NGO comments on Draft Screening Assessment & Risk Management Scope Documents for Selected Batch 11 Chemicals: A Response to *Canada Gazette Part I, Vol. 144, No. 40* — October 2, 2010 on Industry Challenge Chemicals of the Chemicals Management Plan

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Introduction

The Canadian Environmental Law Association (CELA) and Chemical Sensitivities Manitoba (CSM) are submitting the following comments in response to the *Canada Gazette,* Part I, Vol. 144, No. 40 – October 2, 2010 release of the draft screening assessment and risk management scope documents on three substances found to meet the Persistent and Bioaccumulation Regulations under CEPA, 1999: 2-Propanone, reaction products with diphenylamine (PREPOD) (CAS RN: 68412-48-6), 1,4-Benzenediamine, N,N'-mixed Phenyl and tolyl derivatives (BENPAT) and 1,4-Benzenediamine, N,N`-mixed tolyl and xylyl derivatives (BENTAX) (CAS RNs: 68953-84-4 and 68478-45-5); Hexanedioic acid, bis(2-ethylhexyl) ester (DEHA) (CAS RN:103-23-1) and the significant new activity (SNAc) proposals for six substances – (CAS RNs 603-33-8, 10448-09-6, 40615-36-9, 64111-81-5, 69430-47-3 and 125328-28-1), identified under the Chemicals Management Plan (CMP), Batch 11 of the Industry Challenge.

CELA (www.cela.ca) is a non-profit, public interest organization established in 1970 to use existing laws to protect the environment and to advocate for environmental law reform. It is also a legal aid clinic that provides legal services to citizens or citizens' groups who are otherwise unable to afford legal assistance. In addition, CELA also undertakes substantive environmental policy and legislation reform activities in the areas of access to justice, pollution and health, water sustainability and land use issues since its inception. Under its pollution and health program, CELA has been actively involved in matters that promote the prevention and elimination of toxic chemicals addressed in the *Canadian Environmental Protection Act*, including the categorization process and implementation of the CMP.

Chemical Sensitivities Manitoba (CSM), a volunteer organization, was founded in 1997 by four individuals who saw the need to address the affects of toxic chemicals on human health and the possible link between the onset of chemical sensitivities and chemical exposure and, in particular, chronic low-level exposure. CSM raises awareness of the presence of toxic chemicals in the home and the environment and strongly advocates for the safe substitution of these toxins.

Our respective organizations along with other Canadian environmental and health non-governmental organizations (NGOs) have submitted substantial comments on assessment results and proposed management options for substances in Batches 1 through 10 of the Industry Challenge, including the final assessments and draft risk management options for selected chemicals in Batch 1 to 9.

Our organizations have used the public comment periods as opportunities to highlight the gaps and limitations as identified in the risk based assessments and the proposed management instruments for specific chemicals. Consequently, we have developed substantial recommendations to address the gaps and limitations that decision-makers should consider carefully for improving the current approach to the Chemicals

Management Plan in Canada. These recommendations are intended to further strengthen and entrench the precautionary principle in the decision-making process and promote a high level of accountability to all users, manufacturers, importers and sellers of chemicals in Canada. Furthermore, these recommendations are designed to ensure the protection of human health and environment from toxic chemicals throughout their life cycle.

Persistent, Bioaccumulative, Toxic Substances

According to the draft screening assessments conducted on substances under Batch 11, three substances meet the criteria for persistence and bioaccumulation under the *Persistent and Bioaccumulation Regulations* of CEPA, 1999. They are 2-Propanone, reaction products with diphenylamine (PREPOD) (CAS RN: 68412-48-6), 1,4-Benzenediamine, N,N'-mixed Phenyl and tolyl derivatives (BENPAT) and 1,4-Benzenediamine, N,N`-mixed tolyl and xylyl derivatives (BENTAX) (CAS RNs: 68953-84-4 and 68478-45-5).

This finding is critical as the government will be required to take measures that support virtual elimination for these toxic substances. These substances should be added to the Toxic Substances List (Schedule 1) and risk management should focus on the eventual phase out of these substances through regulatory measures.

All three toxic substances are used primarily as antioxidants/inhibitors, or tarnish inhibitor/scavenger/antiscaling agents.

PREPOD

According the risk management scope report for PREPOD, this chemical is relevant for the mounting brackets of engines and has been manufactured in Canada in the quantity range between 100,000 to 1,000,000 kg in 2006.[1]

From the risk management scope report for PREPOD, this toxic chemical is released to surface water and to wastewater treatment plants. However, waste management processes such as incineration and landfill may also contribute to the level of PREPOD released to the environment.

We are supportive of the government's interim proposal to seek the addition of PREPOD to the Toxic Substances List (Schedule 1) of CEPA based on its draft screening assessment results. Furthermore, in the event that the government concludes that PREPOD meets the criteria for persistence and bioaccumulation as required under the Persistence and Bioaccumulation Regulations, we support the government's proposal to "focus on regulatory controls toward virtually eliminating

[1] Environment Canada and Health Canada. Risk Management Scope for2-Propanone, reaction products with diphenylamine (PREPOD) Chemical Abstracts Service Registry Number (CAS RN): 68412-48-6. October 2010. Accessed at http://www.ec.gc.ca/ese-ees/default.asp?lang=En&n=987ED817-1#i2.

releases of the substance to the environment." We encourage the government to develop regulatory controls that ultimately seek the phase out of the use of PREPOD over time. This approach would be considered more effective in protecting the environment from PREPOD rather than developing a level of quantification to be applied to industry for determining control processes for PREPOD.

The focus on a phase out for PREPOD should accompany a rigorous exercise to identify and promote safe substitute to PREPOD. As the process moves forward, the government has identified a number of areas where additional information will be required which will be subsequently used to inform the risk management of PREPOD including information on substitutes, monitoring data from effluents and sludge, receiving water and recycling processes. While it is important to obtain this information to gain a better understanding on the use and extent of contamination from this toxic substance, we hope that the government will act in a preventative manner, even if this information is not provided.

BENPAT and BENTAX

Based on the risk management scope document for BENPAT and BENTAX, the proposal to manage BENPAT and BENTAX, will focus on "regulatory controls toward virtually eliminating releases of the substances to the environment."[2] Regulatory measures that support virtual elimination are supported at this time given the persistence and bioaccumulation properties of these substances. The regulatory measures that should be considered by government should focus on a phase out of use of these substances.

The impacts to the environment are expected to be low for these substances. The use of these substances in the production of rubber and hose products suggest that the main source would come from tire wear, which contributes 7.8% of the releases of BENPAT to surface water or wastewater treatment plants and a greater percentage (87%) ends up in waste management. For BENTAX, surface water and wastewater treatment plants have also been identified as the main sources for the presence of BENTAX.

However, the risk management document for BENPAT and BENTAX does not acknowledge or quantify the production of other toxic chemicals that may result from specific waste management methods such as incineration or leaching from landfills. Incineration processes, for example, are significant sources of various toxic chemicals such as dioxins and furans, heavy metals, PAHs, etc. which are also linked to a range of impacts to the environment and human health that may include cancers, learning disabilities, reproductive and developmental toxicants and endocrine disruption. The

[2] Environment Canada and Health Canada. *Risk Management Scope for1,4-Benzenediamine, N,N'-mixed Phenyl and tolyl derivatives (BENPAT) Chemical Abstracts Service Registry Number (CAS RN): 68953-84-4 and 1,4-Benzenediamine, N,N`-mixed tolyl and xylyl derivatives (BENTAX) Chemical Abstracts Service Registry Number (CAS RN): 68478-45-5*, October 2010. Accessed at http://www.ec.gc.ca/ese-ees/default.asp?lang=En&n=4E5D311C-1#i3.

type and concentration of the by-products of incineration depend significantly on the type and quantity of products being incinerated. The absence of this information should provide support for a regulatory measure that pursues a phase out approach for BENPAT and BENTAX.

While much of the industrial use data in Canada for these two substances are protected under the confidential provisions of CEPA 1999, the 2006 volumes reported for BENPAT were between 1 000 000 and 10 000 000 kg/year and between 100 and 1000 kg/year for BENTAX. BENPAT has also been identified as high volume substance in the United States with imports or uses of over 1 million pounds per year. The high level of use of these toxic substances also provides some justification for additional focus on identifying and promoting safe substitutes that do not exhibit similar toxic properties, such as in the tire manufacturing sector. Currently, this information has not been included in the risk management document but warrants strong consideration for inclusion.[3]

Furthermore, it is important that consideration be given to vulnerable communities such as the northern communities that may be impacted by these substances through the potential presence of these toxic chemicals in products, its release to surface water and wastewater treatment plants, and waste management measures. These sources can eventually contribute to the bioaccumulation of these toxic substances in the environment on which these communities may rely for their livelihood. No consideration on these matters has been included in the development of the risk management scope document.

Recommendation: We support the findings that these three substances are found to meet the criteria for persistence and bioaccumulation under the *Persistence and Bioaccumulation Regulations*. Therefore, these chemicals should be targeted for virtual elimination.

Recommendation: We support the initial proposal to add these toxic substances to the Toxic Substances List (Schedule 1) of CEPA 1999 based on the finding that they meet the criteria of toxic under CEPA 1999.

Recommendation: We urge the government to develop regulatory measures that achieve the goal of virtual elimination of these CEPA toxic chemicals. These regulatory measures should aim to phase out these toxic chemicals over time.

Recommendation: The risk management document should be expanded to provide information on:

a) safe substitutes for these three toxic substances,
b) list and quantify the production of other toxic chemicals and their impacts to the environment and health that result from waste management processes such as incineration and landfill, and

[3] Ibid.

c) the impacts to vulnerable communities including northern communities.

Recommendation: In the absence of information needed to develop management regimes for the three persistent, bioaccumulative toxic substances, the government is urged to take a preventative and protective approach that will result in the phase out of these toxic substances.

Application of SNAc to Selected Substances

Table 1: Categorization and draft screening data for five substances in Batch 11

Substance name **CAS RN**	**Categorization results**	**Draft Screening results**	**Proposed measures and other relevant data**
Bismuthine, triphenyl- 603-33-8	Persistent, Bioaccumulative, Inherent Toxicity to non-human organisms (P,B,iT) Not identified as a high hazard for human health for carcinogenicity, genotoxicity, developmental toxicity or reproductive toxicity.	P, B, iT	For the year 2006 – section 71 (1) (b) – not in commerce above the reporting threshold of 100 kg. Not on the European Union's Candidate List of Substances of Very High Concern for Authorisation ***Proposed measure*** **Significant New Activity provision to be implemented**
Cyclotetrasiloxane, heptamethylphenyl- 10448-09-6	P, B, iT Other info as above	P, B, iT	As above
Benzene, 1,1'-(chlorophenylmethylene)bis[4-methoxy- 40615-36-9	P, B, iT Other info as above.	P, B, iT	As above
Phenol, 2-phenoxy-, trichloro derive. 64111-81-5	P, B, iT Other info as above	P, B, iT	As above
Siloxanes and Silicones, di-Me, reaction products with Me hydrogen siloxanes and 1,1,3,3-tetramethyldisiloxane 69430-47-3	P, B, iT Other info as above	P, B, iT	As above
Phenol, 4,4 -(1-methylethylidene)bis-, reaction products with hexakis(methoxymethyl)melamine 125328-28-1	P, B, iT Other info as above	P, B, iT	As above

Comments & Recommendations

The six substances listed in Table 1 above, were all categorized as being persistent, bioaccumulative and inherently toxic to non-human organisms, according to criteria set out in the *Persistent and Bioaccumulation Regulations*. However, through the s.71 survey seeking data for 2006, there was no recorded commercial activity of these substances in excess of the reporting threshold of 100 kg.

For these substances, the finding for P, B, iT designation has not changed. Hence the government has applied a significant new activity provision (SNAc) to each substance. For previous submissions responding to other substances covered under the Industry Challenge, our organizations have raised several concerns we have with this approach. We urge you to review these comments as the use of SNACs[4] is being applied to many substances and appears to be common element in Canada's risk-based management regime under the CMP.

As stated before in many of our submissions for substances in the Challenge Program, we are concerned that the application of the SNAc provision would not allow for a public comment period and as a result, the process lacks the transparency that should be promoted under the Industry Challenge. Generally, SNACs do not effectively prevent the entry and use of these chemicals in Canada. Future use or import of these chemicals can be prevented by adding the chemicals on the Toxic Substances List and placing it on the *Prohibition of Certain Toxic Substances Regulations*, 2005. Also, these substances are considered high hazard, low volume existing substances that have not been designated as being CEPA-toxic but it is possible that they may be present in commerce below the threshold volume. These chemicals would continue to be used in Canada without any risk management in place. These are the same substances that would be of concern to the government if volume usage increased or use pattern changed.

Phenol, 2-phenoxy-, trichloro derivative (CAS number 64111-81-5)

One of the substances listed above - phenol, 2-phenoxy-, trichloro derivative, CAS number 64111-81-5, is assumed to be in the polychloro phenoxy phenol chemical family and so is phenol, 5-chloro-2-(2,4-dichlorophenoxy)-dichlorophenoxy)-, otherwise known as triclosan – CAS number 3380-34-5. However, the latter substance, triclosan, which also met the Canadian environmental criteria for categorization, is persistent and inherently toxic to non-human organisms but it is not bioaccumulative.[5] Based on the similarities in structure of these two chemicals, we question why they have not been assessed together as we understand that triclosan has been targeted for assessment as part of a pilot study of the categorization process. There is growing evidence that triclosan is linked to a number of health and ecological impacts that are expected to be

[4] See list of submissions by NGOs to proposals re: SNACs, visit the website for the Canadian Environmental Network, CMP Project at http://www.cen-rce.org/CMP/indexcmp.html.
[5] Environment Canada – Categorization results for triclosan. Accessed at http://www.ec.gc.ca/lcpe-cepa/eng/subs_list/DSL/DSLsearch.cfm. Viewed November 23, 2010.

explored in the assessment on triclosan. It is unclear from the Batch 11 assessments when the assessment on triclosan will be released for public comment. Further, it is unclear how the decisions made on similar substances such as CAS RNs 64111-81-5 will impact the decisions to be made on triclosan (CAS RN 3380-34-5).

Based on the mounting scientific evidence of the possibility of human health effects from exposure to triclosan, we are of the opinion that the categorization data for both substances should be updated to include human health endpoints such as endocrine disruption.

Recommendation: The government should release a comprehensive policy and regulatory review to evaluate the applicability of SNAcs to existing substances under the CMP, beginning with the release of a consultation document to establish the framework for such a review process.

Recommendation: The government should make revisions to the New Substances Program immediately to ensure public engagement on all substances that are notified under the SNAc provision.

Recommendation: The government should announce the timeframe for releasing the screening assessment on triclosan and articulate how the finding on other similar chemicals will impact the assessment process, if at all.

Hexanedioic acid, bis(2-ethylhexyl) ester (DEHA) (CASN RN:103-23-1)

Table 2 – Selected Batch 11 Substance - Hexanedioic acid, bis(2-ethylhexyl) ester (DEHA) (CASN RN:103-23-1) - Categorization and Draft Screening Assessment Results, Quantity and Uses

Substance name CAS RN	Categorization results	Draft Screening Results	Quantity and Uses
Hexanedioic acid, bis(2-ethylhexyl) ester (DEHA) 103-23-1	Greatest potential for exposure of individuals in Canada Classified on the basis of potential carcinogenicity as listed in other jurisdictions. Other agencies (US EPA, OECD) – developmental toxicity Not persistent, bioaccumulative or inherently toxic to aquatic organisms	Proposed that "DEHA meets one or more of the criteria set out in section 64 of CEPA 1999". DEHA 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. DEHA is entering or may be entering the environment in a quantity or concentration or under conditions that have or may have an immediate or long-term harmful effect on the environment or its biological diversity.	**QUANTITY** In Canada for 2006: 250,000kg imported and 1-10 million kg produced.[6] **USES** Major use: plasticizer in polyvinyl chloride (PVC) Areas of usage: DEHA is a formulant (non-active ingredient) found in pesticides, which are regulated under the *Pest Control Products Act* in Canada (PMRA 2005). There are five registered pesticide products in Canada containing DEHA as a plasticizer. Recent reassessment of DEHA, a List 1 formulant, concluded it is acceptable for use as a plasticizer in cattle ear tags within the current concentration range. Non-medicinal ingredient in sunscreen. Food packaging materials. Cosmetics and personal care products. Consumer products include - auto interior protectant, heavy-duty hand cleansers, and lubricants.

[6] This does not take into consideration the presence of DEHA in imported products.

Background

DEHA is mainly used as a plasticizer in a wide range of consumer and industrial products. In the draft screening document, there was generally good co-relation between experimental and estimated physical and chemical properties of DEHA with the exception of Henry's Law Constant which showed a wide range of values.[7] However, it was observed that only one modelled value was listed for log K_{oa} so a comparison to other values for accuracy was not possible.

The main source of exposure of DEHA to the general population of Canada is expected to be from food as a result of the migration of the substance from food packaging materials. Health Canada's Food Directorate is currently consulting with the North American food packaging industry to obtain information on current use patterns in food packaging.[8] Also, there is expected to be direct exposure from DEHA as a result of using cosmetics and personal care products that contain this substance. There could also be indirect exposure to DEHA from other consumer products that contain the substance – mainly because of the possible migration of DEHA from products when it is used as a plasticizer.

DEHA has been classified by international agencies to be a potential carcinogen. Increased liver tumours were observed in female mice, occurring at mid and high doses, but this was not observed in rats. The proposed mode of tumour induction was not considered to be relevant in humans as it pertains to human health risk characterization. Also, the draft screening document indicated that DEHA is not likely to be genotoxic. As a result, a threshold approach was used to characterize risk to human health, an approach our organizations perceive as being problematic.

The document also indicated that one of the critical health effects for DEHA is developmental toxicity as confirmed by the US EPA and the OECD. Because of the lack of reported information related to fetal effects and/or developing rats at lower doses than 400 mg/kg-bw per day, the no effect observed concentration (NOAEL) of 200 mg/kg-bw per day was used for the characterization of risk to human health in this assessment. As a precautionary measure, it could be questioned whether this NOAEL should be set at a lower value.

Based on a comparison of estimated exposures of DEHA in Canada to the critical effect levels for developmental effects, the resulting margins of exposure (MOEs) ranged from 91 to 3300. With many uncertainties in the databases on exposure and effects, the document concluded that the resulting MOEs associated with the use of certain cosmetics and personal care products are potentially not adequately protective of human health.

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[7] Government of Canada – Draft Screening Assessment for DEHA, October 2010. Accessed at http://www.ec.gc.ca/ese-ees/default.asp?lang=En&n=39958D25-1#a7, pages 4, 5.
[8] Ibid.

Information submitted under section 71 of *CEPA 1999* indicated that the majority of DEHA released to the environment was to air and water via wastewater effluent. National Pollutant Release Inventory (NPRI) in 2006 reported releases to the air and off-site disposal. However, the NPRI reporting threshold for this substance is the manufacturing, processing or otherwise use of this substance in a quantity that is equal to or greater than 10 000 kg, and the concentration by weight of the substance is equal to or greater than 1%. The current reporting threshold may result in an underestimation of releases or transfer of DEHA as there may be smaller or medium size facilities that are not required to report under NPRI.

DEHA can be released to the environment through industrial uses as well as through the consumer use of products containing the substance. When released into waste water and processed through wastewater treatment plants, DEHA could be released to the aquatic environment and/or possibly result in an increase in its concentration in wastewater sludge. The use of wastewater sludge as fertilizer on agricultural lands as well as the disposal of products containing DEHA in landfill sites can all result in DEHA being released to the environment.

DEHA has been detected in a range of media in reasonablely high concentrations such as in secondary sludge from sewage treatment plants (743 mg/kg), sediment with river water and landfill leachate to be the highest. DEHA has been measured in the influents, effluents and sludge of sewage treatment plants and in grey waste water. However, it is expected to partition more to soil and sediment depending on the compartment of release primarily because of its low experimental water solubility and high estimated values for log K_{ow} and log K_{oc} as well as its degradation and mass-transfer.

With a high experimental log K_{ow} for DEHA, bioaccumulation in aquatic species is expected. However, the screening document concluded that the substance is expected to have low bioaccumulation, most likely because it is rapidly metabolized. The estimated BCF and BAF values for DEHA are all significantly less than 5000. Using the available empirical and modelled values corrected for metabolism, and considering evidence for metabolic potential, DEHA does not meet the bioaccumulation criterion (BCF or BAF > 5000) as set out in the *Persistence and Bioaccumulation Regulations* (Canada 2000). Therefore, it is not expected to be persistent in air, water, soil or sediment and neither is it expected to bioconcentrate or bioaccumulate in aquatic organisms. However, it was concluded that it does have the potential to do harm to aquatic organisms when it is present at low concentrations.

Long range transport potential (LRTP) was not mentioned in the SLRA. Based on the data presented in the screening document, we have assumed that its potential for long range transport is minimal. In other assessments under the Challenge, this omission of data on LRTP has also been observed. Canadian NGOs including our organizations have outlined our concerns about this gap. Often these screening assessment reports do not provide any explanation of the LRTP nor are any monitoring data presented to fill the gaps. It is our view that in situations where there is no potential for long range transport, the screening assessment document should clearly indicate where omissions

or information gaps exist. This topic is of great interest to remote northern communities that are interested in identifying toxic substances that may be present in their ecosystem and may have the potential to impact their sources of food and livelihood.

The high volume of DEHA for manufacturing, import and eventual usage coupled with data of its presence in STP effluents and other measured concentrations in Canada, indicate the potential for widespread release of this substance in the Canadian environment. As previously mentioned, once DEHA is released it will partition mainly to sediment and soil, but will also be found in the water column either dissolved or as an emulsion.

While the majority of acute toxicity studies report no effects at the water solubility limit, there is concern regarding the potential for chronic toxicity to aquatic organisms (chronic lowest observed effect concentration (LOEC< 0.1 mg/L)) as both experimental and modelled data indicate that adverse effects may occur at chronic exposure levels near or below the water solubility limit for DEHA. The SLRA concluded that based on available data, DEHA in fish is metabolized and excreted fairly rapidly, but in invertebrates appear to be more sensitive to this substance in the water column. However, in the case of Rainbow trout, one study indicated acute lethality. Though it was thought that the toxic mechanism may have been a physical effect, it is still considered to be ecologically relevant.

In site-specific industrial release and exposure analyses, predicted effect concentrations (PECs) ranged from 0.00001 to 0.073 mg/L for 9 sites which involved the highest quantities of DEHA. The resulting risk quotients (calculated as PEC/PNEC) for these 9 sites ranged from 0.003 to 21 for this substance, with 5 sites having a risk quotient above 1 therefore indicating the potential for harm to aquatic species at those sites. When considering consumer releases, the consumer release scenario tool predicted that the risk quotients at 30% of the sites (or 324 sites) receiving wastewater across Canada under low (10th percentile) flow conditions ranged from 2.4 to 32. These values indicate that the potential for adverse effects of DEHA on pelagic invertebrates could be widespread in Canadian surface waters as a result of releases from consumer products.

In the draft screening document, it was proposed that DEHA meets the criteria under section 64 of *CEPA 1999* but if there are no changes to this proposal, options for risk management would focus on the following:

1. a regulatory or non-regulatory initiative to prevent or minimize releases of the substance to the environment;
2. the addition of DEHA to the *Environmental Emergency Regulations*, which would require facilities at or above the associated quantities and concentrations to prepare environmental emergency plans that will prevent, prepare for, respond to and recover from an environmental emergency; and
3. the addition of DEHA to the Health Canada Cosmetic Ingredient Hotlist, which is an administrative tool to help manufacturers satisfy the cosmetic safety provisions of section 16 of the *Food and Drugs Act*.

Comments & Recommendations

➢ CEPA-toxic and Toxic Substances List (Schedule 1)

We support that DEHA should be designated CEPA-toxic based on the information from the draft Screening Level Risk Assessment (SLRA) on the basis that DEHA is carcinogencity. Hence, DEHA should be added to Toxic Substances List (Schedule 1) of CEPA. Proposed listing to Schedule 1 under CEPA will trigger the development of management options for DEHA.

DSL Inventory Update

DEHA should be targetted for update under the Domestic Substances List (DSL) Inventory Update. There is a need to maintain the information on quantity, application and number of facilities up to date.

➢ Toxicity of DEHA to aquatic organisms

High experimental Log K_{ow} values for DEHA generally indicate bioaccumulation in aquatic species. However, the screening document concluded that the substance is expected to have low bioaccumulation, most likely because it is rapidly metabolized. However, based on other toxicity data in the document, there was the conclusion that DEHA is toxic to aquatic organisms.

This raises concerns as to presence of DEHA in products and the volume of DEHA that may be continuously released to the environment. It is suspected that there may be releases to the drain with the eventual path into the various water bodies through inadequate treatments by wastewater treatment systems.

There are several options for attempting to decrease the toxicity to the aquatic environment. These options include the elimination of the substance in the many consumer products where releases are likely to make their way to the aquatic environment together with more stringent measures to reduce with eventual elimination, DEHA releases from industry to the aquatic environment.

These are further discussed with some more details under various headings outlined below.

➢ Long range transport potential (LRTP)

As noted above, stakeholders will inappropriately assume based on the absence of data in the SLRA, that DEHA has minimal potential for long range transport. However, this was never discussed in the SLRA. We have indicated that this information is of considerable relevance to various vulnerable communities including the remote northern communities.

Recommendation: Information on long range potential of substances should be included and explained in a screening risk assessment, even if that potential is minimal. All evidence or a mention of lack of evidence on data regarding LRTP should be clearly defined in the assessment report.

- **National Pollutant Inventory Release (NPRI)**

In general, release data is showing a reduction in release – off-site and on-site. From the screening document, information submitted under section 71 of CEPA 1999, indicated that for 2006, the majority of DEHA released to the environment was to air.[9] The screening assessment report does not provide data that explains how reductions were achieved in off-site or on-site releases or what facilities contributed to these reductions. Such analysis would benefit from mandatory reporting by facilities regarding their pollution prevention activities. Currently, reporting on pollution prevention activities is on a voluntary basis. Therefore, it is challenging to analyze the NPRI data for trends without information about a facility process and changes over time.

The data reported to NPRI may represent a portion of the all releases or transfer information for this substance to the environment including air, water and land. Most likely, NPRI data is an underestimate of these releases and transfer. At this time, it would be helpful to know to what extent DEHA is being under-reporting by facilities in Canada. Similarly, it would also be relevant to determine how much of DEHA is being released that is under the reporting threshold.

Recommendation: We urge the government to amend the reporting threshold for DEHA. This amendment would require reducing the reporting threshold for DEHA so that it would capture almost all of the facilities manufacturing, using, transferring or processing the substance.

Recommendation: The government should provide greater details to explain any reductions in releases – on site or off site - reported under NPRI.

Recommendation: The requirements for reporting pollution prevention activities under NPRI should be made mandatory. Reporting on pollution prevention activities will identify opportunities for reductions to air, water, and land.

Recommendation: To improve reporting to all media, we urge the government to undertake an investigation of releases to waterbodies by all facilities using DEHA as releases to NPRI may not be accurate given the total volume usage of DEHA.

- **Presence of DEHA in pest control products**

DEHA is a formulant (non-active ingredient) used in five registered pesticide products that are regulated under the *Pest Control Products Act,* Canada. The presence of a

[9] Ibid. page 12

potential human carcinogen and a developmental toxicant should not be registered as a non-active ingredient in pesticide products under the *Pest Control Products Act* (Canada). While the toxicological properties of the active ingredient/s in a pesticide product are recognized to be intentional, the presence of DEHA in a pesticide go beyond the properties of being a plasticizer; its potential to be a human carcinogen and a developmental toxicant take precedence over its physical use of being a plasticizer. From the draft screening report, it is a proposed CEPA-toxic substance.

If DEHA is found to be CEPA-toxic, the risk management strategy should include a review of its presence in pesticide products as a formulant and consultation with the *Pest Management Regulatory Agency,* Health Canada, on this issue is required. Also, there was no discussion in the screening document as to any possible synergies of DEHA and the active ingredients in the pesticide formations when viewing DEHA as CEPA-toxic. It is not known if this is considered confidential business information.

Recommendation: Based on the proposed CEPA-toxic designation for DEHA, we strongly urge the *Pest Management Regulatory Agency through* Health Canada, to consider the prohibition of DEHA as a formulant – a non-active ingredient, in pesticide products. Any replacement should be government assessed and be safer than DEHA.

- **DEHA – Natural Health Products, Therapeutic Products, Cosmetic Ingredient Hotlist**

The screening document indicated that DEHA is listed as a non-medicinal ingredient in a sunscreen. DEHA is also listed in the Natural Health Products Ingredients Database as an acceptable non-medicinal ingredient for use as a plasticizer or skin-conditioning emollient or solvent in natural health products but since it is not listed in the Licensed Natural Health Products Database, it is not present in any currently licensed natural health products. At present, DEHA is not on the Cosmetic Ingredient Hotlist.

With toxicity data mainly limited to animal studies and a lack of information regarding the potential toxicity of DEHA as related to mainly dermal and inhalation exposure regarding human health endpoints such as neurodevelopmental toxicity, reproductive toxicity, developmental toxicity and genotoxicity, there are concerns as to how more precautionary the government should have been in the human health assessment. These concerns are further entrenched when considering other factors such as the uncertainty in the interpretation of intraspecies and interspecies variation for some of the toxicity data.

We also question the uncertainty as being moderate in the modelled estimates of exposure from consumer products because of a lack of Canadian-specific information on the presence and concentration of DEHA in products, and in particular, cosmetics and personal care products. With a lack of product-specific data and the wide range of margins of exposure in the data, we are of the opinion that it would be more accurate to describe the uncertainty in these modeled estimates as being high to moderate.

To add to the list of uncertainties, the assessment report also concluded that there was uncertainty in the calculation of Jmax value. However, it is very appropriate to mention the possibility of increased absorption rates for DEHA in some products depending on the presence of other products that would accelerate this process.

Recommendation: Based on the toxic properties of DEHA and the lack of data on dermal penetration as it relates to critical health endpoints such as neurodevelopmental toxicity, reproductive toxicity, developmental toxicity and genotoxicity, DEHA should be prohibited as a non-medicinal ingredient in sunblocks – for both adults and children, as a precautionary measure.

Recommendation: We urge the government to ensure that DEHA be not listed on the Licensed Natural Health Products Database.

Recommendation: Based on the finding that DEHA is a CEPA-toxic substance, we urge the government to take a precautionary approach and seek a complete prohibition on the use of this substance in all cosmetics and personal care products.

Recommendation: Because of the extensive use of DEHA in cosmetics and personal products, we urge the government to use its authority and seek additional information on this substance through section 71 of *CEPA 1999* – information on toxicity that would be relevant to reducing the uncertainty in the many areas as alluded to in the screening document.

- **Emergency Measures Regulations**

Our organizations support the general proposal for the addition of DEHA to the *Emergency Measures Regulations* as this would require facilities at or above the associated quantities and concentrations to prepare environmental emergency plans that will prevent, prepare for, respond to and recover from an environmental emergency. However, we are concerned that the establishment of a threshold value in relation to the preparation of environmental emergency plans will mean that some facilities will not require such plans. Based on the risk management scope document, no information has been provided as to the number of facilities that would be required to prepare these plans. It is thought that all facilities should be required to develop such plans which would allow for more appropriate response plans to all types of environmental emergencies that could include spills, leaks or other. There are some communities which may have several facilities that contribute toxic releases to the local environment. It would be of significant value to the local community to have a solid knowledge base about the level of accountability by facilities on their preparedness to environmental emergencies and what how these contingency plans protect the local community.

In these regulations, there should be significant emphasis on how facilities would plan to promote greater accountability to protect occupational health and special consideration

as to the impact on public health and the environment. The regulations should also address containment of waste and stockpiles of DEHA.

Recommendation: Environmental Emergency Regulations should pertain to all facilities that release, use, dispose, sell or import DEHA regardless of volume threshold.

Recommendation: All facilities should be required to prepare Environmental Emergency plans regardless of volume use or release.

Recommendation: Careful consideration should be given to the proposed CEPA-toxic designation of DEHA and its potential to be toxic to aquatic organisms, when deciding upon the concentration or value at or above which a facility must prepare an environmental emergency plan.

- **Regulatory and non-regulatory measures**

As part of the proposed risk management strategy, regulatory and non-regulatory measures to minimize releases to the environment have been included. While details are not expected as this point, some indication of these measures are necessary so that stakeholders could present meaningful comments to the government on any the proposed risk management measures.

As noted in the proposed measures, there was no mention to minimize exposure to humans, outside of the addition of DEHA to the Health Canada Cosmetic Ingredient Hotlist, which is an administrative tool to help manufacturers satisfy the cosmetic safety provisions of section 16 of the *Food and Drugs Act*. This is considered a non-regulatory tool.

Also, there has been no proposal by the government to reduce the migration of DEHA from food packaging materials or consider alternatives to this substance in food packaging materials (post- addition of DEHA).

Based on the data from some industrial site and wastewater facilities and coupled with the toxicity of DEHA to aquatic organisms, there is a need for DEHA concentration reduction. It is unclear if there will be further monitoring at these locations with the intent of DEHA effluent reduction.

Recommendation: For meaningful contribution or comments to the draft screening documents, we request that the government provide greater detail to any proposed risk management measures. For example, an indication as to the government's level of commitment to take regulatory versus non-regulatory measures on specific substances would be very useful.

Recommendation: Our organizations require clarification as to the government's position on the reduction and/or replacement of DEHA in food packaging materials.

Recommendation: Clarification is required as to the government's intent to monitor sites with high releases of DEHA with the intent of reducing those releases.

- **Migration of DEHA from food packaging**

The assessment reported that the main exposure source for DEHA is through food as a result of the migration of the substance from food packaging materials. Intake estimates for DEHA ranged from 0.6 µg/kg-bw per day for formula-fed infants (0 – 6 months old) to 142 µg/kg-bw per day for children age 5 – 11 years old but there was no intake data for adults nor was there information of the presence of DEHA in breast milk.

The limited data indicated higher levels of DEHA in oily foods that were wrapped in food packaging containing DEHA. Since exposure estimates did not include prepared food stored in contact with PVC film, such as microwave reheated precooked meals and prepared foods from supermarkets and take-away food outlets, it is felt that the exposure to the Canadian general public is most likely under-estimated and more so for those who eat a significant amount of prepackaged foods.

There is significant concern that requests to HPFB are voluntary because of no mandatory requirement under the Food Drug Act and Regulations for the pre-market approval of food contact materials in Canada.

The screening document indicated that Health Canada's Food Directorate is currently consulting with the North American food packaging industry to obtain information on current use patterns in food packaging. At the same time, the government should work with the North American food packaging industry to find ways to eliminate the use of DEHA and other plasticizers that are currently being added to formulations that result in an increase flexibility of the packaging – whether it is by post-addition of the plasticizer or by internally plasticizing the polymer. Additionally, the government should seek create opportunities to identify safe substitutes for DEHA in food packaging.

Recommendation: For a more accurate picture of the migration of DEHA to foods, adult intake data is required. The government should require this data from the food processing industry within a specified timeframe. In absence of this data, the government should adopt precautionary measures which would result in the prohibition of DEHA in food packaging materials.

Recommendation: Government should require empirical data by industry within a specified timeframe on the migration of DEHA from prepackaged foods wrapped in PVC film and in particular, microwave reheated precooked foods and typical take-away foods that would be found in cafeterias and fast food restaurants, to

provide accurate migration values for DEHA. The absence of empirical data should prompt the government to take precautionary measures to prohibit the use of DEHA in all food packaging.

Recommendation: In efforts to find safe substitutes for DEHA in food packaging, the government should ensure that residual chemicals in the polymer are not CEPA-toxic.

Recommendation: We urge the government to consider the prohibition of DEHA (post-addition and internal plasticizer) to polymers that are designed for direct food packaging materials.

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