Government of Canada / Gouvernement du Canada

Risk Management Scope for 1,2-Benzenedicarboxylic acid, bis(2-ethylhexyl) ester [DEHP]

Chemical Abstracts Service Registry Number (CAS RN): 117-81-7

Environment and Climate Change Canada

Health Canada

October 2017

Canada

Summary of proposed risk management

Under the Substance Groupings Initiative of the Government of Canada's Chemicals Management Plan (CMP), DEHP was included within the scope of the Phthalate Substance Grouping screening assessment in a cumulative context and identified as posing a risk to the environment. The draft Screening Assessment Report (dSAR) proposes to conclude that DEHP meets criteria under paragraph 64(*a*) of the *Canadian Environmental Protection Act, 1999* (CEPA).

This document outlines the risk management options under consideration for the substance DEHP. In particular, the Government of Canada is proposing to consider:

- Implementation of regulatory and non-regulatory controls to minimize release of DEHP to the Canadian environment.

Moreover, because certain data gaps remain, the following information should be provided (ideally on or before December 6, 2017), to the contact details identified in section 8 of this document, to inform risk management decision-making:

- Information on the current use of DEHP by Canadian manufacturers and users and products or manufactured items containing the substance.
- Chemical and non-chemical alternatives to DEHP.
- Changes to DEHP use patterns and economic impacts.
- Releases of DEHP to the Canadian environment, including from landfill leachate.

The risk management options outlined in this Risk Management Scope document may evolve through consideration of assessments and risk management options published for other Chemicals Management Plan substances as required to ensure effective, coordinated, and consistent risk management decision-making.

Note: The above summary is an abridged list of options under consideration to manage DEHP and to seek information on identified gaps. Refer to section 3 of this document for more complete details in this regard. It should be noted that the proposed risk management options may evolve through consideration of additional information obtained from the public comment period, literature and other sources.

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1. Context

The *Canadian Environmental Protection Act, 1999* (CEPA) (Canada 1999) provides the authority for the Minister of the Environment and Climate Change and the Minister of Health (the ministers) to conduct assessments to determine if substances are toxic to the environment and/or harmful to human health as set out in section 64 of CEPA[1,2], and if so to manage the associated risks.

As part of the Chemicals Management Plan (CMP), the ministers are presently working to assess and manage, where appropriate, the potential health and ecological risks associated with approximately 500 substances, in 9 substance groupings, under the Substance Groupings Initiative (Canada 2011). The Substance Groupings Initiative is a key element of the CMP.

The substance, 1,2-Benzenedicarboxylic acid, bis(2-ethylhexyl) ester, Chemical Abstracts Service Registry Number (CAS RN [3])117-81-7, and referred to throughout this document as DEHP, was included within the scope of the Phthalate Substance Groupings in a cumulative context.

The Phthalate Substance Grouping includes 14 phthalate esters (phthalates) substances. These 14 substances were identified as priorities for assessment under the CMP because they met categorization criteria under section 73 of CEPA and/or were considered a priority based on human health concerns. Due to the possibility that some phthalates may have common health or ecological effects of concern and may co-occur in the environment, the potential for cumulative risk from combined exposure to these substances was addressed by expanding the scope of the assessmentfrom the original 14 phthalates to consider an additional 14 phthalates, including DEHP. These additional 14 phthalates were not assessed individually, with the exception of DEHP, but were

[1] Section 64 [of CEPA]: *For the purposes of* [Parts 5 and 6 of CEPA]*, except where the expression "inherently toxic" appears, a substance is toxic if it is entering or may enter the environment in a quantity or concentration or under conditions that*

- *(a) have or may have an immediate or long-term harmful effect on the environment or its biological diversity;*
- *(b) constitute or may constitute a danger to the environment on which life depends; or*
- *(c) constitute or may constitute a danger in Canada to human life or health.*

[2] A determination of whether one or more of the criteria of section 64 of CEPA are met is based upon an assessment of potential risks to the environment and/or to human health associated with exposures in the general environment. For humans, this includes, but is not limited to, exposures from ambient and indoor air, drinking water, foodstuffs, and products used by consumers. A conclusion under CEPA is not relevant to, nor does it preclude, an assessment against the hazard criteria specified in the *Hazard Product Regulations*, which are a part of the regulatory framework for the Workplace Hazardous Materials Information System for products intended for workplace use. Similarly, a conclusion on the basis of the criteria contained in section 64 of CEPA does not preclude actions being taken under other sections of CEPA or other Acts.

[3] Chemical Abstracts Service Registry Number. The Chemical Abstracts Service information is the property of the American Chemical Society and any use or redistribution, except as required in supporting regulatory requirements and/or for reports to the Government of Canada when the information and the reports are required by law or administrative policy, is not permitted without the prior, written permission of the American Chemical Society

included within the scope of the assessment because of their potential to contribute to cumulative risk from combined exposure to phthalates.

The one exception, DEHP, was assessed for its potential to cause harm to the environment, because a previous assessment of this substance in 1994 (Canada 1994) did not include a conclusion for the environment due to insufficient information at the time. Therefore, to complete the evaluation of DEHP, a proposed conclusion on potential risks to the environment was also included in the Draft Screening Assessment Report (dSAR) for the Phthalates Substance Grouping (Canada 2017).

2. Issue

2.1 Draft screening assessment report conclusion

Health Canada and Environment and Climate Change Canada conducted a joint scientific assessment of phthalates in the Phthalate Substance Grouping, including information relevant to the evaluation of DEHP in Canada. A notice summarizing the scientific considerations of the dSAR was published in the *Canada Gazette*, Part I, on October 7, 2017 (Canada 2017). For further information on the dSAR for the Phthalate Substance Grouping, refer to http://www.ec.gc.ca/ese-ees/default.asp?lang=En&n=516A504A-1.

Based on information examined in the dSAR, it is proposed to conclude that DEHP meets the criteria under paragraph 64(*a*) of CEPA as it 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. It is also proposed to conclude that DEHP does not meet the criteria under paragraph 64(*b*) of CEPA 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 (Canada 2017).

According to the dSAR, DEHP does not meet the criteria for persistence and does not meet the criteria for bioaccumulation, as defined in the *Persistence and Bioaccumulation Regulations* made under CEPA (Canada 2000).

The previous conclusion presented in the 1994 Priority Substance List Assessment Report that DEHP met the criteria under paragraph 64*(c)* of CEPA remains valid. Existing risk management measures are already in place to address human health concerns with DEHP, as outlined in section 7.1.

Considering all available lines of evidence presented in the dSAR, there is risk of harm to organisms, but not to the broader integrity of the environment, from DEHP. As such, this document will focus on the risk management options for areas where risk has been identified (refer to section 5).

Note that the proposed conclusions outlined in the dSAR are preliminary and may be subject to change.

2.2 Proposed recommendation under CEPA

DEHP was assessed by Environment Canada and Health Canada in 1994 under the Priority Substances Assessment Program and identified to meet the criteria under paragraph 11(c) of the previous version of CEPA, i.e., that it is entering or may enter the environment in a quantity or concentration or under conditions constituting or that may constitute a danger in Canada to human life or health (equivalent to paragraph 64(*c*) of CEPA 1999). DEHP has therefore already been added to the List of Toxic Substances in Schedule 1 of the Act.

The dSAR for the Phthalate Substance Grouping proposes to now conclude that DEHP also poses a risk of harm to the environment as it meets the criteria under paragraph 64(*a*) of CEPA. The ministers will take into consideration comments made by stakeholders during the 60-day public comment period on the dSAR and Risk Management Scope document. Since DEHP has already been added to Schedule 1, environmental risk management instruments will be proposed within 24 months from the date on which the final Screening Assessment Report (fSAR) is published, and finalized within 18 months from the date on which the risk management instruments are proposed.

3. Proposed risk management

3.1 Proposed environmental objective

Proposed environmental objectives are quantitative or qualitative statements of what should be achieved to address environmental concerns.

For DEHP, the proposed environmental objective is to reduce the concentration of DEHP in the ambient aquatic environment to levels below the predicted no-effect concentration of 0.07 µg/L, recognizing the current limitation for detection.

3.2 Proposed risk management objective and options under consideration

Proposed risk management objectives set quantitative or qualitative targets to be achieved by the implementation of risk management regulations, instrument(s) and/or tool(s) for a given substance or substances. In this case, the proposed risk management objective for DEHP is to achieve the lowest level of releases of DEHP to water that is technically and economically feasible, taking into consideration socio-economic factors.

This objective will be refined based on consultation with stakeholders, the proposed risk management, consideration of further information received, the outcome of the fSAR, and socio-economic and technical considerations (such as may be outlined in section 6 of this document). Revised environmental and risk management objectives should next be presented in the RM Approach document that will be published concurrently with the fSAR for the Phthalate Substance Grouping (including DEHP), or in subsequent risk management documents (e.g. consultation document on proposed instrument), as the case may be.

To achieve the proposed risk management objective and to work towards achieving the proposed environmental objective, the proposed risk management options under consideration for DEHP are to consider implementation of regulatory and non-regulatory controls to minimize release of DEHP to the Canadian environment.

Note that the proposed risk management options, described in this document, are preliminary and subject to change. Following the publication of this document, additional information obtained from the public comment period and from other sources will be considered, along with the information presented in this document, in the instrument selection and development process[4]. The risk management options outlined in this document may also evolve through consideration of assessments and risk management options published for other CMP substances to ensure effective, coordinated, and consistent risk management decision-making.

3.3 Risk management information gaps

Interested stakeholders are invited to provide further information, such as that outlined below, to inform risk management decision-making regarding DEHP:

1) Information on the current use of DEHP by Canadian manufacturers and users, and products or manufactured items containing the substance
    - Details on the current use of DEHP in plastic products manufacturing and in different products, such as plastic materials, medical devices, floor coverings, electrical and electronic products, wire and cable, and food packaging, including:
        - The quantity of DEHP used in these applications;
        - The concentration of DEHP used in these applications;
        - Description of the specific uses of DEHP for these applications.

[4] The proposed risk management regulation(s), instrument(s) or tool(s) will be selected using a thorough, consistent and efficient approach and take into consideration available information in line with the Government of Canada's Cabinet Directive on Regulatory Management (TBS 2012a), the Red Tape Reduction Action Plan (TBS 2012b), and in the case of a regulation the *Red Tape Reduction Act* (Canada, 2015a).

2) Chemical and non-chemical alternatives to DEHP

- Details on alternatives to DEHP and/or technologies, and their feasibility as applicable to Canadian manufacturers, importers and users in:
    - Various sectors such as: plastics manufacturing (e.g. polyvinyl chloride, plastic compounding), medical devices manufacturing (e.g. surgical drains, tubes, syringes), electrical and electronic equipment manufacturing (e.g. wires and cables, home appliances, computer and peripheral), and chemical manufacturing (e.g. paints and coating).

3) Changes to DEHP use patterns and economic impacts

- Anticipated economic impacts if the import and/or use of DEHP is prohibited or restricted in Canada; and
- Ongoing or anticipated changes in use of DEHP, whether in response to:
    - Market forces;
    - Shifts to alternative substances (please provide commercial name), alternative systems and approaches; and
    - Other reasons (please provide information on these reasons).

Should stakeholders have further information to help address these gaps, they should provide it ideally on or before December 6, 2017 to inform the risk management decision-making process, within the timelines (and to the contact) identified in section 8 of this document.

In addition, due to data gaps related to DEHP in landfill leachate, the Government of Canada proposes to undertake surveillance in order to characterize potential releases from this source.

4. Background

4.1 General information on DEHP

The phthalate DEHP is an organic substance comprised of a benzene ring with two ester side groups in the *ortho* position. Phthalates in the Phthalate Substance Grouping were divided into short-chain, medium-chain and long-chain subgroups, based on the length of the carbon backbone in their ester side-groups. Phthalates within each subgrouping have similar chemical and toxicological properties. DEHP is a medium-chain phthalate substance (Canada 2017).

4.2 Current uses and identified sectors

DEHP is globally the most commonly used polyvinyl chloride (PVC) plasticizer, used to impart flexibility into this otherwise rigid polymer. As one of the most widely used plasticizers in industrial applications, DEHP offers excellent compatibility and performance properties at a low cost. DEHP is found in a wide

variety of flexible plastic products, and can be found in amounts ranging from less than 20% to more than 50% by weight (TURI 2006).

Based on a survey conducted in 2013 under section 71 of CEPA, a total of 47 companies reported under the survey, including manufacturers, importers, users and exporters.

The total quantity of DEHP manufactured in Canada in 2012 was in the range of 1,000 – 10,000 tonnes. The total quantity of DEHP imported into Canada in 2012 was in the range of 100 – 1,000 tonnes, while the total quantity exported from Canada was in the range of 10 – 100 tonnes (Canada 2017).

The total quantity of DEHP that was reported to be used in Canada in 2012 was in the range of 1,000 – 10,000 tonnes. DEHP was reported to be used by a variety of sectors in Canada, including chemical manufacturing, pharmaceutical formulation, medical equipment and supplies manufacturing, paint, coating and adhesive manufacturing, plastic and rubber product manufacturing, computer and equipment manufacturing, and major appliance manufacturing companies, as well as merchant wholesalers, such as professional machinery, equipment and supplies merchant wholesalers and home entertainment equipment merchant wholesalers.

A variety of products, mixtures or manufactured items containing DEHP were reported, including: polyvinyl chloride plastic, plastic compounding, surgical drains, tubes, syringes, flooring tile, wire and cable, computer and electronic equipment, major home appliances, paints and coating, and food packaging.

5. Exposure sources and identified risks

Anthropogenic activities are the major source of phthalates, including DEHP, entering the environment. Releases may occur during the manufacture and processing of phthalates, including transportation and storage, as well as during production, use and disposal of products that contain phthalates. Phthalates are not chemically bound into polymer matrices during processing activities and can migrate to the surface of polymer products over time. The rate of this migration is expected to be slow and will be counteracted by chemical and physical attractive forces which work to hold the phthalates within polymers. Phthalates are used in a variety of consumer, commercial and industrial applications, providing opportunities for widespread release into the Canadian environment. Releases of phthalates to the environment are expected to occur primarily to air and water (Canada 2017).

Information on releases of phthalates in Canada is limited. Six phthalates, including DEHP, are reportable to the National Pollutant Release Inventory (NPRI), where all reported releases were to air. For the 2013 section 71 survey, many submissions indicated no or unknown releases (Canada 2017).

Based on known applications in consumer and industrial products, environmental releases of phthalates, including DEHP are expected to occur primarily to water, through off-site wastewater treatment systems (WWTS)[5] and through disperse releases from consumer products. As such, the aquatic compartment is thought to be the key receiving environmental compartment for all phthalates, including DEHP (Canada 2017).

Once released into the aquatic environment, DEHP is expected to distribute mainly into sediment, although some portion will also remain in the water column. Phthalates biodegrade and are not expected to persist in the environment, although degradation rates vary with phthalate molecular size and physicochemical properties, substrate concentration and environmental conditions. Degradation proceeds more slowly under low oxygen conditions, such as may occur in sediment and soil, potentially increasing exposure times for organisms residing in these media. As well, information on Canadian phthalate use and release patterns suggests that exposure to phthalates in the Canadian environment may be continuous (Canada 2017).

Based on information about releases and the predicted distribution in the environment, aquatic organisms (water column and sediment) will have the highest potential for exposure. The relatively rapid biodegradation rates of phthalates indicate that exposure will be greatest for organisms inhabiting areas close to release sites. Concentrations of phthalates, including DEHP, are expected to decrease with increasing distance from points of discharge (Canada 2017).

Some measured environmental concentrations are available for DEHP. Information on phthalate concentrations, including DEHP, in wastewater collected at on-site industrial and off-site wastewater treatment systems in Canada was obtained through a sampling campaign carried out by ECCC from 2014-2016. Influents and effluents of on-site WWTS from five industrial facilities involved in the manufacture or use of phthalates were collected and analyzed, along with influents and effluents of the off-site WWTS where the industrial sites direct their effluents. In addition to these five industrial sites and corresponding WWTS, eleven other Canadian WWTS were sampled and analyses were conducted. This monitoring data was used to generate 28 predicted

[5] The term “wastewater treatment system” refers to a system that collects domestic, commercial and/or institutional household wastewater and possibly industrial wastewater (following discharge to the sewer), typically for treatment and eventual discharge to the environment. Unless otherwise stated, the term wastewater treatment system makes no distinction of ownership or operator type (municipal, provincial, federal, indigenous, private, partnerships). Systems located at industrial operations and specifically designed to treat industrial effluents will be identified by the terms “on-site wastewater treatment systems” or “industrial wastewater treatment systems”.

environmental concentrations (PECs)[6] for DEHP in the receiving waters near potential discharge points (Canada 2017).

Risk quotient analyses for the aquatic medium were developed for DEHP, using the derived PECs and a predicted no-effects concentration (PNEC) of 0.07 μg/L, which is based on known endocrine effects of DEHP. The analyses determined that DEHP has the potential to cause adverse effects in populations of aquatic organisms in Canada (i.e. risk quotient > 1) at current levels of exposure predicted using sampling data from WWTS effluents (Canada 2017).

There is uncertainty with respect to the sources of phthalates in the aquatic environment. For DEHP, modeling suggests that aquatic releases from industrial users (i.e., plastic products manufacturers) may be a potential source. Furthermore, based on the measured concentrations of phthalates in WWTS that receive both domestic and industrial wastewaters, the contribution of industrial activities may not be the main source of phthalates in most cases. The main sources are potentially from consumer or commercial inputs or landfill leachate, but it is not possible to specifically attribute the sources.

An analysis of the locations where both industrial and municipal monitoring was available suggests that the phthalate loading from the known industrial phthalates manufacturers or users generally accounted for less than 10% of the total phthalate loading in the off-site WWTS influents. This suggests that much of the phthalates, including DEHP, found in the influents of off-site WWTS may be coming from other sources, such as wastewater from residential and commercial sources, industrial sources not captured by the section 71 survey reporting requirements, or landfill leachate (Canada 2017).

Additionally, for each of the WWTS, a per capita influent loading of DEHP was estimated. It was found that the average per capita loading of DEHP for a WWTS that receives landfill leachate was 9.3 times higher than the average per capita loading of DEHP for the WWTS that didn't receive leachate suggesting that landfill leachate may represent a non-negligible source of DEHP in municipal WWTS influent. However, because the total quantity of DEHP entering landfills through end-of-life products, manufactured items or other materials is not known and because the concentration of DEHP in landfill leachate was not measured, it is not presently possible to confirm or quantify the contribution of landfill leachate as a source of DEHP to WWTS (Canada 2017).

6. Risk management considerations

6.1 Alternatives and alternate technologies

[6] A few of these PECs were calculated for industrial sites that were not monitored, although monitoring data from other monitored sites was used to estimate emission factors.

Alternative manufacturing processes to create flexible polymers can involve the replacement of DEHP with another plasticizer, or the use of a polymer or other material that does not require the use of a plasticizer to achieve the same characteristics and performance (TURI 2006). In 2006, the Toxics Use Reduction Institute (TURI) conducted an assessment of various plasticizer and polymer alternatives associated with DEHP in a study for the Commonwealth, entitled "Five Chemicals Alternatives Assessment Study". As part of that study, several alternative plasticizers and polymers were identified for consumer products, as well as medical devices (TURI 2006).

For products available to consumers, the 2006 TURI study focused on resilient flooring as a priority use. Resilient flooring uses include residential flooring as well as commercial and high-traffic industrial applications. TURI identified several plasticizer alternatives for resilient flooring, including di (2-ethylhexyl) terephthalate (DEHT), di isononyl phthalate (DINP[7]), dipropylene glycol dibenzoate (DGD) and di (2-ethylhexyl) adipate (DEHA[8]). Of the materials assessed as alternatives to DEHP/PVC, cork and linoleum appear to be feasible (TURI 2006).

TURI also studied alternatives for PVC wall coverings and found that the two most widely recognized alternatives to DEHP for wall coverings are DEHA and DINP. Numerous alternative materials were assessed, including woven glass textiles, a wood fiber/polyester blend, cellulose polyester blends, a wood pulp/recycled paper blend, biofiber products, and polyolefin/synthetic textiles. Each appears to present a feasible alternative to DEHP/PVC for wall covering applications (TURI 2006).

For medical devices, the most commonly used alternative plasticizers include trioctyl trimellitate (TOTM), DEHA and butyryl trihexyl citrate (BTHC). Materials that have been found to be appropriate alternatives to DEHP/PVC for medical bag devices include: ethylene vinyl acetate (EVA), polyolefins such as polyethylene and polypropylene, and glass. Appropriate alternative medical tubing materials include EVA, polyolefins and glass, as well as silicone and thermoplastic polyurethane (TPU) (TURI 2006).

In 2014, the Chronic Hazard Advisory Panel (CHAP) completed a cumulative hazard assessment of phthalates and phthalate alternatives as used in children's toys and child care articles for the United States Consumer Product Safety Commission (CPSC). As part of the study, the CHAP assessed the risks of 6 phthalate alternatives, including 2,2,4-trimethyl-1,3 pentanediol diisobutyrate

[7] In the dSAR, DINP was considered as a medium-chain phthalate for the purposes of the health assessment, and as a long-chain phthalate for the purposes of the ecological assessment. The dSAR indicates that certain short-chain and medium-chain phthalates that are not expected to be of concern to the environment at current levels could represent a concern for the environment, due to their high hazard potential, if exposure to these substances were to increase.

[8] DEHA was found to meet the criteria for S.64(c) of CEPA, refer to http://www.gazette.gc.ca/rp-pr/p2/2016/2016-12-14/html/sor-dors308-eng.php.

(TPIB), DEHA, di(2-ethylhexyl) terephthalate (DEHT), acetyl tributyl citrate (ATBC), diisononyl hexahydrophthalate (1,2-cyclohexanedicarboxylic acid, diisononyl ester) (DINX), and TOTM. The study found no evidence that the alternatives considered by the CHAP present a hazard to infants or toddlers from mouthing toys or child care articles. However, the CHAP recommended that the appropriate U.S. agencies obtain the necessary exposure and hazard data to estimate total exposure to the phthalate alternatives and assess the potential health risks (CHAP 2014).

In 2010, the Danish Environmental Protection Agency conducted a study to identify and assess alternatives to selected phthalates, including DEHP. A number of alternative plasticisers to DEHP were identified, including diisononyl adipate (DINA), di-isononyl-cyclohexane-1,2dicarboxylate (DINCH), DEHT, ATBC and sulfonic acids, C10 – C18-alkane, phenylesters (ASE). The study found that some of the assessed alternative plasticisers have a broad application scope, while others are more specialized (Denmark, 2010).

The Swedish government has assigned the Swedish Chemicals Agency (KEMI) to push for a phaseout in Sweden of phthalates suspected of causing adverse effects on reproduction and the endocrine system. In 2014, KEMI published a survey of phthalates in articles in Sweden comprising uses and available alternatives to phthalates. The survey found that many Swedish companies have replaced DEHP with the phthalates DIDP, DINP or DPHP or completely different plasticisers that are not phthalates (Sweden 2014).

6.2 Socio-economic and technical considerations

There are some sources of information available about the current state of industry's transition to alternative substances. Socio-economic factors will be considered in the development of the risk management objectivesand in the development of regulations, instruments and/or tools respecting preventative or control actions, as identified in the *Cabinet Directive on Regulatory Management* (TBS 2012a) and the guidance provided in the Treasury Board document *Assessing, Selecting, and Implementing Instruments for Government Action* (TBS 2007).

7. Overview of existing risk management

7.1 Related Canadian risk management context

DEHP was previously assessed by Environment Canada and Health Canada in 1994 under the Priority Substances Assessment Program and determined to present a risk to human health in Canada. DEHP has therefore already been added to the List of Toxic Substances in Schedule 1 of CEPA.

Under the Canadian Council of Ministers of the Environment (CCME), Canadian water quality guidelines were developed for three phthalate esters, including DEHP. For DEHP, the guideline value was set at 16 µg/L for fresh water (CCME 1993). Based on Environment and Climate Change Canada's current analytical methods, the detection limit for DEHP is 1.2 µg/L at a 99% confidence interval. The presence of DEHP in blanks is the limiting factor in the determination of a detection limit for this compound (Alaee 2016). DEHP is reportable to the NPRI. Under the NPRI, DEHP is listed as a core substance and the reporting threshold is 10-tonnes manufactured, processed or otherwise used, or >1% concentration except by-products.

Health Canada developed the *Phthalates Regulations* under the *Canada Consumer Product Safety Act*, to limit the concentration of six phthalates, including DEHP, in the vinyl used in children's toys or child-care articles to <0.1% by weight. The regulations came into force in June 2011 (Canada 2010). Health Canada issued an enforcement report in July 2016 verifying compliance of child care articles and toys with the *Phthalates Regulations* (Canada 2016a).

DEHP is on the List of Prohibited and Restricted Cosmetic Ingredients in Canada (Canada 2015b).

Under the *Food and Drugs Act*, Health Canada developed and implemented the *Medical Devices Regulations*. The Regulations, which came into force in 1998, require that manufacturers indicate when a medical device imported or sold in Canada contains DEHP at a concentration ≥0.1% by weight (Canada 2016b).

The safety of chemicals used in food packaging materials is subject to the provisions of Division 23 of the *Food and Drug Regulations* and section 4(1)(a) of the *Food and Drugs Act*. The use of DEHP in food packaging applications has been assessed and determined not to represent a risk to human health.

7.2 Pertinent international risk management context

7.2.1 United States

Under the *Consumer Product Safety Improvement Act of 2008* (CPSIA), the United States banned DEHP at a concentration of >0.1% by weight in children's toys and child care articles (CPSIA 2008). The CPSIA also directed the U.S. Consumer Product Safety Commission (CPSC) to convene a Chronic Hazard Advisory Panel (CHAP) to study the effects of phthalates and phthalate alternatives used in children's toys and child care articles. In 2014, the CHAP completed a cumulative hazard assessment of phthalates. The CHAP recommended no further action by CPSC on DEHP at this time because it is already permanently banned in children's toys and child care articles at levels >0.1% by weight. However, the CHAP recommended that U.S. agencies responsible for dealing with DEHP exposures from food and other products

conduct the necessary risk assessments with a view to supporting risk management steps (CHAP 2014, CPSC 2016).

In 2009, the United States Environmental Protection Agency (US EPA) released an Action Plan for phthalates which includes conducting an assessment of phthalates under the Integrated Risk Information System program. The US EPA intends to initiate action to address the manufacturing, processing, distribution in commerce, and/or use of eight phthalates, including DEHP (US EPA 2009).

7.2.2 European Union

The EU Phthalates Directive on phthalates (2005/84/EC) limits the concentration of six phthalates, including DEHP, in childcare articles to ≤0.1% by weight. Member states were required to apply these measures from January 2007 (EU 2005).

The EU Restriction of Hazardous Substances (RoHS) Directive restricts the use of certain hazardous substances in electrical and electronic equipment (EEE). In June 2015, DEHP was added to the RoHS Directive list and will be restricted from 22 July 2019 for all electrical and electronic equipment with a maximum concentration of 0.1% by weight (EU 2015).

The European Chemicals Agency (ECHA), in cooperation with the Danish Environmental Protection Agency, is proposing a restriction for various indoor/outdoor articles which contain four phthalates, including DEHP, in concentrations ≥0.1% by weight. These articles include those in contact with human skin or mucous membranes and those that are used or stored indoors where there is potential inhalation exposure (non-occupational). The public consultation period on this proposal ended December 15, 2016 (ECHA 2016).

The European Commission has recently published a decision to authorise the use of recycled PVC containing DEHP to three companies. The authorization allows industrial use of recycled soft PVC containing DEHP to produce PVC articles with specific exceptions such as childcare articles. The authorisation's review period expires on 21 February 2019 (EU 2016).

Since 1999, it has been prohibited in Denmark to manufacture, import and sell toys and certain childcare articles containing phthalates for children under 3 years. Since 2007, it has also been prohibited to manufacture and import toys and childcare articles for children up to the age of 14 years containing the phthalates DEHP, DBP and BBP (Denmark, 2009).

In December 2012, France passed a law that bans the use of tubes containing DEHP in paediatrics, neonatology and maternity wards in hospitals. The ban came into effect on 1 July 2015 making France the first country to ban the use of DEHP-containing tubes in hospitals (France 2012).

7.2.3 Other jurisdictions

In 2006, the Australian National Industrial Chemicals Notification and Assessment Scheme (NICNAS) declared nine phthalates as Priority Existing Chemicals, including DEHP. As a result, NICNAS planned to conduct human health risk assessments on consumer applications of the nine phthalates. DEHP was considered to be the phthalate of potentially greatest concern and was therefore the first to be assessed. The NICNAS draft report recommended that action to be taken to limit the amount of DEHP in children's toys and childcare articles. In 2011, Australia introduced a ban on certain children's plastic products (e.g., toys, childcare articles, eating vessels and utensils) containing >1% DEHP (Australia 2011).

8. Next steps

8.1 Public comment period

Industry and other interested stakeholders are invited to submit comments on the content of this Risk Management Scope or other information that would help to inform decision-making (as outlined in section 3.3). Please submit additional information and comments prior to December 6, 2017. The Risk Management Approach document, which will outline and seek input on the proposed risk management instrument(s), will be published at the same time as the final Screening Assessment Report. At that time, there will be further opportunity for consultation.

Comments and information submissions on the Risk Management Scope should be submitted to the address provided below:

Environment and Climate Change Canada
Chemicals Management Division
Gatineau Quebec K1A 0H3
Tel: 1-888-228-0530 | 819-956-9313
Fax: 819-953-7155
Email: eccc.substances.eccc@canada.ca

Companies who have a business interest in DEHP are encouraged to identify themselves as stakeholders. Stakeholders will be informed of future decisions regarding DEHP and may be contacted for further information.

Following the public comment period on the Risk Management Approach document, the Government of Canada will initiate the development of the specific risk management instrument(s), where necessary. Comments received on the Risk Management Approach document will be taken into consideration in the selection or development of these instrument(s). Consultation will also take place as instrument(s) are developed.

8.2 Timing of actions

Electronic consultation on the Risk Management Scope: October 7, 2017 to December 6, 2017.

Submission of additional studies or information on DEHP: on or before December 6, 2017.

Publication of responses to public comments on the draft Screening Assessment Report and Risk Management Scope: on or before October 2018.

Publication of the final Screening Assessment Report and, if required, the Risk Management Approach document: on or before October 2018.

Publication of responses to public comments on the Risk Management Approach, if applicable and if required, the proposed instrument(s): at the latest, 24-month from the publication of the final Screening Assessment Report

Consultation on the proposed instrument(s), if required: 60-day public comment period begining upon publication of each proposed instrument(s)

Publication of the final instrument(s), if required: at the latest, 18-month from the publication of each proposed instrument(s)

9. References

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