RESPONDING *TO CANADA GAZETTE PART 1*, Volume 142, No. 20 (May 17, 2008): Comments and Recommendations on the Draft Screening Assessment & Risk Management Scope Reports for Selected Substances under Batch 2 of the Chemicals Management Plan:
C.I. Pigment Red 104 (CAS RN 12656-85-8)
C.I. Pigment Yellow 34 (CAS RN 1344-37-2)
Cyclotetrasiloxane, octamethyl (D4) (CAS RN 556-67-2)
Cyclopentasiloxane, decamethyl (D5) (CAS RN 541-02-6)
Cyclohexasiloxane, dodecamethyl (D6) (CAS RN 540-97-6)
Acetic acid ethenyl ester (Vinyl ester) (CAS RN 108-05-4)

Submitted to:
Environment Canada
Health Canada

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CELA publication #622
ISBN # 978-1-897043-93-6

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July 16, 2008

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Introduction

The Canadian federal government released the draft assessment and draft risk management scope documents for substances in Batch 2 of the Industry Challenge, Chemicals Management Plan, at various dates. Documents for Bisphenol A were released on April 19, 2008, and eleven substances on May 17, 2008. For the remaining five substances, draft assessments were released on May 24, 2008 and these assessments indicated that these substances did not meet any of the criteria set out under section 64 of the *Canadian Environmental Protection Act* 1999 (CEPA) so risk management scope documents were not done. For details, please see: http://www.chemicalsubstanceschimiques.gc.ca/challenge-defi/batch-lot_2_e.html.

Canadian Environmental Law Association (CELA) and Chemical Sensitivities Manitoba are submitting the following comments in response to the Canada Gazette Part 1, Vol. 142, No. 20 dated May 17, 2008 to release the draft assessment reports for substances identified under the Chemicals Management Plan, Batch 2 of the Industry Challenge.

The Canadian Environmental Law Association (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 environmental law reforms. It is also a free legal advisory clinic for the public, and will act at hearings and in courts on behalf of citizens or citizens' groups who are otherwise unable to afford legal assistance. CELA is funded by Legal Aid Ontario (LAO). It is one of 80 community legal clinics located across Ontario, 18 of which offer services in specialized areas of the law. CELA also undertakes educational and law and policy reform projects that are funded by LAO as well as government and private foundations. CELA's public policy reform programs focus on four issue areas: pollution and health, water sustainability, land use planning and access to justice. CELA participated and responded to government proposals in implementing section 73 of CEPA which focused on the categorization of the 23, 000 substances under the Domestic Substances List. CELA's interest in the results of categorization and the government's efforts to complete screening level risk assessments and propose management regimes for substances continues. CELA advocates for the elimination of the most hazardous substances, including those substances identified as high priority substances due to its impact to the environment (found to be persistent, bioaccumulative and inherently toxic) or to human health (are carcinogenic, reproductive and developmental, respiratory, genotoxicant, endocrine disruptors or neurodevelopmental toxicants).

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. All four individuals worked in science - chemistry (industry), biochemistry, entomology and veterinary medicine. 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. In the workplace, where safe substitution can often be a challenge, CSM also looks

at preventative measures for reduced occupational exposure. CSM meets with politicians, union representatives and the medical community to bring awareness to the controversial medical condition of chemical sensitivities and the profound impact it has on one's personal life; job and the ability to work; social life and financial stability. Outreach to the public, and lectures to university students are also part of our activities. We act as a resource consultant for undergraduate students in the Department of Community of Health Sciences, Faculty of Medicine, University of Manitoba, who are working on environmental papers applicable to our organization. CSM has been involved in the Chemicals Management Plan stakeholder workshops and continues to be involved as the government publishes the draft risk assessment and risk scoping documents on substances identified through the CEPA categorization. CSM advocates for the elimination of those substances identified through the categorization process that pose a risk to human life and the environment.

For this submission, the following substances will be the focus of our comments and recommendations:
C.I. Pigment Red 104 – CAS RN 12656-85-8
C.I. Pigment Yellow 34 – CAS RN 1344-37-2

Cyclotetrasiloxane, octamethyl (D4) – CAS RN 556-67-2
Cyclopentasiloxane, decamethyl (D5) – CAS RN 541-02-6
Cyclohexasiloxane, dodecamethyl (D6) – CAS RN 540-97-6

Acetic acid ethenyl ester - CAS RN 108-05-4

Although we focused on selected substances for this submission, the government should not assume that our respective organizations do not have issues or concerns relating to the draft assessment and the risk management scope results of other substances released through the Canada Gazette on May 17, 2008.

C.I. Pigment Red 104 (CAS RN 12656-85-8); C.I. Pigment Yellow 34 (CAS RN 1344-37-2)

Results from categorization CEPA section 73

As a result of categorization, C.I. Pigment Red 104 and C.I. Pigment Yellow 34, both lead chromate pigments, were both identified as having a high priority for human health because they were thought to pose the greatest potential for exposure (GPE) to individuals and were also classified by other agencies or jurisdictions on the basis of their carcinogenicity, reproductive toxicity and developmental toxicity. Initially, these pigments also met the ecological categorization criteria for persistence and inherent toxicity to aquatic organisms but the latter decision has since been changed. Under CEPA, both lead and chromium are listed as being CEPA toxic.

Highlights and commentary from draft assessment report

C.I. Pigment Red 104 and C.I. Pigment Yellow 34 share similar chemical properties with both of them having as its principle ingredients, chromium and lead, but C.I. Pigment Red 104 also contains lead molybdate. The draft screening and the risk management scoping documents mentioned that these pigments can be encapsulated within a continuous dense coating of amorphorous silica which results in the reduction of environmental and toxicological impacts of chromium and lead and, in some cases, these encapsulated pigments have special uses.

Both pigments have low water solubility but there will be dissolution and dissociation of the pigments into the moieties – Pb^{2+} and CrO_4^{2-} with the lead sulphate portion having greater solubility than the lead chromate portion. Encapsulation with amorphorous silica will further decrease the solubility of these pigments therefore reducing the bioavailability of the moieties in water, sediments and soil. In the government documents, no experimental data supported these claims.

These pigments are used primarily in industry for non-consumer coatings, plastics, commercial printing inks, road signs, decals, hobby paints, and agricultural equipment among other uses. Under the *Hazardous Products Act* (Canada) toys, equipment and other products used by a child in learning or play, pencils and artists' brushes that have had a surface coating material applied to them, cannot contain more than 600 mg/kg of total lead.

Pigment Red 104 and Pigment Yellow 34 have been classified as Category 3 Carcinogens by the European Commission as possible human carcinogens and genotoxic in laboratory experiments. The European Commission has proposed a reclassification for C.I. Pigment Red 104 as a Category 2 Carcinogen (should be regarded as if they are carcinogenic). Based on the weight of evidence provided by other jurisdictions regarding hexavalent chromium and inorganic lead compounds, the major risk of these two pigments to human health is carcinogenicity.

Animal studies support epidemiological studies demonstrating an increased frequency of lung cancer among workers involved in the production of chromate pigments. The animal studies are also supported by genotoxicity studies as well as cell transformation studies. In spray paints using lead chromate pigments, the only available epidemiological investigation did not indicate a statistically significant association between spray painting and respiratory cancer-caused mortality. Not stated but speculated is that mechanical ventilation and personal protective equipment may have been instrumental in lowering the mortality rate.

It is recognized that a small percentage of the Canadian population could have higher exposures to these pigments because of activities (hobbies), jobs or proximity to manufacturing plants. Again, this could not be quantified due to the lack of data. Our organizations identify this as a significant gap in the draft assessment. Since hobbies is one of the activities identified for potential exposure, this route of exposure warrants

further investigation. The amount and type of products used in hobbies that may contain these pigments should be noted. The lack of such an investigation would severely restrict the level of and type of management activities required by government on these substances, should they be found to meet criteria of toxicity under CEPA section 64. This request would be essential in finalizing the assessment reports

Furthermore, the exposure levels of workers to these pigments are also glaring gaps in the assessment. Not only are workers exposed from the dispersive nature of these substances, there is also the threat of exposure to these substances to their families as a result of the possible contamination and transfer of these pigments from the workers' clothes. In our view, the assessment results should include estimates of exposure to workers in its final assessment. This gap could be addressed by requiring industry to provide information in a timely manner through CEPA section 71.

Currently, the assessment approach conducted by the government does not consider factors such as income and other social economic factors when conducting its screening level risk assessments. CELA, in fulfilling its mandate as a not for profit legal clinic specializing in environmental matters would like to emphasize the need consider such factors. Vulnerable populations, including people with low income, may be significantly impacted from exposure to pollution, including toxic substances that may be found in consumer or industrial products.

The *Hazardous Products Act* outlines specific restrictions on lead levels in products, the mishandling or illegal use of final products. Despite these restrictions, access and availability to products containing lead continue to pose a problem in Canada. For paints designated for industrial application only, we are expressing our concerns that opportunities may exist for the general population to have access to final products containing these pigments. Similarly, there is an opportunity for misuse of such products for non-industrial application. It is unclear whether end products such as playgrounds equipment are painted with industrial paints or to what level people with hobbies may be exposed to these substances.

From section 71 survey data, in 2006, 1,000 to 10,000 tonnes of each pigment were used in Canada. Emissions were reported as being low during manufacturing processes using or making these pigments. Water was cited as being the most likely candidate for contamination. Application and post-application releases could be significant but they have not been quantified. It is noteworthy to mention that the report on page 12, says "Particles of traffic stripping paint containing the substance may enter surface water from surface runoff from roadways into drainage ditches, watercourse or wetlands." However, no estimate data was provided to assess impacts to affected wildlife species that may frequent the receiving water bodies (i.e., wetlands, etc.) or the quality of influent or effluent from sewer systems.

There are also releases from products in landfills and incinerators for which, at this point, estimated quantities remain unknown. However, for assessment purposes, they were actually assumed to be zero. Metal scrap yards are also expected to have metals

coated with paints containing these pigments; they were not evaluated. These are significant gaps in the assessment that should be addressed in the finalization of the assessment results. Again, CEPA section 71 should be applied to require industry to provide this missing information. The absence of this information will influence the quality of the management regime to be determined for these substances.

Monitoring data for Red 104 or Yellow 34 are not available for Canada. Based on all the available data, it was concluded that these substances are not entering the environment in quantities or under conditions that would be harmful to the environment. However, these substances satisfy the criteria for persistence under the *Persistence and Bioaccumulation Regulations.* While current modeling or testing protocols are unable to determine bioaccumulation factors for UVCBs such as Pigment Yellow 34 and Pigment Red 104, the government should direct appropriate resources to address this scientific gap. It has profound impact on the determination of toxicity under CEPA and hence potential significant impacts to the health of Canadians and their environment. Furthermore, the absence of this information makes it premature for the government to conclude that a virtual elimination approach for these substances would not be required.

Due to the carcinogenicity of Red 104 and Yellow 34 and the determination that there are no predicted levels that are considered to be safe for human exposure, the assessors are proposing that these pigments may be entering the environment in a quantity or concentration or under conditions that constitute or may constitute a danger in Canada to human life or health.

The health assessment results and the gaps identified in the ecological assessment suggest that an elimination strategy for these substances is appropriate to effectively protect the health and environment of Canadians. This approach would be in keeping with precautionary principles.

Recommendations

1. We support the draft assessment result which proposes that “C.I. Pigment Yellow 34 be considered as a substance that may be entering the environment in a quantity or concentration or under conditions that constitute or may constitute a danger in Canada to human life or health.” Therefore, the government should consider it toxic under CEPA section 64.
2. C.I. Pigment Yellow 34 should be added to CEPA Schedule 1 (Toxic Substances List).
3. We support the draft assessment result which proposes that “C.I. Pigment Red 104 be considered as a substance that may be entering the environment in a quantity or concentration or under conditions that constitute or may constitute a danger in Canada to human life or health.” Therefore, the government should consider it toxic under CEPA section 64.
4. C.I. Pigment Red 104 should be added to CEPA Schedule 1 (Toxic Substances List).

5. We support the determination that C.I. Pigment Yellow 34 and C.I. Pigment Red 104 are persistent. However, the government assessors should develop appropriate testing protocol to determine the bioaccumulation factor for these substances. The absence of the bioaccumulation data may result in less stringent measures to manage these substances.
6. Recorded releases and assumed low quantities of either pigment in the environment are insufficient evidence to conclude that all requirements for being CEPA toxic are not met. Releases from landfill sites and incinerators should not be assumed to be zero. In fact, since the assessment report indicated that sediment and water are the key releases to the environment, the level of leaching to groundwater or surrounding soil should be critical to the assessment because these substances remain in these locations for many years, if not decades. For products containing these pigments that may be targeted for incineration, the problems are enhanced because the by-products of incineration (i.e., dioxins, other heavy metals, particulate matter) may have impacts to health or environment. The toxicity of these by-product substances are not considered in these assessment reports.
7. Apply CEPA section 71 to fill in data gaps as noted in this submission for: leaching rates; incineration activities; scrap metal yards; occupational exposure; hobbies with materials containing these pigments; and exposure to children and other vulnerable populations (low income populations) in order to complete the assessment reports.
8. The assessment report mentions the special uses for silica-encapsulated lead chromate pigments. For clarity, these special uses should be identified explicitly. Initially, silica encapsulation of some lead chromate (including lead molybdate) pigments was a way to circumvent the health and environmental concerns associated with these pigments, some of which were thought to be 'perceived.'
9. It is uncertain if all grades of silica encapsulated lead chromate pigments actually decrease the toxicity of these pigments. The government should determine the effectiveness of the silicate encapsulated lead chromate pigments by investigating and assessing the level of silica used and the homogenicity of the silica layer.
10. Recognizing that environmental exposures to these pigments are supposedly low but given the potential of these pigments to be carcinogenic, risk management proposals by the government that "focus on ensuring that any potential changes in the use-pattern for C.I. Pigment Yellow 34 do not substantially increase the potential for exposure of the general Canadian population," [1] is wholly inadequate. Pigment Yellow 34 is used at very high level quantities in Canada and there are data to demonstrate that this number is declining. A similar approach is proposed for C.I. Pigment Red 104.[2] We recommend that the government aim to eliminate these substances in its various applications.
11. The federal government should establish an action plan for ultimate elimination of these substances based on carcinogenicity. Clear time lines for reduction targets with ultimate elimination should be established particularly for the non-essential use

[1] Government of Canada. Risk Management Scope for C.I. Pigment Yellow 34 Chemical Abstract Service (CAS) Registry Number: 1344-37-2, May 2008. pg. 6.
[2] Government of Canada. Risk Management Scope for C.I. Pigment Red 104 Chemical Abstract Service (CAS) Registry Number: 12656-85-8, May 2008. pg. 6.

of these pigments. The identification and assessment of alternatives should be integrated into this action plan.

12. To support and achieve the goal of elimination, an appropriate regime should include the establishment of a stakeholder task force to identify and assess alternatives to C.I. Pigment Yellow 34 and C.I. Pigment Red 104 for all applications. There is an understanding that cost and chemical properties are often issues when alternatives are sought. All pertinent data should be available for alternatives used by industry in order to effectively assess their safety. Where the technology is not available, the encapsulated versions of these pigments could be used – if applicable.
13. While occupational health does not fall under CEPA, it is noteworthy to mention the increased cancer rates in occupations where these pigments and chemically similar pigments, are used or manufactured. There is the refinish market where sanding has to be done, possibly under less than optimum conditions. Several safe replacements have been readily available for many years. As in a previous recommendation, pigment replacement with a safe alternative should be identified, assessed and pursued by the government.
14. C.I. Pigment Yellow 34 and C.I. Pigment Red 104 share a similar chemistry with each having two toxic metals, lead as Pb^{2+} and chromium (hexavalent) as CrO_4^{2-}. In risk assessment, considerations should be given to the combined effects for exposure to these two metals.
15. Similarly, the assessment should also include consideration of cumulative or additive impacts from exposure to other carcinogenic substances.
16. Vulnerable populations such as children and low income populations are not adequately considered in these assessments. Children may be exposed through various routes including accidental exposure from a parent who may have occupational exposure (particulates may remain on clothes), through hobbies that rely on products containing these pigments, etc. Similarly, low income people and people with chemical sensitivity may be vulnerable to exposure to these substances. The government should begin to consider social and economic factors such as income and chemical sensitivity in these assessments.

Cyclotetrasiloxane, octamethyl (D4) (CAS RN 556-67-2); Cyclopentasiloxane, decamethyl (D5) (CAS RN 541-02-6); and Cyclohexasiloxane, dodecamethyl (D6) (CAS RN 540-97-6)

Results from categorization CEPA section 73

Through the process of ecological categorization, octamethylcyclotetrasiloxane (D4), decamethylcyclopentasiloxane (D5), and dodecamethylcyclohexasiloxane (D6), were identified as high priorities for assessment because under CEPA 1999, they all satisfied the criteria for persistence, bioaccumulation potential and inherent toxicity (PBiT) to non-human organisms.

Also through categorization, D4, under CEPA 1999, was considered to pose an intermediate potential for exposure to individuals in Canada (IPE) and has been classified by another agency on the basis of reproductive toxicity. Although D5 and D6 were not considered a priority with respect to human health risks, human health assessments were conducted because of the similarity in structure and use patterns to D4.

Highlights and commentary from draft assessment report

For this submission, D4, D5, D6 are being reviewed together because of similarities in their use patterns, chemical structures and properties.

D4 is classified by the European Commission as a Category 3 for reproductive toxicity based on reproductive effects observed in rats following inhalation exposure. The Danish Environmental Protection Agency (EPA) has also included the liver as a target organ for D4 exposure but it did not distinguish between exposure routes. For repeat dose toxicity inhalation dose (inhalation at 420 mg/m3), adverse effects on the adrenals, lungs and thymus of laboratory rats were also observed. Oral and dermal exposure routes are also important but due to a lack of dermal studies for some endpoints, only experimental data on absorption were used in the assessment.

No international agency has classified D5 or D6 for carcinogenicity, genotoxicity nor reproductive/developmental toxicity but based on Danish EPA findings for D5, the potential effect for repeat-dose toxicity is carcinogenicity, as observed in a 2-yr rat study. It is noted that the uterine tumours in this study were observed at higher levels than the effects identified for the lung and liver, as in several other toxicity studies. The lung was identified as a target organ for inhalation exposures and the liver was identified as a target organ for oral and inhalation exposures. The lack of recognition by an international agency for carcinogenicity, genotoxicity and/or reproductive/developmental toxicity should not be considered the final word to determine human health priority for D5 and D6 given that other jurisdictions recognize the impacts of these substances in the laboratory settings (e.g. Dutch government). Since D4, D5 and D6 are similar in structure and the assessors have used D4 and D5 as analogues to determine toxicity of exposure in the assessment of D5 and D6, respectively, it is appropriate and consistent to apply a precautionary approach when considering the human health priority determination with respect to D5 and D6.

Data from 2006 indicated that these cyclic siloxanes were not manufactured in Canada in quantities in excess of 100kg. D4 and D6 are imported in quantities ranging from 100 to 1,000 tonnes but D5 was imported in larger quantities, from 1,000 to 10,000 tonnes. In 2005, Canada was a net importer of 11,500 tonnes of all types of silicone polymers and siloxanes. The rates of increased usage of these substances since 1986 have been significant and should be given careful consideration when making final conclusions in the assessment results and development of management measures. Particular emphasis should be given to ensure that D5 isn't considered as a potential replacement for D4.

D4, D5 and D6 are all used extensively in the manufacture of silicone polymers and copolymers either as raw materials or as intermediates with all polymers containing trace amounts of cyclic siloxanes. They are also used as surfactants (surface acting agents) and defoamers. A mixture with varying levels of low molecular weight, volatile cyclic siloxanes such as D4, D5 and D6, are the principal components of polydimethylcyclosiloxane (CAS RN 69430-24-6), termed cyclomethicone in the cosmetics industry. In 1986, 2,220 tonnes of cyclomethicone were reported in commerce in Canada and most likely, that figure has since increased. The knowledge that D4, D5 and D6 are found in the polydimethylcyclosiloxane should be considered additional evidence that these substances may have synergistic and cumulative implications that are not considered in the assessment results. In fact, the impacts to the environment and human health from these substances would not be addressed comprehensively should measures only target specific siloxanes. A management approach that includes targeting D4, D5, D6 and polydimethylcyclosiloxane (CAS RN 69430-24-6) is necessary in this regard.

In Canada, approximate figures for the presence of these cyclic siloxanes in cosmetics are: D4 -100, D5 - 3,000, D6 - 530, and cyclomethicone - 6,000. These figures indicate the widespread use of these substances in consumer products indicating that exposure can be through inhalation, ingestion or dermal routes. The assessors estimated that at least 90% of D4, D5 and D6 used in cosmetics evaporate into the atmosphere. Though significant, is it recognized that the content of cyclosiloxanes in any individual product may be low but the accumulated amount may be significantly higher because of the number of products used on any one day and the cumulative amount during our life.

Silicone polymers are used extensively in varying concentrations in commercial and consumer products, as previously mentioned. Silicone polymers are used in products such as skin and hair products; antiperspirants and deodorants; cleaners and detergents; polishing compounds; coatings and specialty coatings (high heat); carpets; textiles; barrier materials; paper; heat transfer and dielectric fluids; pesticides; pharmaceuticals; sealants and adhesives; encapsulation compounds; medical and dental devices. Although this is not an exhaustive list of uses, it does indicate the diverse use of D4, D5, D6 and the silicone polymers based on these cyclic siloxanes.

D4 is a major component of cyclomethicone (CAS RN 69430-24-6), and it is also present in dimethicone – PDMS (CAS RN 63148-62-9) in a concentration up to 3%. Releases from these compounds are not known since they were not included in the survey conducted under the Industry Challenge. This data gap in the draft assessment is significant. Given the diversity of products containing these substances and the large quantity of cyclic siloxanes in use in Canada, the absence of this data could potentially result in risk management proposals that are less restrictive and less protective to human health and the environment. This could also negatively impact on the government's decision when determining if these substances meet the criteria of toxicity under CEPA section 64.

D4, D5 and D6 releases are not reported as part of Environment Canada's National Pollutant Release Inventory (NPRI). Because of their high volatility, releases are to the air but mainly from D5 and D6 (approx. 65%) since most of D4 (80%) is chemically converted in processing. There are also releases to water via consumer use and industrial processes and via D4, D5, D6 containing products in landfills, residual sludge from treatment processes which can eventually get transported to landfill sites, incinerators or agricultural soils. These releases have not been addressed. Again, these are significant gaps in the assessment that should be addressed in the finalization of the assessment results. CEPA section 71 should be applied to require industry to provide this missing information. The absence of this information will influence the quality and extent of the risk management to be determined for these substances.

The assessment reports also indicate that these substances have been detected in air, STP influent and sediments in Canada including the Great Lakes region. This information would be consistent and support claims that siloxanes are considered substances of emerging concerns in the Great Lakes basin.[3]

D4, D5 and D6 are persistent in air, water and soil with a high potential to accumulate in aquatic organisms. D5 and D6 have some potential to biomagnify in terrestrial food-chains. All appear to behave like persistent organic pollutants (POPs). They have the potential to travel long distances with D4 having the longest range but modeling data suggest that transfer efficiency for these substances have "high potential for travel in the atmosphere without being deposited to Earth's surface in any particular remote region…"[4] Furthermore, it is suspected that D4 will have "low Arctic contamination potential." The assessment report does not provide details on where these siloxanes will deposit. There is a lack of Canadian data to quantify these claims but Norwegian studies show that these substances bioaccumulate in fish livers and other marine life. Despite the assessments claim that arctic communities would not be a target region for these siloxanes, they remain a significant concern to our northern communities as their characteristic properties suggest that they may pose a threat to their environment, lifestyle and health. The evidence of bioaccumulation and biomagnification are areas that warrant further investigation, assessment and management by the Canadian government.

The characteristics of D4, D5 and D6 support the need to consider action under the Stockholm Convention on Persistent Organic Pollutants (POPs). Based on data presented in the assessment report, D4, D5, D6 meet the criteria for persistence, bioaccumulation, long range transport potential and demonstration of adverse effects as outlined in Annex D of the Stockholm Convention on POPs required to nominate substances.[5] Since D4, D5 and D6 are found in varying proportions in both

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[3] See presentations by Derek Muir and Philip Howard to the Great Lakes Binational Toxic Strategy Meeting June 2-4, 2008 in Burlington, Ontario.

[4] Environment Canada and Health Canada. Draft Screening Assessment for Cyclotetrasiloxane, octabmethyl-(D4) (CAS # 556-67-2, May 2008, p.19.

[5] See Annex D under the Stockholm Convnetion on Persistent Organic Pollutants outlining criteria for persistence, bioaccumulation, long range trasprot and adverse effects.
http://www.pops.int/documents/meetings/poprc/about/AnnexD_e.pdf

cyclomethicone (CAS RN 69430-24-6), and dimethicone – PDMS (CAS RN 63148-62-9) these siloxane mixtures should also be considered for action under the Stockholm Convention on POPs.

The sheer volume and diversity of use of these cyclic siloxanes and their blends, polymers and copolymers, should have warranted a mention of occupational health in the draft assessment documents. This is another critical gap in the draft assessments. These substances are very volatile and contaminate their surroundings quite easily – hence the difficulty in getting accurate blanks for testing. Because of the potential for D4 to be a reproductive toxicant, and the similarities of D4 to D5 and D6, the final assessment should include estimates of exposure of workers to these substances.

Similarly, the assessment report lacks consideration of exposure and toxicity data to children and the chemically sensitive population. The absence of this information brings into question the adequacy of the conclusion made by the government that these substances are not a priority concern for human health. The government assessment of substances conducted under the Chemicals Management Plan should be including the consideration of impacts of exposure to these substances to the most vulnerable subpopulations.

The draft screening assessment reports propose that D4, D5 and D6 are entering or may be entering the environment in a quantity or a concentration or under conditions that have or may have an immediate or long-term harmful effect on the environment or its biological diversity, but are not entering the environment in a quantity or concentration or under conditions that constitute a danger in Canada to human life or health.

The draft screening assessment reports also propose that D4, D5 and D6 meet the criteria for persistence and bioaccumulation, as defined by the *Persistence and Bioaccumulation Regulations* made under CEPA 1999. The presence of D4, D5 and D6 in the environment results primarily from human activity.

The risk scoping document suggests that consideration will be given to the reduction of D4, D5 and D6 releases that may occur at the point of disposal or recycling. Also, D4, D5 and D6 will also be considered for environmental monitoring under the Chemicals Management Plan program. This data would provide the basis for the understanding of transport range, exposure levels, trends for these substances in the environment, and human health effects or trends thereby allowing appropriate actions to be taken for management or virtual elimination. Details of these considerations were not provided.

The health assessment results and the gaps identified in the ecological assessment suggest that an elimination or prohibition strategy for these substances is appropriate to effectively protect the health and environment of Canadians.

Recommendations

17. We support the draft screening assessment reports that propose D4, D5 and D6 are entering or may be entering the environment in a quantity or a concentration or under conditions that have or may have an immediate or long-term harmful effect on the environment or its biological diversity.
18. We do not support that D4, D5 and D6 are not entering the environment in a quantity or concentration or under conditions that constitute a danger in Canada to human life or health. Considering the quantities of these substances used; the diversity of product use; in particular, use in cosmetic products, evaporation; rates, toxicity of D4; similarity of structure of D4 to D5 and D6, we recommend that all the siloxanes are entering the environment at a concentration that could constitute a danger to the health of Canadians.
19. Based on the above, the government should consider D4, D5 and D6 to be toxic under CEPA Section 64.
20. D4, D5 and D6 should be added to CEPA Schedule 1 (Toxic Substances List).
21. There is agreement that D4, D5 and D6 are persistent and bioaccumulative. There is evidence for the inherent toxicity of D4 and limited evidence for D5. However, given the chemical similarities to D4, further evaluation could possibly indicate that D5 and D6 are similar to D4 for toxicity. Using a precautionary approach, we recommend that D4, D5 and D6 as well as cyclomethicone (CAS RN 69430-24-6), and dimethicone – PDMS (CAS RN 63148-62-9) should be targeted for elimination or prohibition in industrial and personal/consumer products. Since these products are used extensively in personal and cosmetic products, these substances should be added to the Prohibition of Certain Toxics Substances Regulations under CEPA. To implement this regulation, an action plan for ultimate elimination with clear timelines should be developed for these substances. A stakeholder process to identify and assess the toxicity of safer alternatives to D4, D5 and D6 should be an important element for elimination. For those uses where substitutes have not been developed a one time-limited exemption may be granted to ensure that research and development of alternatives are in place.
22. D4 is a suspected reproductive toxicant. We recommend that D4 be prohibited from use in all cosmetics and personal care products particularly since they are used by pregnant women, women of child bearing age and children. Furthermore, since uses of D5 and D6 are similar to D4, their uses should not be considered as adequate substitutes for D4 in cosmetics and personal care products. As noted in the previous recommendation, D5 and D6 should be considered for ultimate elimination as part of an action plan.
23. We recommend that D4, D5 and D6 be added to Canada's cosmetics 'Hotlist' as ingredients that should be prohibited for use.
24. As previously mentioned, data gaps exist in the draft assessments for the siloxanes that are relevant to decision making in the assessments and the proposed risk management. CEPA section 71 should be applied to collect needed data from industry for cyclomethicone and dimethicone usage, leaching rates, incineration activities, scrap metal yards, worker exposure, exposure in northern communities and exposure to children.

25. Long range transport models suggest that these substances exceed the threshold for distance considered for long range transport. We are very concerned that the proposed assessment report takes great length to outline that these substances have the potential to travel long distances from their sources but the impacts to the northern communities is not expected to be significant. Despite the absence of information on where these substances are expected to land, these substances will deposit in various locations far from its original source. Due to their persistent and bioaccumulative nature some impact to the environment and health of wildlife communities and the surrounding populations may result. The assessors should avoid making such general comments and provide the necessary detail to determine the fate of these long range transport substances.
26. As part of the proposed environmental monitoring for D4, D5 and D6 under the Chemicals Management Plan, we propose the following monitoring programs: workers in plants that use high levels of these substances, particularly D4; children using personal care products containing these substances and northern communities.
27. Because of the significant presence of D4 in cyclomethicone (CAS RN 69430-24-6) and its presence of up to 3% in dimethicone (PDMS) (CAS RN 63148-62-9), these two compounds should have been assessed for siloxane releases. For a more accurate picture of environmental exposures from all three cyclic siloxanes, releases from cyclomethicone and dimethione should be included in the final assessments.
28. Given the persistence and bioaccumulative nature of these substances and the understanding that D4, D5 and D6 releases may occur at the point of disposal or recycling, the application of safe substitution, the goal of elimination or a gradual phase out of these substances for their non-essential use is eminent and essential. The government should carefully incorporate measures to address elimination of releases of these substances to landfills, treatment plant waste and incinerators as they are also sources of contamination from these persistent substances.
29. In its management options, the government should prohibit the application of sewage sludge contaminated with D4, D5, D6 and cyclomethicone (CAS RN 69430-24-6), and dimethicone – PDMS (CAS RN 63148-62-9) to agriculture land because of its impact on crops as well as groundwater contamination.
30. The government should work with industry to determine the feasibility of the reduction of residual cyclic siloxanes in polymers.
31. Based on the proposed assessment results D4, D5, D6, cyclomethicone (CAS RN 69430-24-6), and dimethicone – PDMS (CAS RN 63148-62-9) should be considered for nomination by Canada to the POPs Review Committee under the Stockholm Convention on POPs. These substances are used in significant quantities, particularly in import volumes, meet the criteria for persistence, bioaccumulation, toxicity and meet the long range transport potential as required under Annex D of the Stockholm Convention on POPs.

Acetic acid ethenyl ester (CAS RN 108-05-4)

Results from categorization CEPA section 73

Vinyl acetate, CAS RN 108-05-4, was identified in the categorization process as having a high priority as it was considered to pose the greatest potential for exposure to individuals in Canada (GPE). It was also classified by another agency on the basis of carcinogenicity. It was determined that vinyl acetate did not meet the ecological categorization criteria for persistence, bioaccumulation potential, or inherent toxicity to aquatic organisms hence the draft screening focused on the effects of vinyl acetate on human health.

Highlights and commentary from draft assessment report

Vinyl acetate, the most important vinyl ester, is an industrial chemical, a monomer precursor, that is utilized in the manufacture of polymers and copolymers from which various products are made. According to 2006 statistics, it was not manufactured in Canada in quantities greater than 100kg. In Canada, imports average at least 10,000 tonnes annually with almost all of the vinyl acetate being used for (co)polymers in the manufacture of products such as packaging and construction adhesives, water-based coatings, adhesives, flexible food packaging and other industrial, commercial and consumer products.

Vinyl acetate releases are reportable under Environment Canada's National Pollutant Release Inventory (NPRI). The majority of releases are from industrial manufacturing within the province of Alberta accounting for 90% of the total emissions to ambient air. For Canada: releases to ambient air - 110 tonnes, other releases to land - 1.25 tonnes and off-site releases and disposal - 96 tonnes. These releases as reported by NPRI are in agreement with reported releases from the submissions made under Section 71 of CEPA 1999, for 2006.

We are pleased to see that the assessment reports rely on the pollution release data collected through the NPRI. However, the NPRI only offers one source of release data – only for those facilities that meet the reporting threshold under NPRI. The assessment report doesn't indicate whether facilities reporting to the Industry Challenge surveys included other data for vinyl acetate releases in addition to NPRI data. Are there facilities that do not meet the NPRI reporting threshold but release vinyl acetate?

It is important to have a comprehensive understanding of the life cycle of vinyl acetate – what percentage is lost in production processes, how much is contained in consumer products and what type of by-products are produced from vinyl acetate. This data is important for understanding the impact to the environment or human health.

From the International Agency for Research on Cancer (IARC), the risk to human health from vinyl acetate exposure is carcinogenicity. Vinyl acetate is rapidly transformed into

acetaldehyde in human blood and animal tissues and IARC claims that there is sufficient evidence in experimental animals for the carcinogenicity of acetaldehyde. Vinyl acetate inhalation resulted in tumours of the nasal cavity in male and female rats. Squamous cell carcinomas of the upper digestive tract in both sexes of mice and rats were observed following oral exposure to vinyl acetate. Vinyl acetate was also found to be genotoxic in human cells in vitro and in vivo.

Products manufactured from vinyl acetate based polymers and copolymers have residual, unreacted vinyl acetate present which can get released. Human exposure to vinyl acetate is mainly from commercial and industrial products, food contact plastics, food packaging, adhesives, cosmetics, personal care products, pesticides, coatings, among other products. The primary route of exposure appears to be inhalation from residual vinyl acetate in products. Vinyl acetate has a high vapour pressure.

In Canada, consumer products using these polymers contain residues of unreacted monomer (vinyl acetate) less than 10,000 ppm for plastics and less than 5,000 ppm for paints and adhesives. Exposure may also result from living in close proximity to a facility using vinyl acetate, waste transfers or landfills. There is no Canadian data on concentrations of vinyl acetate in ambient air, indoor air, drinking water or food; some studies indicate that indoor air is the main environmental source of exposure.

Vinyl acetate is permitted in pesticides and is also present in some registered pesticides as a list 2 formulant at 0.009 -1.75% where it functions as a binder, sticker or spreader. Product labeling for pesticides does not indicate its presence and neither is there any obligation to do so.

In Canada, vinyl acetate is not classified as a food additive but vinyl acetate containing adhesives are applied to food packaging cover seams and surfaces and generally do not come into direct contact with foods. Ethylene vinyl acetate copolymers and polyvinyl acetate polymer derived plastics are approved as food contact plastics; some migration of vinyl acetate is expected from them. Under European Union regulations, a maximum migration of vinyl acetate from articles us 12 mg/kg and the allowable maximum daily intake is 0.2 mg/kg of body weight.

Polyvinyl acetate made from vinyl acetate, is the basis of most chewing gums on the market and traces of vinyl acetate are possible in these products. This information was not mentioned in the draft assessment. This gap in information in oral exposure is significant. CEPA section 71 should be applied for industry to provide this missing information or provide clarifying information to confirm if this application of vinyl acetate is undertaken in Canada. The absence of this information could influence the assessment and risk management outcomes for this substance.

Under the Canadian *Food and Drug Act*, vinyl acetate is neither a prohibited or restricted cosmetic ingredient on the cosmetics ‘Hotlist’. It is used in cosmetics and personal care products as a film former and is found in several hair grooming products, eye makeup preparations and in one nail polish product. These products are a potential

source of exposure to vinyl acetate through inhalation and dermal contact In data from the draft screening, the maximum exposure (dermal and inhalation) of total vinyl acetate exposure is 0.07 mg/kg-bw/day for all cosmetic products with a low degree of confidence in this modeling result. Again, CEPA section 71 should be applied for industry to provide the levels of free vinyl acetate in these consumer products. Furthermore, the assessment should consider the cumulative impact to vinyl acetate from exposure from the number of consumer products containing vinyl acetate. It would appear prudent that vinyl acetate be listed on the cosmetics 'Hotlist' with the appropriate actions resulting in its removal from cosmetics and personal care products.

As previously mentioned, there is no Canadian monitoring data on vinyl acetate. Inhalation of indoor residual levels of vinyl acetate in consumer products is the main route of exposure for the Canadian general population. Not mentioned is the possible difference in exposure levels for Canadians who live in colder regions as compared to those who live in the warmer regions of the country. Because of the lack of Canadian indoor air monitoring data, it is not known if this difference is significant.

The draft risk assessment concluded that the health of Canadians could also be at risk due to potential short-term exposure in the vicinity of industrial facilities releasing vinyl acetate to ambient air. Without the appropriate monitoring data, excluding NPRI statistics, this may not be totally accurate. There is the possibility that the exposure could be categorized as chronic with varying but undetermined concentration levels. It is important to reiterate that the risk to human health is carcinogenicity and there is the probability of harm to human health at any level of exposure.

Under Appendix 1 of the draft assessment report,[6] estimates of exposure to vinyl acetate for different age groups are provided. As previously mentioned, data gaps exist for drinking water, food and soil sources. This data gap is significant particularly when considering the impacts of exposure to specific vulnerable populations such as children, low income communities and people with chemical sensitivities. The total estimate exposure level may be underestimated due to these data gaps.

Occupational exposure to vinyl acetate was not included in the draft assessment. Its high vapour pressure makes inhalation of the vapours very probable in the workplace. There is also skin contact. The risk to human health from vinyl acetate exposure is carcinogenicity. If not monitored in Canadian workplaces, data from other countries could have been presented in the draft assessment. Because of the widespread use and health risks associated with vinyl acetate, including this data in the final assessment would give a more complete picture of exposure for Canadians.

The draft assessment concluded that vinyl acetate may be entering the environment in a quantity or concentration or under conditions that constitute or may constitute a danger in Canada to human life or health. This was based on applying a precautionary approach, carcinogenicity data, the probability of harm at any level of exposure and the

[6] Environment Canada and Health Canada. Draft Screening Assessment for Vinyl Acetate (108-05-4). May 2008. p. 26.

potential inadequacy of the margins of exposure for non-cancer effects. Vinyl acetate does not meet the criteria in paragraph 64(a) and 64(b) of CEPA 1999, but it does meet the criteria in paragraph 64(c) of CEPA 1999.

From the risk scoping document, if the final risk assessment is in agreement with the above, risk management would focus on the potential for releases of vinyl acetate from adhesives, paints and plasters, cosmetics and personal care products. However, the document does not provide explicit commitment to phase out and prohibit the use of vinyl acetate from these products. Similarly, the draft risk management report does not commit to establish a stakeholder process that aims to assess the suitability of safer alternatives to vinyl acetate. Other possible management considerations mentioned included measures to decrease industrial emissions of vinyl acetate to the environment and to maintain the low residual level of vinyl acetate in consumer products. The phrase 'maintain the low residual level of vinyl acetate in consumer products' proposed by the government is not well understood. To reduce residual vinyl acetate levels to negligible concentrations in consumer products, that is, to have concentrations significantly lower than present concentrations, may not be technically feasible. Furthermore, an attempt to determine what the 'safe level' is for vinyl acetate would be in contradiction with the probability that there is no safe level of exposure for this carcinogenic substance. A phase out of this substance in consumer products would be more beneficial to the health of Canadians.

The risk scope document also indicated that at present, use-patterns or pathways are not being considered for additional investigation or risk management for products including flexible food packaging, pest control products, laminated steel, fuel additive and hydraulic and lubricant oils. This approach is inadequate given the extensive uses for vinyl acetate. In particular, the government should take necessary steps to ensure that these substances be prohibited from contact with any food products through packaging.

The draft risk assessment proposed that on the basis of ecological hazard and reported releases of vinyl acetate, it is not entering the environment in a quantity or at a concentration under conditions that have or may have an immediate or long-term harmful effect on the environment or its biological diversity on which life depends.

Recommendations

32. We recommend that vinyl acetate be classified as CEPA toxic in support of the weight-of-evidence assessment of the International Agency for Research on Cancer (IARC) for vinyl acetate. A critical effect for characterization of risk to human health for vinyl acetate is carcinogenicity and it is assumed that there is a probability of harm to human health at any level of exposure.
33. We recommend that vinyl acetate be added to CEPA Schedule 1 (Toxic Substances List).

34. Based on the carcinogenicity of vinyl acetate, the government should aim to phase out the use of vinyl acetate in consumer products and industrial applications. An action plan for phase out with clear timelines should be established to allow for identification and assessment of safer alternatives that do not exhibit the same human health effects as vinyl acetate.
35. The government should apply CEPA section 71 for industry to provide the levels of free vinyl acetate in all consumer products.
36. In keeping with the recommendation to phase out vinyl acetate, we recommend that vinyl acetate be prohibited from use in cosmetics and personal care products and replaced with safer alternatives.
37. We recommend that vinyl acetate to be added to Canada's cosmetics 'Hotlist' under the *Food and Drug Act*, as a prohibited substance for use in cosmetics and personal care products.
38. In keeping with the recommendation to phase out vinyl acetate, we recommend that vinyl acetate be prohibited from food packaging. The government should establish a stakeholder process to identify a safer polymer for food packaging to ensure the protection of human health.
39. There should be no free vinyl acetate in chewing gum; safer alternative products are available on the market. Should these substances be used in manufacture of chewing gums in Canada, appropriate exposure levels from free vinyl acetate be estimated and included in the final assessment report.
40. We recommend that the government establish a stakeholder process with adequate resources to assess safer alternatives to vinyl acetate polymers used in adhesives, paints and plasters, pesticides and other non-essential commercial and consumer products. This process should include an investigation of the use of other existing polymers that when formulated, will meet all the physical and chemical properties required for the specific product.
41. The government should consider changes to or introduction of labeling of all commercial and consumer products with free vinyl acetate – labels should indicate its presence and the health risks associated with it. Some industrial products may have this data on their material data sheets but may only list it, depending on the concentration in the formula.
42. It is costly and not practical to identify only one volatile substance in an indoor (residential) and outdoor air quality survey. To fill this data gap as mentioned in this report, we suggest that vinyl acetate be added to the list of substances to be monitored as one of the volatile organic compounds in an indoor residential air quality and outdoor air quality study. This should be a longitudinal survey done during the winter when air contaminants are at their highest concentrations in indoor air. Such a study would allow for a more complete and accurate risk assessment and risk management for vinyl acetate since the primary route of exposure appears to be inhalation (indoor air) from residual vinyl acetate in consumer products.
43. Occupational exposure is as important as non-occupational exposure to industrial chemicals. The final risk assessment for vinyl acetate should include data on occupational exposure and measures to reduce occupational exposure in the final risk management.

44. We recommend that the government require mandatory pollution prevention planning for all industries using, releasing or transferring vinyl acetate and raw materials using vinyl acetate, to promote reduction and releases of these substances. To support these reductions efforts, the NPRI reporting thresholds should be revised to lower reporting thresholds.
45. We support the draft risk assessment conclusion that the health of Canadians could also be at risk due to potential short-term exposure in the vicinity of industrial facilities releasing vinyl acetate to ambient air. There is disagreement with the assumption that exposure could be short-term. There is a possibility that some of these exposures could be chronic with variable levels of exposure to vinyl acetate, keeping in mind, the relatively short half-life of this substance (ten - fifteen hours).
46. In Canada, data gaps exist for drinking water, food and soil sources. This data gap should be addressed in the final risk assessment with specified timelines. Exposure data sets need to be more complete and specifically consider vulnerable populations including children, low income communities and people with chemical sensitivities. The total estimated exposure level may be underestimated due to these data gaps.

Concluding Comments

The above comments and recommendations presented by the CSM and CELA focus on six specific substances: C.I. Pigment Red 104 – CAS RN 12656-85-8; C.I. Pigment Yellow 34 – CAS RN 1344-37-2; Cyclotetrasiloxane, octamethyl (D4) – CAS RN 556-67-2; Cyclopentasiloxane, decamethyl (D5) – CAS RN 541-02-6; Cyclohexasiloxane, dodecamethyl (D6) – CAS RN 540-97-6; and Acetic acid ethenyl ester - CAS RN 108-05-4. Based on the government's proposal that all selected substances meet the one or more criteria outlined under section 64 of CEPA, our organizations highlighted our support for this conclusion and the need to add these substances to schedule 1 of CEPA. We outlined 46 recommendations to the government on these 6 substances which would result in the protection of human health and environment.

The addition of these substances to CEPA schedule 1 will trigger the development of management regimes. We urge the government to develop regimes that call for the elimination of those substances that are found to be carcinogenic as in the case for C.I. Pigment Red 104 (CAS RN 12656-85-8), C.I. Pigment Yellow 34 (CAS RN 1344-37-2) and Acetic acid ethenyl ester (CAS RN 108-05-4); or are persistent, bioaccumulative, inherently toxic in the case of the three siloxanes-D4,D5, D6. An integral component for phase out of these substances is the need to establish a stakeholder process that would begin to identify and assess the alternatives available to these substances.

CELA and CSM also indicated the need to address specific gaps that exists in these assessments including comprehensive consideration of exposure to vulnerable populations including children, pregnant women, people with low income and people with chemical sensitivities. A revised survey conducted under Section 71 of CEPA as outlined under the Industry Challenge of the Chemicals Management Plan would be an appropriate tool to require this information.

Similarly, exposure data for specific environmental media is also critical to the assessment results. Industry should be required to supply this information for review by government. In the absence of this data, the precautionary principle should apply when making decisions on toxicity as well as management measures.

Our organizations also noted that the assessments lacked a focus and consideration of cumulative impacts of these substances to both environment and human health.

Finally, with the understanding that these six substances have wide ranging applications both in industrial applications and consumer products, we made several recommendations focused on the need to eliminate the use of these substances in consumer and personal care products.

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