaction products with styrene and 2,4,4-trimethylpentene (BNST),CAS RN 68921-45-9, be considered toxic under Section 64, CEPA 1999 and that this substance be added to CEPA Schedule 1 (Toxic Substances List).

Recommendation 8: Require elimination of persistence, bioaccumulation and inherent toxic chemical. We support the government that BNST meets the criteria for persistence and bioaccumulation potential as set out in the Persistence and Bioaccumulation Regulations (Canada 2000). The goal for BNST should be elimination.

Recommendation 9: Support regulations to prohibit BNST without exemptions. A regulation to outline the conditions under which BNST or a product containing it may be imported, manufactured, processed, used or disposed limit the amount of BNST is rejected. But a regulation to prohibit use, sale, manufacture and import of BNST without exemption and include import products that may contain this substance is supported. This prohibition would ensure that current and future uses of BNST are not permitted in Canada.

Recommendation 10: Promote safe alternatives for BNST. In support of regulations to prohibit BNST, we also recommend that industry be called upon to identify and implement safe alternatives to BNST. The development, promotion,

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RN): 68921-45-9. January 2009 Access at http://www.ec.gc.ca/substances/ese/eng/challenge/batch4/batch4_68921-45-9_rm_en.pdf

and implementation of safe alternatives to address persistence and bioaccumulation in the environment are timely and appropriate.

B. Substances in Batch 4 identified as a high priority for human health

The five substances below were originally categorized as meeting categorization criteria for human health. However, the draft SLRAs reports proposed that only two of the five substances listed below now meet the criteria for being declared CEPA 'toxic'. The remaining three substances do not meet the criteria for CEPA Section 64 for toxicity (see table 2).

Table 2: Batch 4 substances categorization – CEPA 'toxic'

Substance Name (CAS RN)	Proposed finding under CEPA Section 64	Proposed SNAc	Human health effects	Use data
Sulfuric acid, diethyl ester (diethyl sulfate) (**CAS RN 64-67-5)**	Yes	No	Classified by other agencies on the basis of human carcinogenicity and genotoxicity at any exposure level	Chemical intermediate: • tissue paper industry Other documented as a chemical intermediate for: • dyes, fragrances • quaternary ammonium salts (surfactants or flocculants in water treatment) Ethylating agent usage as for: • dyes, agricultural chemicals • pharmaceuticals • textiles, organoclays, sanitizers)
Propane, 2-methyl (Isobutane) **(CAS RN 75-28-5)**	No	No	For residue – 1,3-butadiene: Likely human carcinogenic, with possible genotoxicity and reproductive toxicity	Confidential business information claimed by industry Other documented uses: • propellant/blowing agent, fuel or fuel additive • solvent carrier, and formulation component Non-fuel uses:

				• insulating polyurethane foam, aerosol sprays and coatings • paint dyes and automotive spray waxes Consumer products: • cosmetic/beauty preparations, air freshener, cleaners • activator/primers and, coatings - (concentration of isobutane may range up to 70 w/w %)
Sulfuric acid, dimethyl ester (dimethyl sulfate) **(CAS RN 77-78-1)**	Yes	No	Classified by other agencies on the basis of human carcinogenicity and genotoxicity at any exposure level	Pharmaceutical intermediate cited. Other documented uses Alkylating agent for: • dyes, agricultural chemicals • drugs and other specialty products Intermediate for: • pesticides, dyes, fragrances Methylation with amine to make quaternary ammonium salts, usage: • surfactant, fabric softener • flocculant in water treatment (sewage sludge control)
Butane **(CAS RN 106-97-8)**	No	No	For residue – 1,3-isobutadiene: likely human carcinogenic, with possible genotoxicity and reproductive toxicity	As in isobutene
Hexane **(CAS RN 110-54-3)**	No	No	Classified by the European Commission on the basis of reproductive toxicity	Extraction solvent: • food processing Solvent carrier in: • adhesives, sealants, binders and, fillers • lubricants, various formulation components, fuel components, • laboratory reagent and solvent.

B. 1. Substances proposed as not being CEPA 'Toxic': Propane, 2-methyl (75-28-5); Butane (106-97-8)

Butane and Propane, 2-methyl (isobutane) both containing 1,3-Butadiene (CAS RN 106-99-0)

Highlights and Issues

Butane and isobutane, containing 1,3-butadiene as a residue, are imported into and manufactured in Canada in large quantities with typical levels of the residue at 0.1 by weight or less, as reported from data collected under section 71 of the Act.

Butane and isobutene, both determined to be high priorities for assessment with respect to human health, were also determined to be persistent but not bioaccumulative or inherent toxicity to aquatic organisms. It has been proposed that both butane and isobutene, once containing 1,3- butadiene, meet the criteria for being toxic under section 64 of CEPA 1999. It has also been proposed that under CEPA 1999, no further action will be taken since these substances are already on Schedule 1 of the Act and risk management procedures are already in place. There is a need to strengthen the current risk management strategies. Also, we cannot ignore the cumulative effect with regards to 1,3-butadiene nor multiuse of products containing 1, 3-butadiene. Mentioned but not expanded upon is occupational exposure for this substance.

1,3-Butadiene is listed on the Priority Substances List 2 of CEPA and it is a likely human carcinogenic. It may also be associated with genotoxicity and reproductive toxicity. In Europe, butane and isobutene have been classified as carcinogenic if they contain 1,3-butadiene (CAS RN 106-99-0) at a concentration greater than or equal to 0.1%. While there may be significant variation in sensitivity within the population, epidemiological studies conducted on workers in a rubber industry revealed an association between occupational exposure to 1,3-butadiene and incidence of leukemia. We question the 'safe level' that has been adopted by the government. To promote greater protection to workers and the general population from a substance considered to be a likely human carcinogen, this level should be critically reviewed.

Without the presence of 1,3-butadiene, these two substances would have been assessed in the Medium Priority substances of the Chemicals Management Plan. As end-used fuels, they will be addressed under the Petroleum Sector Stream Approach of the Chemicals Management Plan. To this date, there has been very limited information on what management activities will be undertaken through the Petroleum Sector on toxic chemicals. This limitation does not provide adequate confidence that these chemicals will be dealt with effectively. It is our view that regulatory rather than a non-regulatory approach (as framed for the Petroleum Sector) is required for these substances. The draft assessment reports should be revised to reflect such an approach when discussing these chemicals in the presence of a CEPA toxic chemical, 1,3 butadiene.

As indicated in Table 2, butane and isobutene are utilized in a wide variety of products including cosmetics, consumer and food contact products. Although the concentration of isobutene is typically less than 0.1% by weight of isobutene or butane, there are cases where its level in a product is unknown, even for a substance that is a likely human carcinogen. It is concerning to know that 1,3-butadiene limits are not specified or required to be publicly known when butane and isobutene are included as propellant substances under the *Food and Drug Act*. When a substance is a likely human carcinogen, it is inappropriate to assume that a chemical is safe just because it is in low and negligible levels. This rationale also applies to the other consumer and commercial products that contain butane and/or isobutene with 1,3-butadiene as a residual compound. It is also important to stress that exposure to these substances including 1,3-butadiene, result from multiple sources and in winter, as the draft assessment has indicated, indoor levels of 1,3-butadiene are higher as compared to summer levels.

By extension, one would also have to question the actual safety with respect to the use of butane and isobutene in consumer products and, in particular, cosmetics. The draft risk assessment report has indicated that isobutene is considered safe as a cosmetic ingredient under the appropriate concentration and circumstances of usage. However, there was no cited evidence to conclude this.

Recommendations

Recommendation 11: Designate CEPA toxic. We are in agreement with the proposal that both butane and isobutene, once containing 1,3-butadiene, meet the criteria for being toxic under section 64 of CEPA 1999.

Recommendation 12: Need for action on these toxic substances. We do not support the proposal that under CEPA 1999 no further action will be taken on these substances simply because they are already on Schedule 1 of CEPA and risk management regimes are already in place. It is our view that the measures to reduce 1,3-butadiene levels should be strengthened with a phase out of 1,3 butadiene. This will ensure the protection of human health and environment from consumer and cosmetic products containing isobutene and butane with residuals of 1,3 butadiene.

Recommendation 13: Prohibit 1,3 butadiene from cosmetic products. Since 1,3-butadiene is a likely human carcinogen, the government should ensure that 1,3-butadiene be prohibited from the cosmetic products and personal care products. This may include but not restricted to the addition of 1,3-butadiene to the Health Canada's Cosmetic Ingredient Hotlist, which should be accompanied by enhanced enforcement measures.

Recommendation 14: Phase out 1,3-butadiene in consumer and commercial products. We recommend that the government phase out 1,3–butadiene as a contaminant from all consumer products with specified timelines.

Recommendation 15: Prohibit 1,3-butadiene in Food contact product. Based on the properties of 1,3-butadiene, we recommend that the government take regulatory action to phase out the presence of this substances as a contaminant from food contact products with specified timelines. The use of alternative food packaging may be required in this regime.

Recommendation 16: Require substitution with a safer alternative. We recommend that the government and industry, over a specified time period, identify, review and implement the use of safer alternatives to butane and isobutane containing residual 1,3-butadiene, in all consumer and commercial products.

Recommendation 17: Promote monitoring programs for 1,3-butadiene in consumer and commercial products. A revised management strategy aimed at 1,3-butadiene should include a government monitoring program that would quantify the levels of 1,3-butadiene in commonly used consumer and commercial products.

Recommendation 18: Reduce 1,3-butadiene from outdoor wood burning stoves. Although 1,3-butadiene from outdoor wood burning stoves is not specifically addressed in the current draft risk management. We recommend that the government severely restrict the use of these stoves or put a ban on them and, in particular, in those areas of the country where the occurrence of smog is common for many months of the year, including winter because of their contribution to 1,3-butadiene levels. This can be done in conjunction with the provincial governments.

B. 2. Substances that are proposed CEPA toxic: Sulfuric acid, diethyl ester (diethyl sulfate) – (CAS RN 64-67-5); Sulfuric acid, dimethyl ester (dimethyl sulfate) – CAS RN 77-78-1)

Highlights and Issues

It has been proposed that diethyl sulfate and dimethyl sulfate be classified as toxic under section 64, CEPA 1999. However, they do not meet the criteria for persistence and bioaccumulation as described under the *Persistence and Bioaccumulation Regulations,* CEPA 1999. Both substances are listed on the Ingredient Disclosure List of the *Hazardous Products Act* with a maximum weight percent of 0.1% (Canada 2008).

The critical effect for the characterization of risks to human health for both substances is carcinogenicity and their potential to do harm at any concentration. They were also was found to be consistently genotoxic in a range of *in vivo* and *in vitro* assays and are strong DNA alkylating agents.

The actual recorded amounts for import of these substances were not high but not included is data on the residual quantities that may possibly occur in imported intermediates or finished products. There is concern that these substances when used as intermediates in many consumer and commercial (industrial) products may actually be present as residues but possibly at very low concentrations. The draft assessments indicated that information was not available on residues.

Dimethyl sulfate is emitted when sulfur containing coal/fuel is burnt in power plants but under CEPA 1999 through a section 71 notice, companies reported no release of this substance in 2006. Modeled estimates of exposure did not take into account this scenario. Because of the rapid hydrolysis of dimethyl sulfate in the atmosphere, it was concluded that the general population would be adequately protected from the non-cancer effects of this substance but this was not adequately quantified.

Recommendations

Recommendation 19: Designate as CEPA toxic. We are in agreement that both diethyl sulfate and dimethyl sulfate should be classified toxic under section 64, CEPA 1999.

Recommendation 20: Eliminate the acceptable concentration of dimethyl sulfate on the Ingredient Disclosure List of the Hazardous Products Act. The Hazardous Product Act does not adequately protect humans from exposure to dimethyl sulfate found in products. In light of these substances being potentially carcinogenic to humans and having the potential to do harm at any concentration, we recommend that the weight of 0.1% for the Ingredient Disclosure List of the Hazardous Products Act be eliminated entirely, in order to fully protect human health.

Recommendation 21: Prohibition of diethyl sulfate and dimethyl sulfate from Cosmetic products. Since there is the possibility that there can be residual diethyl sulfate or dimethyl sulfate in cosmetics and personal care products and based on the carcinogenic potential of both substances, we recommend that these chemicals be prohibited from cosmetic and personal care products. This may include but not restricted to the addition of these chemicals to the Health Canada's Cosmetic Ingredient Hotlist, which should be accompanied by enhanced enforcement measures.

Recommendation 22: Other areas for residue prohibition. We recommend that diethyl sulfate and dimethyl sulfate be registered as prohibited contaminants in pesticides, fertilizer, livestock feed, natural health products and pharmaceuticals.

Recommendation 23: Dye and textile industries and other industries – safer alternatives. Government to collaborate with the dye and textile industries regarding the feasibility of indicating residual levels of diethyl sulfate and dimethyl sulfate in their products and work on reducing these levels. Also, an

investigation of the availability of safer and effective alternatives in all industries employing the use of these substances is warranted.

Recommendation 24: ***NPRI reporting. Recognizing that these substances are generally used in closed systems but with their potential to be carcinogenic, we recommend that there should be no thresholds for reporting releases under the NPRI.***

Recommendation 25: Occupational exposure. Because of the volatility of these substances and their potential to be carcinogenic, occupational exposure limits should be reviewed and acted upon by the government. Also, ambient air concentrations for both substances should be set, if they do not already exist.

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