Ecological State of the Science Report

Hexanedioic acid, bis(2-ethylhexyl) ester
(DEHA)

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Synopsis

On September 10, 2011, the final decision on the screening assessment of hexanedioic acid, bis(2-ethylhexyl) ester (or DEHA) Chemical Abstracts Service Registry Number 103-23-1 was published in the *Canada Gazette*, Part I, pursuant to subsection 77(6) of the *Canadian Environmental Protection Act, 1999* (CEPA 1999). It was concluded that DEHA is entering or may enter 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, and that constitute or may constitute a danger in Canada to human life or health.

Since predicted environmental concentrations (PECs) – based largely on published monitoring data – were expected to exceed the predicted no effects concentration (PNEC) in surface waters at locations receiving effluent from municipal wastewater treatment plants, it was determined that releases of DEHA from industrial and other sources may be harming aquatic organisms in Canada. Evidence indicated that DEHA does not meet the criteria for persistence or bioaccumulation as set out in the *Persistence and Bioaccumulation Regulations* of CEPA 1999.

Follow-up studies were undertaken to further quantify releases of DEHA and the levels of this substance in the Canadian environment. New information relating to industrial practices at facilities that manufacture or use DEHA was collected, and modelled PECs were recalculated taking into account the new information. Additionally, samples of industrial wastewaters and municipal wastewater treatment plant effluents were obtained, and ambient surface water and sediment monitoring studies were undertaken in areas potentially impacted by point-source or diffuse releases of DEHA. DEHA analysis was also included in a landfill leachate study. Concentrations of DEHA in the newly collected samples were determined using two different analytical methods – both of which are less prone to analytical interference than the method used in previously published Canadian monitoring studies.

The new analytical results indicate that concentrations in municipal wastewater treatment plant effluents, surface waters and sediment in Canada are much lower than had been thought, and call into question the validity of the previously available Canadian monitoring data. Furthermore, since PECs based upon the new information (including those estimated using exposure models) are typically well below concentrations expected to cause harm to aquatic organisms, DEHA is not believed to be causing environmental harm in Canada. Therefore, DEHA is no longer considered to meet criteria under paragraph 64(*a*) of CEPA 1999 as it is not 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. Efforts to obtain information to more accurately model DEHA releases from truck cleaning facilities is ongoing, and potential risk from these sources will be considered when the needed information becomes available.

Introduction

On September 10, 2011, the final decision on the screening assessment of hexanedioic acid, bis(2-ethylhexyl) ester (or DEHA) Chemical Abstracts Service Registry Number 103-23-1 was published pursuant to subsection 77(6) of the *Canadian Environmental Protection Act, 1999* (CEPA 1999) (Canada 1999; Canada 2011). The screening assessment that was conducted pursuant to section 74 of CEPA 1999 (Environment Canada and Health Canada 2011a) concluded that DEHA is entering or may enter 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, and that constitute or may constitute a danger in Canada to human life or health. The main lines of evidence pertaining to ecological harm that were considered in the screening assessment are described below.

Based on its low water solubility and strong tendency to partition into organic carbon, when released into the environment DEHA is expected to partition to particles and lipids (fat) of organisms, and to accumulate in the organic phase of sediments and soils. DEHA has, nevertheless, been observed to have a low bioaccumulation potential, likely due to rapid metabolic breakdown. Both empirical and modelled data demonstrate that DEHA biodegrades quickly in water, as well as in air, sediment and soil. DEHA, therefore, does not meet the criteria for persistence or bioaccumulation as set out in the *Persistence and Bioaccumulation Regulations* of CEPA 1999 (Canada 2000).

Toxicity tests conducted at concentrations up to the water solubility limit generally report no acute effects, but chronic toxicity was observed by Felder et al. (1986) in invertebrates at concentrations close to the solubility limit that they measured. The results of Felder et al. (1986) were used to derive a chronic predicted no-effect concentration (PNEC). As a range of solubilities have been measured for DEHA using different methods, there is some uncertainty as to the mode of action causing a detrimental impact observed in this study. The aquatic PNEC used in the screening assessment (3.5 µg/L) was the same as that supported in the Organisation for Economic Co-operation and Development's SIDS initial assessment report for DEHA (OECD 2005). The sediment PNEC (5.6 mg/kg) was developed using an equilibrium partitioning approach based on the critical toxicity value used in developing the aquatic PNEC.

When determining predicted environmental concentrations (PECs) in the screening assessment, published data on measured concentrations in Canadian surface waters or effluents from municipal wastewater treatment plants (WWTPs) constituted the primary line of evidence. Modelled estimates of PECs based on conservative assumptions regarding industrial releases were also considered. Since PECs exceeded the PNEC at several of the locations considered, it was determined that releases to surface water from municipal WWTPs receiving wastes from the manufacture and industrial use of DEHA may be harming aquatic organisms in Canada.

Potential for widespread presence and continual release of DEHA into the Canadian environment was expected based on the information available at the time of the screening assessment. Studies have been undertaken to further quantify sources of releases of DEHA to the environment throughout its lifecycle, and to further quantify levels of this substance that may be found in the Canadian environment.

Follow-up targeted monitoring was focused on industrial facilities manufacturing or using the largest quantities of DEHA in Canada. These included the four facilities identified during the screening assessment to be associated with risks to aquatic organisms. Additionally, new information relating to industrial practices was collected using questionnaires and interviews (Cheminfo 2012). Sampling of municipal WWTP effluents, surface waters and sediment, and landfill leachates was also undertaken in 2011-2012 in areas potentially impacted by both point-source and diffuse releases of DEHA (Cheminfo 2012; Conestoga-Rovers and Associates 2012; Smyth and Parsa 2012; June 7, 2012, email from Water Science and Technology Directorate, Environment Canada to Science and Risk Assessment Directorate, Environment Canada, unreferenced). In addition, modelled exposure concentrations (i.e., PECs) were recalculated, taking into account results of the monitoring at industrial facilities and associated WWTPs and new information on industrial manufacturing and use practices. The following presents an analysis of the recently obtained scientific information. Information from the screening assessment that is relevant to this analysis is also presented.

Summary of Results and Scientific Considerations

Manufacturing and Industrial Uses

DEHA is an industrial chemical that is mainly used as a plasticizer in Canada, according to information for 2006 submitted pursuant to section 71 of CEPA 1999 (Environment Canada 2010), as well as voluntary surveys and interviews conducted more recently with stakeholders (Cheminfo 2012). It is used in a wide variety of plastic applications, particularly where flexibility is required at low temperatures, and mainly in flexible polyvinylchloride (PVC) food film (cling wraps) for food packaging. It also has minor uses in rubber, urethane, adhesives, sealants, hydraulic fluids, lubricants, auto protectants and hand cleansers, as well as in some cosmetics and personal care products.

In 2006, between 1 000 000 and 10 000 000 kg of DEHA were manufactured in Canada, and approximately 250 000 kg were imported into Canada, according to information submitted pursuant to section 71 of CEPA 1999 (Environment Canada 2010). New data collected through industry questionnaires and interviews indicates that the quantity of DEHA manufactured in 2011 was similar to that reported for 2006, although a higher proportion (about 75%) of this quantity was exported outside of Canada. Import quantities were also higher in 2011, with the result that the overall quantity of DEHA consumed by the largest industrial users in Canada was similar to the amount estimated for 2006 (Cheminfo 2012). Approximately 97% of the total amount of DEHA in Canadian commerce is used for PVC applications, with a large percentage of this (up to 89%) representing the manufacture of PVC cling film for food packaging (Cheminfo 2012).

DEHA production reported by manufacturers represented a small fraction of their overall production activities (in number of days per year). Details of production processes, the number and length of production periods per year, batch processing information (if applicable), and quantities of DEHA produced were provided by the companies (Cheminfo 2012). Details of on-site wastewater treatment systems were also provided. Facilities confirmed discharging their wastewater to a municipal WWTP and indicated that DEHA was normally shipped to industrial users by tanker truck.

The industrial users of DEHA also provided details of their production processes, including the number and length of production periods per year, batch processing information (if applicable), and quantities of DEHA used. The production of PVC cling film using DEHA was reported to take place most of the year, whereas other PVC compounding operations using DEHA typically occupied a small fraction of the facilities' overall operations (in number of days per year). All facilities confirmed discharging their wastewater to a municipal WWTP (Cheminfo 2012).

Monitoring

Targeted Sampling

Wastewater sampling was undertaken in early 2012 at five industrial facilities (2 manufacturers of DEHA and 3 major users) to refine industrial exposure analyses at the facilities associated with the highest quantities of DEHA (Cheminfo 2012). As part of that study, samples of influent and effluent from two municipal WWTPs were also collected – one receiving industrial wastewater from one of the studied DEHA manufacturers and the other receiving industrial wastewater from one of the studied industrial users. As noted previously, the industrial facilities visited include the four industrial sites with releases identified in the screening assessment (Environment Canada and Health Canada 2011a) as having potential to harm aquatic organisms.

Chemicals Management Plan Sampling: 2011-2012

DEHA was also included in the Chemicals Management Plan (CMP) 2011-2012 monitoring and surveillance program to further quantify levels of this substance that may be found in the environment. Three components relevant to the collection of data for DEHA included the sampling of wastewater at municipal WWTPs, a synoptic survey of surface waters and aquatic sediment, and a landfill leachate study.

Wastewater and Biosolids

Under the 2011-2012 CMP monitoring and surveillance program, samples of influent, effluent and biosolids were taken at 5 municipal WWTPs located in Ontario and Quebec. Effluent from one of the 5 sampled WWTPs was identified from previously published monitoring data cited in the screening assessment as having elevated concentrations of DEHA.

Water and Sediment

A synoptic survey of surface waters and sediment was conducted in November of 2011 under the CMP monitoring and surveillance program (June 7, 2012, email from Water Science and Technology Directorate, Environment Canada to Science and Risk Assessment Directorate, Environment Canada, unreferenced). A number of sites were sampled upstream and downstream of municipal WWTP discharges in Ontario. The water and sediment sites sampled included several located a short distance (up to 3 km) downstream of WWTPs that receive waste from industrial facilities that either use or manufacture DEHA. A total of 30 water samples and 29 sediment samples were collected.

Landfill Leachate

DEHA is a component of many PVC-based products, including PVC cling film, all of which are likely to end up in landfills at the end of their life cycle. Therefore, DEHA was included in the list of substances being investigated in a landfill leachate study conducted under the 2011-2012 CMP monitoring and surveillance program (Conestoga-Rovers and Associates 2012). Voluntary participation was solicited from landfills having an annual fill rate greater than 40 000 tonnes of municipal solid waste per year, currently having greater than 1 000 000 tonnes of waste in place, and having an operating leachate collection system. A total of 12 sites participated in the sampling study, including two sites in western Canada and ten sites in central Canada. Leachate samples were collected at each of the twelve landfill sites prior to on-site treatment. A sample of treated leachate was also collected from three of the twelve landfill sites.

Other Chemicals Management Plan Sampling

DEHA concentrations were measured in samples of 4 municipal WWTP effluents that had been collected previously in Ontario, Alberta and Quebec as part of Environment Canada's 2010-2011 CMP monitoring and surveillance program (August 1, 2012, email from Water Science and Technology Directorate, Environment Canada to Chemicals Sector Directorate, Environment Canada, unreferenced).

Analytical Methods

Surface water, influent and effluent samples were extracted either with dichloromethane (DCM) using a liquid/liquid system or with a solid phase extraction (SPE) system (SGS 2010; Smyth and Parsa 2012; Lee 2012; June 7, 2012 email from Water Science and Technology Directorate, Environment Canada to Science and Risk Assessment Directorate, Environment Canada, unreferenced). Biosolid samples were dried with anhydrous sodium sulphate, then extracted with DCM in a fluidized bed extraction system (Smyth and Parsa 2012). For sediment samples, the extraction was made with DCM using an ultrasonic bath followed by distillation (June 7, 2012, email from Water Science and Technology Directorate, Environment Canada to Science and Risk Assessment Directorate, Environment Canada, unreferenced).

DEHA content was determined using two different analytical methods. Nearly all samples were analysed using standard gas chromatograph–mass spectrometer (GC-MS) based methods. Reported detection limits for GC-MS methods were in the 0.4 – 1.0 µg/L range for water and wastewaters, 2.0 mg/kg for biosolids and 0.2 mg/kg for aquatic sediments (SGS 2010; Smyth and Parsa 2012; June 7, 2012 email from Water Science and Technology Directorate, Environment Canada to Science and Risk Assessment Directorate, Environment Canada, unreferenced). Most of the industry-associated wastewaters sampled were also analysed using a new liquid chromatography–mass spectrometer/mass spectrometer (LC-MS/MS) method (Lee 2012). Relative to GC-MS, this method is more selective and can achieve significantly lower detection limits - 0.010 µg/L or better in wastewaters (Lee 2012).

Both the GS-MS and LC-MS/MS methods used in the new studies are less prone to analytical interference and are thus more selective and more sensitive than the gas chromatography–flame ionization detector (GC-FID) method used in the monitoring studies upon which PECs in the screening assessment were mostly based.

Exposure and Risk Characterization

Results for DEHA from the targeted monitoring studies and CMP monitoring are summarized in Tables 1 and 2, respectively.

In Table 1, results are for split samples that were unfiltered prior to solvent extraction and analysis by GC-MS or LC-MS/MS. Samples from Site 2 were extracted and analyzed 16 days after sampling, whereas all other samples were extracted and analyzed within the recommended 14-day period. In comparing results of the two analytical methods, differences are expected due to the increased sensitivity and selectivity of the LC-MS/MS method, and the variability associated with splitting samples containing suspended solids.

Table 1. Targeted monitoring and estimated results for DEHA

Sampled Media		**Concentrations Based on GC-MS Analysis (µg/L)** [a]	**Concentrations Based on LC-MS/MS Analysis (µg/L)** [b]
Measured industrial wastewater discharge	Site 1 (manufacturer)	857	1125
	Site 2 (manufacturer)	5777	2091
	Site 3 (user)	41	37
	Site 4 (user)	2443	286
	Site 5 (user)	2287	2630
Measured municipal WWTP influent	Site 1	11.9	14.4
	Site 3	< 1.0 (MDL)	0.99
Estimated municipal WWTP influent	Site 1	9.5	12.5
	Site 2	24.6	8.9
	Site 3	0.21	0.19
	Site 4	0.50	0.059
	Site 5	0.034	0.039
Measured municipal WWTP effluent	Site 1	2.16	1.46
	Site 3	< 1.0 (MDL)	0.36
Estimated municipal WWTP effluent	Site 1	4.1	5.4
	Site 2	2.8	1.0
	Site 3	0.031	0.028
	Site 4	0.073	0.0085
	Site 5	0.005	0.0057

[a] Cheminfo (2012); samples were analyzed by an accredited lab
[b] Lee (2012)

With respect to the CMP monitoring results in Table 2, the GC-MS results are based on unfiltered samples that had undergone solvent extraction prior to analysis. The LC-MS/MS results are for filtered samples extracted using SPE, and thus results are expected to be lower than for those samples not filtered.

Table 2. Chemicals Management Plan monitoring results for DEHA

Sampled Media		Concentrations Based on GC-MS Analysis (µg/L for liquids or mg/kg for solids)	Concentrations Based on LC-MS/MS Analysis (µg/L for liquids or mg/kg for solids)
Influent from municipal WWTPs	facilities receiving wastewater from various sources	< 1.0 – 1.4 [a]	NA
Effluent from municipal WWTPs	facilities receiving wastewater from various sources	< 1.0 – 2.4 [a]	0.02 – 0.25 [b]
Biosolids – 12 samples [a]		< 2	NA
Surface water – 30 samples [c]		< 0.4	NA
Aquatic sediment – 29 samples [c]		< 0.2	NA
Landfill leachate – 15 samples [d]		< 0.1 – 1.0	NA

Abbreviations: NA, not available

[a] Smyth and Parsa (2012); 5 facilities

[b] Lee (2012); August 1, 2011, email from Water Science and Technology Directorate, Environment Canada to Chemicals Sector Directorate, Environment Canada, (unreferenced); 4 facilities; results are considered semi-quantitative as a surrogate standard was not yet available

[c] June 7, 2012, email from Water Science and Technology Directorate, Environment Canada to Science and Risk Assessment Directorate, Environment Canada (unreferenced)

[d] Conestoga-Rovers and Associates (2012)

Predicted environmental concentrations in surface waters receiving WWTP effluents were derived using the monitoring data presented in Tables 1 and 2, and associated risk quotient values are summarized in Table 3. The derivation of these PECs is described in the following sections of this report. Risk quotients were calculated by dividing the PEC by the PNEC (water PNEC = 3.5 µg/L; sediment PNEC = 5.6 mg/kg; as reported in Environment Canada and Health Canada 2011a).

Table 3. PECs and associated risk quotients for DEHA

Exposure Conditions		PECs Based on GC-MS Analysis (µg/L or mg/kg)	PECs Based on LC-MS/MS Analysis (µg/L or mg/kg)	Risk Quotients (PEC/PNEC)[a]
Industrial Man-ufacture	Site 1	8.2	10.8	2.3-3.1
	Site 1 (PECs based on measured WWTP effluent)	4.3	2.9	0.8–1.2
	Site 2	2.8	1.0	0.3–0.8
Industrial Use	Site 3	0.018	0.016	0.0045–0.005
	Site 3 (PECs based on measured WWTP effluent)	< 0.6	0.2	0.06–0.2
	Site 4	0.049	0.006	0.002–0.014
	Site 5	0.0005	0.0006	0.0001–0.0002
Other sources[b]	various WWTPs	< 0.1 – 0.24	0.002 – 0.025	< 0.03 – 0.07
Surface water – 30 samples		< 0.4	NA	< 0.1
Aquatic sediment – 29 samples		< 0.2	NA	< 0.04
Landfill leachate – 15 samples		< 0.1 – 1.0	NA	< 0.03 – 0.3[c]

Abbreviations: NA, not available

[a] For water, the PNEC = 3.5 µg/L; for aquatic sediment, the PNEC = 5.6 mg/kg

[b] None of these WWTPs are associated with industries that manufacture or use DEHA. The LC-MS/MS data are for filtered effluent samples, while the GC-MS data are for unfiltered samples.

[c] PECs and risk quotients will be lower than these values because dilution at the point of effluent release and partial removal in WWTPs will reduce concentrations in surface water relative to those of the leachates.

Results for WWTPs Serving Industries Manufacturing or Using DEHA

Average concentrations of DEHA measured in the unfiltered industrial wastewater at five different industrial sites varied from 41–5777 µg/L based on GC-MS analysis (Cheminfo 2012) and 37–2630 µg/L based on LC-MS/MS analysis (Lee 2012) (Table 1). With one exception, results for the two methods were similar – i.e., within a factor of 2 to 3. DEHA concentrations differed from site to site depending on whether the facility was manufacturing or using DEHA, the specific production processes in place, and the resulting volume of effluent. For example, the reason for high concentrations of DEHA in some of the wastewaters from industrial users was due to the accumulation of DEHA in the re-circulated cooling water and the limited volumes of cooling water used. The reason for high concentrations of DEHA in the industrial wastewaters from manufacturers of DEHA was also be due to a smaller volume of process water used. The two DEHA manufacturing facilities have on-site waste treatment. All wastewater from industrial manufacturing and uses of DEHA are discharged into municipal sewer systems and enter WWTPs having primary, secondary, or lagoon treatment.

As noted previously, samples of influent and effluent from two municipal WWTPs were collected – one receiving industrial wastewater from one of the studied DEHA manufacturers and the other receiving industrial wastewater from one of the studied industrial users. The highest concentration of DEHA measured in unfiltered effluent was 2.2 µg/L, and results were consistent across the two methods (Table 1).

PECs based on these monitoring data (Table 3) were calculated to estimate the exposure concentration in the receiving environment near the discharge point (i.e., a site-specific, near-field PEC). The measured concentration of DEHA in the municipal WWTP effluent associated with the DEHA manufacturer was used to calculate a PEC, taking into account the possibility that the peak concentration could have been up to a factor of 20 times higher (due to timing of sampling relative to hydraulic matching for this batch release; Stropky et al. 2007), as well as taking into account a site-specific dilution capacity (applying a limiting dilution factor of up to 10) of the receiving water in the near-field. The measured concentration of DEHA in the municipal WWTP effluent associated with the DEHA industrial user was used to calculate a PEC, taking into account site-specific dilution capacity only, as release was considered to be continuous. Since DEHA was measured in the industrial wastewater of this manufacturer and this industrial user, PECs were also calculated in a similar fashion to the other three industrial sites where DEHA was measured in industrial wastewaters only (i.e., where associated municipal WWTP effluents were not sampled), as described below.

Site-specific PECs were determined for all 5 manufacturing and industrial sites using daily DEHA loadings to the local WWTPs, which were estimated from the industrial wastewater monitoring data in Table 1. It was first determined which municipal WWTP the facility discharges to, what treatment type is used at the WWTP, and its discharge rate in litres per day. Estimates of WWTP removal efficiencies for DEHA were determined to be 85 to 89% using the models ASTreat (2006) and STP-EX (2012). The PEC was determined from the calculated WWTP effluent concentration by considering the dilution capacity of the receiving water in the near-field. In cases where the receiving water was a large lake or river, a limiting dilution factor of 10 was applied to the calculated effluent concentration.

PECs for WWTPs serving DEHA manufacturing facilities were estimated to be in the range of 1.0–10.8 µg/L, depending on the location and method of analysis. Associated risk quotients ranged from 0.3 to 3.1 (Table 3). These results suggest that there is little likelihood of risk associated with industrial manufacturing of DEHA. For the manufacturing facility associated with the highest PEC and risk quotient (i.e., Site 1), exposure estimates may be somewhat precautious as measured municipal wastewater effluent concentrations were adjusted upwards (by a factor of 20) to reflect possible peak concentrations of DEHA in effluent, which may have occurred at a time different from the timing of sample collection associated with batch release. This is supported by the fact that PECs based on DEHA measured in industrial effluent are higher than those measured in WWTP effluent by a factor of 2 to 4. Furthermore, the PNEC applied is conservative for DEHA manufacturers, because it assumes chronic (relatively long-term) exposures. However, because of the batch approach to manufacturing, the peak concentrations resulting from manufacturing are expected to be of relatively short duration. Given these factors, the risk quotients associated with DEHA manufacturing are not considered significant.

All the PECs for WWTPs serving industrial users of DEHA were estimated to be less than 0.6 µg/L (Table 3). Risk quotients were below 1 and ranged from 0.0001 to 0.2. Results for these three facilities indicate that releases from industrial users of DEHA are unlikely to cause harm to aquatic organisms.

For all five facilities examined in these exposure analyses, results indicate that releases of DEHA from industrial sources to the aquatic environment in Canada are not likely to result in harm to aquatic organisms.

Results for Other WWTPs

With respect to the CMP monitoring results in Table 2, none of the municipal WWTPs in Ontario, Alberta or Quebec were associated with industries that manufacture or use DEHA (Smyth and Parsa 2012; Lee 2012; August 1, 2012, email from Water Science and Technology Directorate, Environment Canada to Chemicals Sector Directorate, Environment Canada, unreferenced). These WWTPs employ a variety of primary and secondary sewage treatment processes and receive various types of influents, including landfill leachates as well as industrial/commercial and consumer releases. Samples collected included raw influent, effluent, and treated biosolids.

A total of about 30 unfiltered influent and effluent samples obtained from five WWTPs in Ontario and Quebec were analyzed by GC-MS. DEHA was detected at 1.4 µg/L in one influent sample and 2.4 µg/L in one effluent sample (Table 2), which were collected on different days from the same WWTP. This facility was identified as also receiving landfill leachate. DEHA was not detected in the other influent or effluent samples, or the 12 samples of biosolids (detection limits = 1.0 µg/L and 2 mg/kg; Smyth and Parsa 2012).

In addition, DEHA concentrations were measured in filtered influent and effluent samples from four WWTPs in Ontario, Alberta, and Quebec using the LC-MS/MS method (Lee 2012; August 1, 2012, email from Water Science and Technology Directorate, Environment Canada to Chemicals Sector Directorate, Environment Canada, unreferenced). Although results are not directly comparable to the GCMS results (which were based on unfiltered samples), results indicate that DEHA concentrations are low (in the 0.02–0.25 µg/L range in effluents; Table 2) at all of the tested facilities. These results are considered semi-quantitative as a surrogate standard was not yet available.

A PEC was estimated for the WWTP effluent with the highest concentration (2.4 µg/L) in its effluent. The PEC was determined to be 0.24 µg/L, allowing for a limiting 10-fold dilution in the receiving water. PECs for the other WWTPs were also estimated using a limiting 10-fold dilution in the receiving water, and values were all less than 0.1 µg/L. As indicated in Table 3, the resulting risk quotients range from less than 0.03 to 0.07.

These results indicate that at WWTPs not known to receive wastes from industrial manufacturing or uses of DEHA, potential diffuse releases of DEHA to the aquatic environment are not likely to result in harm to aquatic organisms.

Results for Ambient Water and Sediment

As indicated in Table 2, DEHA was not detected in any of the surface water or sediment samples collected in November 2011 from various watersheds in Ontario (June 7, 2012, email from Water Science and Technology Directorate, Environment Canada to Science and Risk Assessment Directorate, Environment Canada, unreferenced). For surface water and sediment, concentrations reported in Table 2 were used directly (no dilution) to determine PECs for these media in the ambient environment (i.e., far-field PECs).

The detection limits of 0.4 µg/L for water and 0.2 mg/kg for sediment were used to estimate upper bound PECs for risk quotient calculation. As indicated in Table 3, the resulting maximum risk quotient values are less than 0.1, indicating that concentrations of DEHA in ambient surface waters and sediment in Canada are unlikely to be harmful to either pelagic or benthic aquatic organisms.

Results for Landfill Leachate

DEHA was not detected in any of the pre-treatment or post-treatment leachate samples obtained from landfills in central and western Canada (Table 2). The detection limit for DEHA ranged from 0.1 to 1.0 µg/L (Conestoga-Rovers and Associates 2012).

Measured landfill leachate concentrations were used directly (no dilution) to determine PECs in the aquatic environment. Many landfill leachates are discharged to the municipal WWTP and are diluted and treated before entering the environment. Since DEHA was not detected in any samples, the method detection limits were used to determine upper bound near-field PECs. This represents a worst-case since actual concentrations were below detection limits, and concentrations in leachate will be reduced by WWTP removal and by dilution when it mixes with surface waters. As indicated in Table 3, the resulting risk quotient values are low (< 0.03–0.3), indicating that concentrations of DEHA in Canadian landfill leachates are unlikely to be harmful to aquatic organisms.

Comparison with Screening Assessment Results

In the screening assessment of DEHA (Environment Canada and Health Canada 2011a), critical support for the final conclusion was provided by published monitoring data for WWTP effluents from a number of municipalities in Quebec. These Canadian data indicated the potential for risk from diffuse sources of DEHA, as a number of near-field PECs estimated for the ambient environment were well above the PNEC. However, results for the sampling initiatives described in this report indicate that DEHA concentrations in Canadian WWTP effluents and in ambient surface waters and sediment are significantly lower than relevant PNECs. Therefore, the reliability of the monitoring data used in the screening assessment was re-evaluated.

Monitoring data reported by Horn et al. (2004), Barnabe et al. (2008), and Beauchesne et al. (2008) were used as key lines of evidence relating to exposure in the screening assessment. These authors employed GC-FID for analysis of DEHA in extracts of wastewaters, river water, landfill leachate, sludge and snow. Critical review of their procedures revealed several potential short-comings (De Silva 2012; Lee 2012). In particular, the FID quantification method used is non-specific, and is therefore prone to error due to the potential for analytical interference of organic chemicals in complex environmental mixtures typical of sludge and wastewaters. The preferred approach for complex matrices is to use an analyte-specific detector, such as the mass spectrometry–based methods (GC-MS and LC-MS/MS) used in the recent monitoring studies described in this report.

As part of preliminary work done in 2011, mass spectrometry-based analysis of two influent samples and one effluent sample from Canadian WWTPs revealed the presence of a substance (9-octadecenamide, CAS RN 301-02-0) that was co-eluting with DEHA (Lee 2012). This co-eluting substance interfered with the identification and quantification of DEHA, as demonstrated using GC-MS in scanning mode, which is useful for identifying non-target compounds from the standard mass spectra library. Considering that the GC-FID method lacks the specificity and sensitivity demonstrated by the GC-MS and LC-MS/MS methods (as the GC-FID method identifies an analytical peak by its retention time only), it is believed that the monitoring studies used in the screening assessment overestimated the amount of DEHA because of interference from sample co-extractives (De Silva 2012; Lee 2012).

Based on these considerations, the DEHA concentration data reported by Horn et al. (2004), Barnabe et al., (2008) and Beauchesne et al. (2008) are considered to be superseded by the more recent monitoring results.

Exposure associated with transport truck cleaning facilities, was not re-evaluated in this report. Based on the new information collected on industrial handling practices for DEHA, most of the transport of DEHA is by tanker trucks. As the trucks used are not dedicated to DEHA transport, they typically require cleaning after each use (Cheminfo 2012), which is done at specialized cleaning facilities. Based on some of the newly collected information, the exposure model calculations for container cleaning presented in the screening assessment may have underestimated the quantity of DEHA potentially released from those truck cleaning facilities. However, all of the information needed to more accurately model releases from these types of operations is not currently available. Efforts to obtain this information are ongoing, and potential for risk from these sources will be considered when the needed information becomes available.

Uncertainties

The more recent monitoring data used to estimate exposure concentrations in this report are based on more reliable analytical methods than the published monitoring data considered in the screening assessment. As in the screening assessment, the new data are expected to be representative of conditions close to major point sources of DEHA release. The new data are more comprehensive than those used in the screening assessment, in terms of the regions of the country represented (Ontario, Quebec and Alberta) and the number and types of samples collected (surface water, sediment and wastewaters). Because of its tendency to partition to organic phases, DEHA that is released into the aquatic environment will tend to accumulate in bottom sediments. Therefore, the inclusion in this report of exposure data for Canadian sediment is of particular importance.

The aquatic PNEC used to estimate risk in this report is the same as that used in the screening assessment and in the OECD (2005) SIDS initial assessment report. It is important to note that the aquatic PNEC is close to the method detection limits currently being used by commercial labs. Improvements in standard analytical methodologies (e.g., more rigorous sample cleanup, use of isotopically labelled DEHA as a surrogate standard, analysis of dissolved vs.

particulate phases) would enhance the quantitative determination of DEHA in various media.

Finally, although the amount of DEHA in commerce in Canada appears to have remained stable in recent years, DEHA is a potential substitute for phthalate plasticizers based on the new information collected (Cheminfo 2012). Given the high percentage of the global plasticizer market that uses phthalate products, a market shift leading to an increase in the amounts of DEHA used and released into the environment is possible in the future. If these amounts increase significantly, it may be necessary to undertake additional actions.

Conclusions

In the screening assessment for DEHA (Environment Canada and Health Canada 2011a), it was concluded that this substance does not meet the criteria for persistence or bioaccumulation as set out in the *Persistence and Bioaccumulation Regulations* (Canada 2000). It was further determined that PECs in the aquatic environment are high enough to potentially cause harm to the aquatic biota. However, the more recent industry information and monitoring results described in this report have called into question the validity of the published monitoring data that were an important line of evidence in the screening assessment. Exposure estimates in follow-up analyses, including those calculated using models, have therefore been based on the more recent information, which is considered to be more reliable. The new ecological exposure information indicates that concentrations in the aquatic environment are likely to be below those causing environmental harm. Based on these considerations, DEHA is not believed to be harming pelagic or benthic aquatic organisms in Canada.

It is therefore concluded that DEHA (CAS RN 103-23-1) is no longer considered to meet the criteria under paragraph 64(*a*) of CEPA 1999, as it is not 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. DEHA also does not meet the criteria under paragraph 64(*b*) of CEPA 1999, as it is not entering the environment in a quantity or concentration or under conditions that constitute or may constitute a danger to the environment on which life depends.

When the new information needed to more accurately model releases from transport truck cleaning operations is obtained, potential for risk from these sources will be considered. Regulatory assessment activities in other jurisdictions will be followed with the aim of identifying any new information or regulatory decisions pertaining to DEHA.

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