A Response to Draft Risk Assessment Results for Chemicals Management Plan Industry Challenge Batch 3 Substances Published in *Canada Gazette* Part I, Vol. 142, No. 34 — August 23, 2008

Submitted to:
Science and Risk Assessment Directorate and Chemical Sectors Director
Environment Canada

Safe Environments Programme
Health Canada

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Introduction

Canadian Environmental Law Association (CELA) and Chemical Sensitivities Manitoba (CSM) are submitting the following comments in response to the *Canada Gazette* Vol. 142, No. 34 — August 23, 2008 release of the draft risk assessment and management reports for substances identified under the Chemicals Management Plan, Batch 3 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 *Canadian Environmental Protection Act* (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.

General comments

Our respective organizations and other Canadian non-governmental organizations have submitted substantial comments on assessment results and proposed management options for Batch 1 and Batch 2 substances including preliminary comments on Bisphenol A. In those comments, we have expressed concerns with regard to specific gaps in the assessment process as well as the proposed management measures for these substances. Many of these concerns are relevant to Batch 3 substances and will be reiterated throughout this document.

We are summarizing a few of these issues for your further consideration and response as they relate to the substances covered under Batch 3.

1) Investigating and responding to the cumulative and synergistic impacts of these substances on human health and the environment and, in particular, those substances to which there is chronic exposure by the general public;
2) Require from industry through the surveys , specific toxicity data (i.e. neurodevelopmental toxicity and endocrine disruption) to complete the assessments;
3) Investigate the full life cycle of these substances, including consideration of exposure and leaching potential of these substances and their break down products in the disposal methods;
4) Disclosure of information on substances gathered through the Industry Challenge and how this information was used to complete the assessment and development of proposed management tools. The limited transparency in this area and the absence of data undermines the quality of the assessment or proposed management decisions made by government.
5) The absence of consideration of occupational exposure to substances is an area that should be revisited by government. Workers are at the front line of exposure and have provided important information on potential impacts to the general public. While we recognize that occupational health is not currently considered under CEPA, the quality of assessments undertaken are significantly affected. 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 strategy on these substances should take account of these situations and ensure that management steps are protective and preventative.
6) Because of the potential of some substances in Batch 3 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. All potential health risks should also be identified in the MSDSs. This information should be included in the assessment reports.

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

A) Substances identified during categorization as persistent, bioaccumulative, and inherently toxic to non-human organisms and believed to be in commercial use in Canada

The fifteen 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 it is believed they are in commerce in Canada. These substances do not satisfy the criteria for being CEPA 'toxic' with the exception of Pigment Red 3 - CAS RN: 2425-85-6, a decision that was made based on its human health toxicity not its ecological criteria.

Chemical	**CAS RN**	**Proposed finding under CEPA Section 64**
Benzenesulfonamide, *N*-(4-amino-9,10-dihydro-3-methoxy-9,10-dioxo-1-anthracenyl)-4-methyl- (Disperse Red 86)	81-68-5	No
9,10-Anthracenedione, 1-hydroxy-4-[[4-[(methylsulfonyl)oxy]phenyl]amino]-(Disperse Violet 57)	1594-08-7	no
2-Naphthalenol, 1-[(2-chloro-4-nitrophenyl)azo]-(Pigment Red 4)	2814-77-9	No
2-Naphthalenol, 1-[(2,4-dinitrophenyl)azo]-(Pigment Orange 5)	3468-63-1	No
1-Propanaminium, 3-[[4-[(2,4-dimethylphenyl)amino]-9,10-dihydro	60352-98-9	No
9,10-Anthracenedione, 1-[(5,7-dichloro-1,9-dihydro-2-methyl-9-oxopyrazolo[5,1-b]quinazolin-3-yl)azo]-	74336-60-0	No
2-Naphthalenol, 1-[(2-nitrophenyl)azo]-(Pigment Orange 2)	6410-09-9	No
2-Naphthalenol, 1-[(4-chloro-2-nitrophenyl)azo]-(Pigment Red 6)	6410-13-5	No
2-Naphthalenecarboxamide, *N*-(5-chloro-2,4-dimethoxyphenyl)-4-[[5-[(diethylamino)sulfonyl]-2-methoxyphenyl]azo]-3-hydroxy-(Pigment Red 5)	6410-41-9	No
2-Anthracenesulfonic acid, 4,4'-[(1-methylethylidene)bis(4,1-phenyleneimino)]bis[1-amino-9,10-dihydro-9,10-dioxo-, disodium salt (Acid Blue 127)	6471-01-8	No
9,10-anthracenedione, 1,8-dihydroxy-4-nitro-5-(phenylamino)-(Disperse Blue 77)	20241-76-3	No
Peroxide, [1,3(*or* 1,4)-phenylenebis(1-methylethylidene)]bis[(1,1-dimethylethyl)	25155-25-3	no
Benzenesulfonic acid, 3-[[4-amino-9,10-dihydro-9,10-dioxo-3-[sulfo-4-(1,1,3,3-tetramethylbutyl)phenoxy]-1-anthracenyl]amino]-2,4,6-trimethyl, disodium salt (Acid Violet 48)	72243-90-4	No
2-Naphthalenol, 1-[(4-methyl-2-nitrophenyl)azo]-(Pigment Red 3)	2425-85-6	Yes
9,10-Anthracenedione, 1-amino-4-(phenylamino)-	4395-65-7	no

General issues related to assessment for substances that are PBiT

The following comments were highlighted in our submission dated September 3, 2008 in response to the final assessment reports for Batch 1 substances under the Industry Challenge. Specifically, these comments reflect concerns we have on substances originally found to be persistent, bioaccumulative and inherently toxic through categorization. These general comments were made for Batch 1 substances that are found to be PBiT but we think that they are also relevant for Batch 3 substances. We urge you to consider them in the context of the draft assessments completed for Batch 3 substances.

1) Timing of data - Industry has been provided with ample time to generate data on these substances, we question why the identification and use of analogues were not used prior to finalizing the decisions on these substances.

2) Role of Expert Panel in final decision - The Expert Panel on Precautionary Principle and Weight of Evidence was given the mandate to advise the government on the proposed decisions for these substances. It is unclear through the assessment reports whether there was discussion among the expert panel on the application of analogues to make a determination on persistence, bioaccumulation and inherent toxicity.

3) **Application of analogues** – We question the use of analogues to make a determination on persistence, bioaccumulation or inherent toxicity, in particular during the phases of the assessment process when the opportunity to identify analogues was available during categorization. In some cases, the rationale and the information to demonstrate the chemical structure for the analogue was not provided in an adequate manner. This is a significant gap in the risk based approach. Furthermore, some of the assessment reports did not highlight other possible analogues for consideration and provide specific rationale on why the analogues used were the most appropriate. It is important to understand when analogues should be selected and utilized. According to the government response to public comments, the analogues for pigments were selected by industry. The public needs to be provided with the information necessary to understand the criteria applied by the government in supporting the analogues proposed by industry.

4) Results on inherent toxicity - The use of analogues for either persistence or bioaccumulation automatically results in a reconsideration of inherent toxicity. A shift in the decision on inherent toxicity for these substances would result in “no further action” required under section 77. The use of analogues to replace the use of QSAR models should be discussed in a fulsome way. This approach causes great confusion for the public interested in responding to the government assessment results. Furthermore, it demonstrates a significant flaw in the risk based approach which is rather subjective in nature.

5) Absence of further action – Further evaluation on the safety of these substances is warranted despite the government’s final decision that they are not considered toxic under CEPA s. 64. Simply targeting these substances for the DSL update is inadequate. In our view, government should aim to reduce the use of substances identified as being only persistent or only bioaccumulative in the environment. It is wholly inadequate to only require that these substances be part of the DSL inventory update initiatives.

Proposal for SNAc on three PBiT chemicals

For three of these PBiT substances with CAS RNs 4395-65-7, 60352-98-9 and 74336-60-0, the proposed conclusion of the draft screening assessments is that these substances be subject to the Significant New Activity (SNAc) provisions specified under subsection 81(3) of CEPA. Based on the Industry Challenge, no new data was submitted to review the designation of PBiT. Furthermore, there is concern that the Industry Challenge survey and the subsequent assessment on these substances did not account for uses or applications of these substances because of the established threshold of 100 kg/year. This is a gap in the government approach.

There is concern that these three substances being PBiTs could have new applications not currently assessed under CEPA 1999. This would ensure that any new manufacture, import or use of any of these substances, in quantities greater than 100 kg/year, be notified and will have to subjected to ecological and human health risk assessments as specified in section 83 of the Act, prior to the substance being introduced into Canada.

An appropriate response for these substances would be to designate them as CEPA toxic due to their PBiT properties. Further, these substances should be added to the Prohibition of Certain Toxic Substances Regulations, 2005, to 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.

Application of SNAc on these substances will not guarantee that the Canadian environment and human populations will not be exposed to these substances in the future. Therefore, any stakeholder interested in using these substances are required to notify the government and provide specific information based on intended volume. The government's proposal for SNAc does not include the type of information that will be required for assessment. Furthermore, the use of SNAcs on these substances does not allow the public to comment on any subsequent assessments.

Recommendations:

- CAS RNs 4395-65-7, 60352-98-9 and 74336-60-0 should be found toxic under CEPA, added to Schedule 1 of CEPA and added to the Prohibition of Certain Toxic Substances Regulations.
- CAS RNs 4395-65-7, 60352-98-9 and 74336-60-0 should not be flagged for SNAc since there is a lack of details by government on what type of data is required to be submitted and there is a lack of public comment period on any subsequent assessments conducted using SNAcs.

Due to time and resources, the level of comments on the chemicals meeting the PBiT criteria is limited to the following four substances. This does not reflect our lack of interest or the urgency needed to take action on these substances. The above comments reflect general comments that are relevant for assessments of PBiTs.

Comments on selected proposed PBiT chemicals

1) Benzenesulfonamide, N-(4-amino-9,10-dihydro-3-methoxy-9,10-dioxo-1-anthracenyl)-4-methyl- (Disperse Red 86): CAS RN - 81-68-5

Issues

We oppose the use of analogues to determine inherent toxicity to aquatic environment for Benzenesulfonamide, *N*-(4-amino-9,10-dihydro-3-methoxy-9,10-dioxo-1-anthracenyl)-4-methyl- (Disperse Red 86): CAS RN - 81-68-5. The use of two analogues (Disperse Blue 7 and Disperse Red 60) in the absence of experimental data or QSAR data for Disperse Red 86 is very questionable. The assessment report provides a list of analogues under consideration for this chemical (table 4 of assessment report). However, the assessment report fails to provide full justification on the suitability of the selected analogues for this substance. One analogue was used to determine and justify why Disperse Red 86 did not meet the bioaccumulation criteria. In the determination of inherent toxicity, several analogues and their experimental data were considered. While these analogues included experimental data for inherent toxicity, this is not adequate justification for using this data to indicate aquatic toxicity of CAS RN 81-68-5. In our view, this approach is not in keeping with the precautionary principle. The uncertainty around the decision on bioaccumulation and inherently toxic is questionable based on this approach.

Recommendations:

- We oppose the determination that Benzenesulfonamide, N-(4-amino-9,10-dihydro-3-methoxy-9,10-dioxo-1-anthracenyl)-4-methyl- (Disperse Red 86): CAS RN - 81-68-5 is not persistent, bioaccumulative and inherently toxic based on the use of several analogues to determine bioaccumulation and inherent toxicity.
- We urge the government to apply the precautionary principle in light of absence of experimental data for CAS RN - 81-68-5 and propose CEPA toxic for this substance. Furthermore, this substance should be placed on Schedule 1 of CEPA and targeted for Track 1, virtual elimination.
- Given the availability of analogues and their comparability to CAS RN 81-68-5, the selected analogue for this chemical should have been well defined at the onset of the assessment process. Furthermore, it should be appropriate to use one analogue that best reflect the structure and functionality of this chemical. This promotes better transparency in the decision making process of the assessment.
- The methodology for obtaining experimental data as undertaken for the analogues identified for this substance should provide guidance to generate experimental data for this chemical. The industry proponent interested in the use of this substance should be required to submit this information**.**

2) 2-Naphthalenol, 1-[(4-methyl-2-nitrophenyl)azo]-(Pigment Red 3): CAS RN: 2425-85-6

Issues

While Pigment Red 3, CAS RN 2425-85-6, was found to be PBiT and high human health priority, the draft assessment found that this substance no longer met the criteria for B and iT as required under CEPA for Virtual Elimination. However, through the human health assessment, this chemical meets criteria set out under section 64 of CEPA.

This pigment is one of the top 20 highest-produced organic pigments (by volume) in the world. Although this chemical is considered CEPA toxic, it is found in a several cosmetics and personal care products in Canada. Whether this pigment is used in children's toys was not specified.

The draft screening indicated that this pigment has the potential to degrade in anoxic waters and sediment and one breakdown product could be an aromatic amine that has mutagenic potential. Some azo pigments are restricted for use in Europe based on the potential release of these aromatic amines but there is uncertainty as to the breakdown products of this pigment.

Recommendations:

- We support the finding that 2-Naphthalenol, 1-[(4-methyl-2-nitrophenyl)azo]-(Pigment Red 3): CAS RN: 2425-85-6 is toxic under CEPA and the addition of Pigment Red 3 to Schedule 1 (Toxic Substances List).
- We object to the weak management options under consideration for this pigment. It is not sufficient nor protective to rely on "providing health and safety information and education materials for consumers regarding paint and coatings products". This places the burden on consumers and the general public to protect themselves from toxic substances.
- 2-Naphthalenol, 1-[(4-methyl-2-nitrophenyl)azo]-(Pigment Red 3): CAS RN: 2425-85-6 should be prohibited from use in all consumer products as well as in industrial applications based on its toxicity.
- We support the listing of Pigment Red 3 to the Cosmetic Ingredients Hotlist as a substance that should be prohibited. However, the Cosmetic Regulations should be strengthened to ensure the enforceability of the Cosmetic Hotlist.
- The draft screening should have included notation of the ban on the use of some azo pigments/dyes in Europe because some of these substances can have banned aromatic amines as breakdown products similar to those for Pigment Red 3. There is still uncertainty about the amines for Pigment Red 3
- We object to the lack of action proposed on plastics and pest control products on the basis of lack of evidence of concern to human health. Based on the uncertainty of the carcinogenicity of this substance, additional action on plastics and pest control

products are warranted. Furthermore, the limitations of the screening level risk assessment contribute to the lack of findings for this use pattern**.**

3) 2-Naphthalenol, 1-[(2-chloro-4-nitrophenyl)azo]-(Pigment Red 4), CAS RN 2814-77-9

Issues

We continue to find it difficult to assess whether the data provided in the assessment report was gathered through categorization or through the Industry Challenge. Furthermore, we question why the experimental log (Co/Cw) of Pigment Red 4 was used during assessment rather than during categorization. Similarly, the use of kinetic mass-balance and QSAR models to determine bioaccumulation is also being questioned. Were these data unavailable to the evaluators at the time of categorization? If not, why not?

The changes in solubility data have been problematic for this pigment as well as other chemicals in Batch 3. The solubility data for this chemical was defined during categorization by government with this data being instrumental in determining and confirming properties such as P, B, and iT. The changes that we have seen for many of these pigments, particularly in Batch 3, have significant impacts on the determination of bioaccumulation classification. Furthermore, there is a lot of uncertainty on why there was also a change in iT of these substances. Accurate solubility data is a fundamental data for any chemical. We are questioning why the log (Co/Cw) for all this and other pigment substances were not available during categorization.

The changes in information, particularly on the solubility of these pigments, demonstrate a clear lack of industry accountability for chemicals they have been using for decades. The confidence in government's process in making categorization decisions are is declining as it included significant level of industry-government exchange on these matters. We are concerned that the recent trends on "new" data being submitted through the Industry Challenge will continue to be seen for the rest of the chemicals identified under the CMP for high priority as well as medium priority substances. Such a trend is showing that not much action is required on these substances.

Recommendations:

- The government should apply rigorous requirements for industry to supply experimental data on toxicity for all substances under CMP on the basis that ample time was provided to industry to generate needed data on chemicals already in Canadian market.
- Based on the persistence of 2-Naphthalenol, 1-[(2-chloro-4-nitrophenyl)azo]-(Pigment Red 4), CAS RN 2814-77-9 and the moderate use of this chemical in Canada (up to 10,000 kg/year) and more importantly, the wide range of consumer products containing this chemical, management actions to reduce or eliminate its use is warranted, in particular for cosmetic products.

- The government should promote the use of safe alternatives to CAS RN 2814-77-9 on the basis of its extensive uses in consumer and cosmetic products such as eye makeup, lipstick and bath products.
- The government should require better accountability for the decisions made during categorization process, particularly with respect to determining the solubility of these substances. Only experimental data for the specific chemical should be considered adequate information for consideration during the screening level risk assessments.

4) 9,10-anthracenedione, 1,8-dihydroxy-4-nitro-5-(phenylamino)-(Disperse Blue 77) CAS RN 20241-76-3

Issues

Like the previous comments made on pigments, there remains a lot of questions on the change in solubility data and the use of analogues to make the determination on P, B and iT for this substance. The assessment report highlights that this substance has a low bioaccumulation potential and a moderate to low potential for inherent toxicity to aquatic organisms. However, it is unclear whether the information had been gathered through categorization process or during the Industry Challenge.

Furthermore, we are raising concerns that information on current use of this chemical has not been disclosed in the assessment reports because of confidential business information (CBI). The assessment report fails to provide adequate rationale as to why such information would constitute confidential information.

The assessment reports do not include health assessments. Regardless of the knowledge that this substance was found to be an ecological priority, the human health assessment should be included to demonstrate the level of information gathered to make a decision on human health hazard and potential for exposure. The absence of this assessment contributes to an incomplete assessment process.

Recommendations:

- Based on the persistence of 9,10-anthracenedione, 1,8-dihydroxy-4-nitro-5-(phenylamino)-(Disperse Blue 77)- CAS RN 20241-76-3, management options to reduce and eliminate its use is warranted, and, in particular, for textile application.
- As with other pigments assessed under Batch 3, the government should use the solubility information gathered through categorization to make determination of P, B, and iT. The government should only consider experimental data for the target chemical to consider changes in the decisions on P, B and iT.
- A further review on the use of CBI, particularly on the recent use patterns for a chemicals should be investigated. The lack of this information impacts the decision making process. It also provides a false impression that the public is not required to know how these chemicals are used in Canada.

Additional Recommendations on Proposed PBiTs

- Based on the persistence of these pigments, action to reduce these substances is warranted by government including the need to promote, develop and implement alternatives as well as reformulation of these substances to address persistence in the environment.
- Similarly, based on persistence of these substances, the government should focus and address the inadequacy of existing sewage treatment plants to handle these types of releases to the water system. Sewage sludge should not be applied to agricultural land to ensure that such substances are not released into the environment.

B) Substances identified during categorization as a high hazard to humans and as having a high likelihood of exposure to individuals in Canada

Substances:

- Ethanol, 2-methoxy-, acetate (2-methoxyethanol acetate, 2-MEA): CAS 110-49-6
- Ethanol, 2-(2-methoxyethoxy)- (Diethylene glycol monomethyl ether, DEGME) – CAS RN 11-77-3
- 1-Propanol, 2-methoxy, (2-Methoxypropanol)– *CAS RN* 1589-47-5
- Ethanol, 2-ethoxy-, acetate (2-EEA): CAS RN - 111-15-9

1) Ethanol, 2-methoxy-, acetate (2-methoxyethanol acetate, 2-MEA): CAS 110-49-6

Highlights from draft assessment and risk scope documents

2-MEA was considered to pose an intermediate potential for exposure to individuals in Canada and has also been classified by the European Commission on the basis of reproductive and developmental toxicity.

In the calendar year 2006, data collected under section 71 of CEPA 1999 indicated that 2-MEA was not manufactured in or imported into Canada by any company at a quantity greater than a reporting threshold of 100 kg. Some imports below the threshold were reported for an industrial cleaning product.

Data from Canada's National Pollutant Release Inventory (NPRI), 1994 to 2006, have reported no releases of 2-MEA (NPRI 2007). Therefore, total industrial releases of 2-MEA to the environment are expected to be negligible. Based on this information, Health Canada has considered the exposure of the general population in Canada to 2-MEA to be very low.

Data from toxicological studies in experimental animals and epidemiological investigations in occupationally exposed populations for 2-MEA and its ethanol

analogue, 2-methoxyethanol (2-ME), indicate developmental and reproductive toxicity, including severe and irreversible teratogenic effects associated with exposure. These effects have been observed at very low doses included the lowest tested dosage. Both of these substances also show some potential to interact with genetic material in germ cells. There is no available data with respect to the potential carcinogenicity or chronic effects of 2-MEA or 2-ME.

The draft risk assessment stated that although human exposure to 2-MEA may be low, the non-distinguishable human health hazard potential between MEA and 2-ME (namely reproductive and developmental effects) at any level of exposure, has resulted in the proposal of the Priority Substance List assessment for 2-ME be expanded to include its acetate moiety, 2-MEA. It has also recommended that 2-MEA be included in the Domestic Substances List inventory update initiative, to be launched in 2009. Furthermore, the PSL assessment of 2-ME resulted in the proposal to add the substance to the Prohibition of Certain Toxic Substances in 2005. According to the proposed listing for prohibition, "replacement of 2-ME is technically feasible in most if not all applications. …In consumer products, which pose the highest health risk, and in other uses such as anti-icing agent for jet fuel, 2-ME can be directly replaced by substitutes. Overall, substitution is considered to be technically feasible and economically achievable, given the market prices and relative performances of available substitutes." [1]

From data collected under section 71 of CEPA 1999, there is no evidence to indicate that 2-MEA is present in consumer products in Canada. There has been no notified current use of 2-MEA in cosmetics but its corresponding alcohol, 2-ME, is prohibited for cosmetic use in Canada (it is on Canada's Cosmetic Ingredient Hotlist). The Personal Care Products Council has noted that there are a few active suppliers of 2-MEA. Since 2-MEA is not used in consumer products in the United States and the European Union countries, it was concluded that it is not likely to be present in many Canadian consumer products. The assessment report does not mentioned if there is the possibility of 2-MEA to be present in consumer products including cosmetics, not manufactured in the above mentioned countries. The U.S. requires notification for any significant new use of 2-MEA and 2-ME.

In Canada, 2-MEA is allowed as one of the ingredients in cleaners for the food industry but in the case of direct food contact, it is rinsed off with water. For non-direct food contact, rinsing with water was not specified.

The most likely cited route of exposure to 2-MEA is from indoor consumer products but these exposures are not expected to be significant. Inhalation of 2-MEA during use of household solvent products containing the substance may also be possible.

The following are issues and recommendations related to 2-MEA.

[1] Regulations Amending the Prohibition of Certain Toxic Substances Regulations, 2005 (2-Methoxyethanol, Pentachlorobenzene and Tetrachlorobenzenes), *Canada Gazette* Notice, Vol. 139, No. 28 — July 9, 2005

Issues and Recommendations:

2-MEA and its ethanol analogue, 2-ME, are practically non-distinguishable with regards to their health effects including reproductive and developmental endpoints and the probability of harm at any level of concentration. Both substances show serious health effects at very low levels of concentration.

CEPA – toxicity

Recommendations:

- We support the conclusion for 2-MEA to be considered toxic under Section 64, CEPA 1999 and addition of 2-MEA to CEPA Schedule 1 (Toxic Substances List).

Phase out of 2-MEA

Recommendations:

- Based on the health risks of 2–MEA at very low concentrations, 2-MEA it should be prohibited from use, import, manufacture, export, sale in Canada, particularly for use in industrial applications and in consumer products.
- Ensure that the prohibition of 2-MEA include prohibition of use in the food industry for both indirect and direct food contact.
- Like 2-ME, the use of alternatives should be identified and promoted for 2-MEA. A stakeholder process to assess the safety of alternatives should be established to ensure that alternatives to 2-MEA in consumer products are safe, and that industry supply complete documentation to demonstrate this. All parties need to know if suitable and safe alternatives are feasible, and if so, are they currently being utilized.
- In view of the health effects of 2-MEA, consideration should be given to vulnerable populations such as babies, children, pregnant women and the aged when reviewing exposure to 2-MEA – for both dermal contact and inhalation.

Domestic Substances List, Priority Substance List, National Pollutant Release Inventory (NPRI) and the Cosmetic Ingredient Hotlist

Recommendations:

- We support the recommendation for 2-MEA to be included in the Domestic Substances List inventory update initiative, to be launched in 2009.
- We recommend that 2-MEA be added to the Cosmetic Ingredient Hotlist as a substance that is prohibited from use in cosmetics and a timeline be included. Strengthen the Cosmetic Regulations to ensure that the Hotlist is enforceable to its full extent.
- We support the proposal that the Priority Substance List assessment for 2-ME be expanded to include its acetate moiety, 2-MEA, based on the non-distinguishable human health hazard potential (mainly reproductive and developmental effects),

between MEA and 2-ME, at any level of exposure. This inclusion would be in keeping with the listing of 2-MEA on the Schedule 1.

- 2- MEA is currently listed under NPRI. However, given that it is CEPA toxic, the reporting requirements for 2-MEA under NPRI should be lowered to ensure that all facilities releasing or transferring 2-MEA are tracked in Canada.

2) Ethanol, 2-(2-methoxyethoxy)- (Diethylene glycol monomethyl ether, DEGME) – CAS RN 11-77-3

Highlights from draft assessment and risk scope documents

DEGME was considered to pose greatest potential for exposure to individuals in Canada.

From information collected under section 71 of CEPA 1999, DEGME was imported into Canada in 2006 in a quantity ranging between 1,000,000 and 10, 000,000 kg. No Canadian companies reported manufacturing DEGME in a quantity greater than or equal to the 100 kg reporting threshold in 2006: It is not manufactured in Canada.

DEGME releases into the air are not currently reported to the National Pollutant Release Inventory (NPRI) but from data collected from section 71 of CEPA 1999, 10,000 kg to 100,000 kg of DEGME were released into the air, in 2006. This does not include releases from consumer and commercial products containing DEGME. If included, it was concluded that the resulting concentration of DEGME in the air would be low.

DEGME meets one of the criteria set out in section 64 of CEPA 1999. The substance will be included in the Domestic Substances List inventory update initiative, to be launched in 2009.

DEGME usage is very varied from industrial to consumer products. It can be present in products such jet fuel, brake fluid, pesticides, pulp and paper industry, paint solvent, floor care products, food industry cleaners, windscreen washer fluids, inks for some pens, perfumes, hairspray, skin creams and cleansers.

For some paints and consumer products in Canada, DEGME levels will be reduced as a result of the proposed reduction of volatile organic compounds in consumer and commercial products. In the European Union, DEGME is not allowed in cosmetics and there is a proposal that the maximum allowable amount for paint strippers and consumer paints be 0.1%.

Based on observations in experimental animals, the health effects associated with exposure to DEGME are mainly developmental, reproductive toxicity and hematological effects. The European Commission has classified DEGME as a Category 3 substance with Risk Phrase R63 (“possible risk of harm to the unborn child”). No data on the potential developmental toxicity via inhalation exposure to DEGME were identified.

While the draft assessment gives the confidence in the toxicity dataset as being moderate - experimental data for developmental toxicity, reproductive toxicity, repeated-dose toxicity, genetic toxicity and acute toxicity, it states that some of the studies were not performed according to the current standard (EURAR 2000). The details as to the actual differences were not specified and where uncertainties lie were not detailed.

Consumer products were identified as the main source of exposure to DEGME that may pose a risk to the health to Canadians. While exposure to DEGME in the environment is expected to be low, the draft assessment concluded that the estimated indoor air concentration of DEGME from the use of consumer products is at a level that it can be considered 'adequately protective'. This, however, may not be accurate for susceptible populations including children, babies and pregnant women. For indoor air, it is not certain if chronic exposure was a considered factor.

For dermal exposure from consumer products containing DEGME, it was concluded that we may not be adequately protected against its negative health effects. Floor cleaners, floor sealer, latex wall paint, paint remover or stripper, caulking/sealant, floor polish and cosmetics were included for dermal exposure reference. It is felt that while there would be some dermal contact from these products, inhalation of DEGME from paint strippers and caulking /sealants, and to a lesser degree, latex paints, is significant but not a frequent source of exposure. This is indicated in the draft assessment.

In general, there is insufficient data to derive exposure estimates for all potential consumer products containing DEGME. As a result, there is low confidence in the modelled estimates of exposure from consumer products but since these estimates are conservative, confidence is high that actual exposure levels are not in excess of the estimates in the risk assessment. With this background information, how can a safe level of exposure be defined?

It was concluded that the potential oral exposure to DEGME from the environment is not expected to be of concern. This conclusion was based on the properties of the substance, its known uses and releases, as well as animal data. Of concern is the fact that there are uncertainties associated with the use of quantitative structure-activity relationship (QSAR) models to estimate persistence and bioaccumulation. Another important area of uncertainty is the water/octanol partition coefficient which had to be modelled.

The following are some issues and recommendations related to DEGME.

Issues and Recommendations:

Considering the lack of sufficient inhalation exposure data for DEGME and its known health effects, there is uncertainty when it is claimed that we are 'adequately protected'. What is 'adequate protection' and who is being 'adequately protected'?

There are also concerns about the confidence level in the toxicity dataset as being moderate and that some of the studies were not performed according to the current standard (EURAR 2000). We question whether the information on persistence and bioaccumulation were included in this dataset. The details as to the actual differences were not specified and where some of the uncertainties lie, were also not detailed.

CEPA – toxicity

Recommendations:

- We support the proposal that DEGME is toxic under Section 64, CEPA 1999 and that this chemical be added to CEPA Schedule 1 (Toxic Substances List).
- Based on the knowledge that the standards used for some of the toxicity dataset are not the current standards, we urge the government to ensure that more detailed information is gathered to outline the differences in these test procedures and the impact that this information would have on the accuracy of the toxicity data. This information should be well defined and be included in the draft assessment, possibly the appendix.
- We have concerns as to the decisions made regarding the full impact to human health from inhalation and dermal exposure to DEGME. We are not certain if the draft assessment accurately portrays the full extent to which this substance is capable of doing harm to human health. In light of such uncertainty, the precautionary principle should apply if the government evaluators are unable to fully demonstrate lack of harm to humans. Hence, adequate management measures to prevent exposure to DEGME are appropriate.

Phase out of DEGME

Recommendations:

- Based on the health risks associated with DEGME, the government should prohibit the use, import, export, sale and manufacture of DEGME in all industrial application and consumer products. This action is warranted despite the understanding that commonly used products containing DEGME (floor sealer, latex wall paint, paint remover/stripper, sealant/caulking, floor polish, floor cleaner) require further investigation.
- The government should promote the use of alternatives and support increased accountability on the part of industry on the use of DEGME. Furthermore, the government should establish a stakeholder process to assess the safety of alternatives to promote transparency in management implementation.
- In keeping with our recommendation to impose a prohibition of DEGME, additional emphasis is required to protect vulnerable populations such as babies, children, pregnant women and the aged when looking at exposure of DEGME from dermal and inhalation exposure routes.

- Again in keeping with our recommendation for a prohibition, the government should ensure that DEGME be prohibited for use in the food industry for both indirect and direct food contact.

Domestic Substances List (DSL), National Pollutant Release Inventory (NPRI) and Canada's Cosmetics Ingredient Hotlist

Recommendations:

- We support the government's recommendation for DEGME to be included in the Domestic Substances List inventory update initiative, to be launched in 2009.
- All substances found to be CEPA toxic should be listed for reporting under NPRI with alternate or lower thresholds for reporting to support monitoring and surveillance efforts in Canada and to ensure that full life cycle accounting for these substances are incorporated into the management regimes.
- We recommend that DEGME be added to the Cosmetic Ingredient Hotlist as a substance that is prohibited for use in cosmetics and an implementation time should be included. However, the Cosmetic Regulations should be strengthened to ensure that the Hotlist is enforceable.

3) 1-Propanol, 2-methoxy, (2-Methoxypropanol) – CAS RN 1589-47-5

Highlights from draft assessment and risk scope documents

2-methoxypropopanol was identified as an intermediate potential for exposure to individuals in Canada.

From information collected under section 71 of CEPA 1999, 2-methoxypropanol was imported into Canada in 2006 in a quantity ranging between 10, 000 and 100, 000 kg. No Canadian companies reported manufacturing 2-methoxypropanol in a quantity greater than or equal to the 100 kg reporting threshold in 2006. It is a by-product in the manufacture of the solvent, propylene glycol monomethyl ether (PGME). Releases for 2-methoxypropanol were less than 100 kg in 2006.

With limited information on this substance for releases and concentrations in environmental media and its use patterns, among other data, environmental exposure to the population is expected to be negligible. Data from experimental animals indicate that the critical health effects associated with exposure to 2-methoxypropanol is primarily developmental toxicity. Effects on blood and male reproductive systems were also observed in experimental animals. The European Commission has classified 2-methoxypropanol as a Category 2 substance with Risk Phrase R61 - may cause harm to the unborn child.

2-methoxypropanol will be included in the Domestic Substances List inventory update initiative, to be launched in 2009. Some consumer and commercial products containing 2-methoxypropanol will see levels of this substance reduced as part of the

government's proposed Volatile Organic Compound (VOC) Concentration Limits for Certain Products Regulations.

The solvent, propylene glycol monomethyl ether (PGME), of which 2-methoxypropanol is an impurity, is widely used in industrial and consumer products. These products include pesticides, nail polish and remover, hair dye, hair spray, false eyelash adhesive, inks, cleaners for food applications, general purpose cleaners, consumer and industrial paints. Therefore, exposure can be through the dermal and/or inhalation routes.

Some of these paints or coatings can be used for containers transporting dry food materials, storing dry grains but it is expected that solvents have been released from these coatings and that they are fully cured. For the latter uses, it was concluded that human exposure under these conditions is negligible.

The draft assessment also mentioned that 2-methoxypropanol could be present in low concentrations (< 5%) in other PGME containing products such as adhesives, electronics, non-structural caulking compounds and sealants, synthetic resins and rubber adhesives, wood protection, waterproofing, shoes and leather, photographic chemicals, hydraulic brake fluids and lubricants, disinfectants, pickling solutions and perfumes. In the European Union, labelling regulations require that commercially available PGME should contain less than 0.5% of 2-methoxypropanol as an impurity.

For indoor air, the draft assessment concluded that we may not be adequately protected for inhalation when considering the potential inadequacy of the margin between estimated exposure via inhalation and the critical effect levels for developmental toxicity, and in particular, when there are multiple exposures within a day.

There were no dermal studies indicated for 2-methoxypropanol but dermal exposure to the acetate moiety of 2-methoxypropanol did not induce effects in experimental animals at the highest dose tested – lower absorption rate than 2-methoxyproponal. Although there are many uncertainties in the database regarding exposure and effects for this substance, it was assumed that the margin for safety was adequate.

Based on available use information, physical and chemical properties of 2-methoxypropanol and the low potential for bioaccumulation, the draft assessment reported that the concentrations of 2-methoxypropanol in food and beverages are not expected to be significant.

Potential carcinogenicity or chronic toxicity studies were not available for 2-methoxypropanol. The draft assessment stated that there is moderate confidence in the toxicity dataset for 2-methoxypropanol exposure although there is very limited data and that, in itself, is supported by data on its acetate analogue, its principal metabolite. There is also uncertainty regarding the neoplastic potential of the substance due to the lack of appropriate long-term animal study data.

It was proposed that 2-methoxypropanol is 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 and, therefore, be considered "toxic" as defined in paragraph 64(c) of CEPA 1999. The draft assessment recommended the addition of this substance to the Cosmetics Ingredient Hotlist. It was also determined that 2-methoxypropanol does not meet the criteria for persistence or bioaccumulation as set out in the *Persistence and Bioaccumulation Regulations*.

The following are issues and recommendations related to 2-methoxypropanol.

Issues and Recommendations:

The draft screening has identified that consumer products, through inhalation (indoor air) and dermal contact, represent the main source for exposure to 2-Methoxypropanol. With data from experimental animals indicating that the critical health effects associated with exposure to 2-methoxypropanol is primarily developmental toxicity, there is concern about inhalation and dermal absorption of this substance. The document has cited that human health may not be adequately protected but in reference to the substance present in indoor air. While it was proposed that dermal contact should not be of concern there was a lack of scientific evidence to prove this.

CEPA – toxicity

Recommendations:

- We support the government proposal that 2-methoxypropanol be considered toxic under Section 64, CEPA 1999 and that it should be added to CEPA Schedule 1 (Toxic Substances List).
- We do not support that dermal exposure is not a health risk. Dermal exposure can be often chronic. Without actual supporting scientific evidence to prove otherwise, that assumption is considered not accurate. Also of concern is that its acetate moiety has a lower skin absorption rate as compared to 2-methoxypropanol and as its principal metabolite, it may have neoplastic potential.

Phase out of 2-methoxypropanol

Recommendations:

- 2-methoxypropanol (through the use of PGME) should be prohibited for use, import, manufacture, export and sale in all consumer products and a timeline for this action should be stated.
- Based on the health effects of 2-methoxypropanol, we recommend that the substance be prohibited for use in the food industry for both indirect and direct food contact.
- We recommend a phase out of 2-methoxypropanol for industrial products. This would, in effect, mean phasing the use of PGME in these products.

- The government to establish a set of guidelines as to requirements and protocol for accurate and timely assessment of alternative 'industrial' substances. This would ensure that alternative substances are not as hazardous as the original substance or that they would not introduce other health and environmental issues.
- Consultations with industry and NGOs for safe alternatives are needed so that the process is transparent. All parties need to know if suitable and safe alternatives are feasible, and if so, are they currently being utilized.
- In view of the health effects of 2-methoxypropanol, consideration should be given to vulnerable populations such as babies, children, pregnant women and the aged when looking at exposure – both dermal and inhalation.

Domestic Substances List (DSL), National Pollutant Release Inventory (NPRI) and Canada's Cosmetics Ingredient Hotlist

Recommendations:

- We support the government's recommendation for 2-Methoxypropanol to be included in the Domestic Substances List inventory update initiative, to be launched in 2009.
- All substances found to be CEPA toxic should be listed for reporting under NPRI with alternate or lower thresholds for reporting to support monitoring and surveillance efforts in Canada and to ensure that full life cycle accounting for these substances are incorporated into the management regimes.
- We recommend that 2-methoxypropanol be added to the Cosmetic Ingredient Hotlist as a substance that is prohibited for use in cosmetics.

4) Ethanol, 2-ethoxy-, acetate; (2-EEA): CAS RN - 111-15-9

Highlights from draft assessment

2-EEA has been identified as a high priority as it was considered to pose greatest potential for exposure to individuals in Canada. It has also been classified by the European Commission on the basis of reproductive and developmental toxicity.

Data from section 71, CEPA 1999 indicated that in 2006, 2-EEA was not manufactured in Canada above the reporting threshold of 100 kg/year. For 2006, the quantity imported was 10,000-100,000 kg.

2-EEA is used mainly in industrial applications including, paints, coatings and cleaning solutions. These products are limited to professional use only and are not intended for use by the general population.

For the general population, indoor air is likely the main source of exposure to 2-EEA through the use of consumer products. These products were either determined not to be in the Canadian marketplace or are used primarily by professionals. Comparing the concentration of 2-EEA at which adverse hematological effects have been reported in workers and the highest concentration identified in surveys of indoor air considered

most relevant to potential current exposures in Canada, it was concluded that the margins were sufficiently adequate. Therefore, exposure to 2-EEA via consumer products is not expected to be significant.

2-EEA is prohibited for use in cosmetics products in Canada and the European Union.

Environmental exposure to 2-EEA in the atmosphere is also a source of exposure but it is expected to be low. Releases into the environment are reportable under the National Pollutant Release Inventory (NPRI) and in 2006, the on-site releases were 1.4 tonnes with the increase in releases of 2-EEA in recent years being mainly from one company in Ontario.

There is very limited data about concentrations in environmental media and there are uncertainties associated with the use of quantitative structure-activity relationship (QSAR) models to determine persistence and bioaccumulation.

From observations in experimental animals and exposed workers, the health effects associated with exposure to 2-EEA are mainly developmental and reproductive toxicity and hematological effects. Since 2-EEA is rapidly hydrolysed to 2-EE in the body, toxicological information on 2-EE is relevant to the assessment of 2-EEA. Under CEPA 999, the Priority Substances List assessment for 2-EE, the critical health effects reported were reproductive and developmental toxicity, as well as effects on the hematological system. The International Programme on Chemical Safety (IPCS) has assessed the toxicity of 2-EEA, 2-methoxyethanol (2-ME) and its acetate (2- MEA), and 2-ethoxyethanol (2-EE) and has concluded that the major human health effects of these chemicals are developmental, testicular and haematological toxicity. Also, there is extensive and consistent data in animals and some human data to justify these claims.

Also noted in the draft screening is that hematological effects were reported in workers at concentrations lower than effect levels observed in experimental animals. Because of a lack of data, there is uncertainty as to the carcinogenicity potential of 2-EEA. Genotoxicity studies as well as the primary chronic toxicity data for 2-ethoxyethanol does not suggest that 2-EEA is carcinogenic.

The draft screening concluded that workers in an environment using 2-EEA are adequately protected. But again, are the workers using this substance really adequately protected?

It was proposed that 2-EEA is not 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 draft screening therefore proposed that 2-EEA does not meet the criteria set out in section 64 of CEPA 1999 (CEPA toxic).

It was also proposed that 2-EEA does not meet the criteria for persistence or bioaccumulation as set out in the *Persistence and Bioaccumulation Regulations*.

2-EEA is listed on the DSL so it is not subjected to notification under subsection 81(1) for import and manufacture in Canada. Because of the health risks associated with this substance, the draft screening stated that there are concerns new activities which have not been identified or assessed under CEPA 1999 could lead to 2-EEA meeting the criteria set out in section 64 of the Act. It is the intent to subject 2-EEA to the Significant New Activity provisions specified under subsection 81(3) of the Act. Therefore, any new manufacture, import or use of 2-EEA is notified and will undergo ecological and human health risk assessments as specified in section 83 of the Act prior to the introduction into Canada.

The following are issues and recommendations related to 2-EEA.

Issues and Recommendations:

CEPA – toxicity

- We oppose the proposed assessment conclusion that ethanol, 2-ethoxy, acetate (2-EEA) (CAS RN 111-15-9), does not meet one or more of the criteria set out in section 64 of CEPA 1999. From the NPRI data and the usage of this substance in 2006, the figures cannot be termed insignificant. Based on the type of products, there are both dermal and inhalation routes of exposure. The draft screening indicated that 2-EEA was used mainly in products used by professionals but the inhalation of this substance does not stop with the applicator. There is the possibility than other individuals would be subjected to the inhalation of this substance depending on the end use of the product. We would also to emphasize that the draft screening noted hematological effects were reported in workers at concentrations lower than effect levels observed in experimental animals. We would conclude 2-EEA meets at least one criteria in section 64 of CEPA 1999, therefore making it CEPA toxic.
- The evidence presented in the assessment demonstrate that exposure to 2-EEA results in a range of reproductive and developmental toxicity in laboratory animals, including reduced fertility, reduced litter number, sperm abnormalities and reduced testis . The exposure of 2-EEA along with 2-methoxyethonal (2-ME) and its acetate (2-MEA) and 2-ethoxyethanol have also demonstrated a range of developmental, testicular and haematological effects. The assessment report states that "the confidence in the database for reproductive and developmental toxicities and for hermatological effects of 2-EEA is high. These data are supported by some epidemiological observations …"[2] Furthermore, the use of occupational exposure evidence in the assessment demonstrate that a designation of toxicity under CEPA is warranted.
- In the section "Characterization of Risk to Human Health," it was stated that indoor air would be the principle route of exposure to human health and the use of occupational exposure was used to rationalize that exposure to the general public would be low. Furthermore, the assessment also identified that consumer products also be a source

[2] Environment Canada and Health Canada. August 2008. Draft Screening Assessment for The Challenge Ethanol, 2-ethoxy-, acetate (Chemical Abstracts Service Registry Number 111-15-9). Accessed at http://www.ec.gc.ca/substances/ese/eng/challenge/batch3/batch3_111-15-9.cfm

of exposure to Canadians. Since products containing these substances were not expected to be in the Canadian market place or were found in "limited/specialized activities" it was concluded that "exposure to 2-EEA … is not expected to be significant." There were many limitations and gaps in the assessment (absence of information on carcinogenicity, mutagencity, etc) that were not adequately considered when it concluded that 2-EEA under CEPA is not toxic. Based on its developmental and reproductive toxicity as well as hematological effects, it is appropriate to conclude toxic under CEPA for 2-EEA.

We oppose the proposed assessment conclusion that ethanol, 2-ethoxy, acetate (2-EEA) (CAS RN 111-15-9), does not meet one or more of the criteria set out in section 64 of CEPA 1999.

Phase out of 2-EEA

Recommendations

- Consideration should be given to prohibit the use, import, export and sale of 2-EEA in all industrial application and consumer products in Canada. Also, more information is required on the actual presence of 2-EEA in consumer products.
- Based on its reproductive and developmental toxicity, the government should establish a process to discuss safe alternatives for 2-EEA given the extent of its application in consumer products (solvents, cleaning products), cosmetic products and industrial application (adhesives, solvents). This would ensure that alternative substances are not as hazardous as the original substance or that they would not introduce other health and environmental issues.
- Based on its reproductive and development toxicity, 2-EEA should be prohibited in any products that vulnerable subpopulation such as babies, children, pregnant women and the aged come into contact, in particular through exposure – both dermal and inhalation.

National Pollutant Release Inventory (NPRI)

Recommendation:

- All substances found to be CEPA toxic: Ethanol, 2-methoxy-, acetate; Ethanol, 2-(2-methoxyethoxy)-; 1-Propanol, 2-methoxy- (2-Methoxypropanol) should be listed for reporting under NPRI with alternate or lower thresholds for reporting to support monitoring and surveillance efforts in Canada and to ensure that full life cycle accounting for these substances are incorporated into the management regimes.

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