Government of Canada Gouvernement du Canada

Canada

Risk Management Approach

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

December 2020

Summary of Proposed Risk Management

This document outlines the proposed risk management actions for 1,2-benzenedicarboxylic acid, bis(2-ethylhexyl) ester, commonly known as diethylhexyl phthalate (DEHP), which has been found to be harmful to the environment.

In particular, the Government of Canada is proposing measures to manage anthropogenic releases of DEHP from all industrial sectors and activities by:

- Amending the *Prohibition of Certain Toxic Substances Regulations, 2012,* to prohibit the manufacture, use, sale, offer for sale, and import of the substance DEHP and products containing it. Consideration will be given to establishing a maximum concentration for DEHP in products of 0.1% by weight, whereby products containing greater than 0.1% by weight DEHP would be subject to the prohibition. This limit would be consistent with limits set in other existing controls on DEHP in Canada and in other jurisdictions.

Note that the proposed risk management option described in this document may be 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[1]. The risk management options outlined in this Risk Management Approach document may evolve through consideration of assessments and risk management options published for other Chemicals Management Plan (CMP) substances as required to ensure effective, coordinated, and consistent risk management decision-making.

Several data gaps remain to be addressed, therefore the following information is requested (on or before DATE), to the contact details identified in section 8 of this document to further inform risk management decision-making:

Activity	Information Needs
Import, use, sale, and/or offer for sale of DEHP or a product containing it for use in applications including: • plastic products such as plastic materials; • medical devices; • floor coverings; • building construction materials;	• Description of the specific use of DEHP in your activity, including its quantity and concentration. • Known alternatives to DEHP suitable to the specific use/function.

[1] The proposed risk management regulation 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 Regulation (TBS, 2018), the Red Tape Reduction Action Plan (TBS, 2012b), and in the case of a regulation the *Red Tape Reduction Act* (Canada, 2015a).

• electrical and electronic products; • wire and cable; and • food packaging materials	• Achievable timeline for your company to complete a phase out of DEHP, explaining significant challenges, cost estimates and efficiency or suitability of alternatives.

Substitution considerations:

DEHP is one of twenty-eight substances considered in the assessment of the Phthalates Substance Grouping of the CMP's Substance Groupings.

Of these twenty-eight substances, there are twenty substances associated with human health or ecological effects of concern, but for which exposure of the general population or the environment is not of concern at current levels. Some of these substances have been identified as potential alternatives to DEHP. Therefore, changes in use patterns for these substances, such as using them as an alternative for chemicals with similar uses or functions, could lead to higher levels of exposure. For this reason, follow-up activities to track changes in exposure or use patterns for these substances are being considered, including information gathering, and biomonitoring and/or environmental monitoring. Further information on alternatives to DEHP can be found in section 6.1 Alternative and Alternate Technologies.

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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 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[2,3], and if so to manage the associated risks.

The substance, 1,2-benzenedicarboxylic acid, bis(2-ethylhexyl) ester, Chemical Abstracts Service Registry Number (CAS RN [4]) 117-81-7, and referred to throughout this document as DEHP, was included within the scope of the Phthalate Substance Grouping in a cumulative context.

The Phthalate Substance Grouping includes 14 phthalate ester (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 that there may be exposure of the general population and the environment, the potential for cumulative risk from combined exposure to these substances was addressed and the scope of the assessment expanded to consider an additional 14 other similar phthalates, including DEHP. These additional 14 phthalates were not assessed individually, with the exception of DEHP, but were included within the scope of the assessment because of their potential to contribute to cumulative risk from combined exposure to phthalates.

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. As sufficient information was now available to complete the evaluation of DEHP, a

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[2] 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.*

[3] A determination of whether one or more of the criteria of section 64 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.

[4] 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.

conclusion on potential risks to the environment was also included in the Screening Assessment Report (fSAR) for the Phthalates Substance Grouping (Canada 2020).

2. Issue

Environment and Climate Change Canada (ECCC) and Health Canada conducted a joint scientific assessment of the Phthalate Substance Grouping, which included information relevant to the evaluation of DEHP in Canada. A notice summarizing the scientific considerations of the Screening Assessment Report for these substances was published in the *Canada Gazette*, Part I, on December 5, 2020 (Canada 2020). For further information, refer to the Screening Assessment Report for the Phthalate Substance Grouping.

2.1 Screening Assessment Report Conclusion

The Screening Assessment Report concludes that DEHP is toxic under section 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 (Canada 2020).

The Screening Assessment Report also concludes that 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 which stated that DEHP met the criteria paragraph 11(*c*) of the previous version of CEPA (equivalent to 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 Screening Assessment Report, there is risk of harm to organisms, but not to the broader integrity of the environment, from exposure to DEHP. The risks of concern, identified in the Screening Assessment Report, are based on the release of DEHP from off-site wastewater treatment systems (WWTS) and disperse releases from consumer products. As such, this document will focus on the risk management options for areas where risk to the environment has been identified (refer to section 5.2).

2.2 Recommendation Under CEPA

The Screening Assessment Report for the Phthalate Substance Grouping concludes that DEHP poses a risk of harm to the environment as it meets the criteria under paragraph 64(*a*) of CEPA. DEHP has already been added to the List of Toxic Substances in Schedule 1 of the Act and no further recommendation under CEPA is required.

The ministers have taken into consideration comments made by stakeholders during the 60-day public comment period on the draft Screening Assessment Report (dSAR) and Risk Management Scope document. Environmental risk management instruments will be proposed within 24 months from the date on which the SAR is published, and finalized within 18 months from the date on which the risk management instruments are proposed.

2.3 Public Comment Period on the Risk Management Scope

The Risk Management Scope document for DEHP, which summarized the proposed risk management actions under consideration at that time, was published on October 7, 2017. Industry and other interested stakeholders were invited to submit comments on the Risk Management Scope document during a 60-day comment period. Comments received on the Risk Management Scope document were taken into consideration in the development of this document. A summary of responses to public comments received is available from the Summary of public comments received on the screening assessment report for the phthalate substance group.

3. Proposed Risk Management

Section 3 presents the environmental and risk management objectives, as well as the proposed actions to achieve them. For more information on the context and rationale for these actions, please consult sections 4 and 5.

Following the publication of this Risk Management Approach, additional information obtained during the public comment period and from other sources will be considered. The risk management actions outlined in this document may evolve through consideration of assessments and risk management actions published for other Chemicals Management Plan substances to ensure effective, coordinated and consistent risk management decision making.

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 focused on addressing the risks of concern identified in the risk assessment and outlined in section 5 of this document. As such, the proposed environmental objective for DEHP is to reduce

the concentration of DEHP in the Canadian environment to the greatest extent practicable.

3.2 Proposed Risk Management Objective

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 risk management objective for DEHP is to achieve the lowest level of releases of DEHP into the Canadian environment, taking into account economic, social and technical matters.

To achieve the risk management objective and to work towards achieving the environmental objective, the proposed risk management action for DEHP will focus on preventing environmental releases of DEHP from all sources including releases from industrial and off-site WWTS and diffuse releases from consumer products.

3.3 Proposal to Amend the Prohibition of Certain Toxic Substances Regulations, 2012, to include DEHP

To achieve the proposed risk management objective and to work towards achieving the proposed environmental objective, the proposed action for DEHP is to develop regulations amending the *Prohibition of Certain Toxic Substances Regulations, 2012* to include the substance DEHP and all products containing DEHP.

This would prohibit the manufacture, import, use, sale and offer for sale of DEHP and products containing DEHP and therefore would target all manufacturers, importers and users of the substance DEHP and products containing DEHP. As part of the risk management of products consideration will be given to establishing a maximum concentration for DEHP in products of 0.1% by weight, whereby products containing greater than 0.1% by weight DEHP would be subject to the prohibition. This limit would be consistent with limits set in other existing controls on DEHP in Canada and in other jurisdictions.

3.4 Risk Management information gathering

To address remaining data gaps and understand the challenges faced by stakeholders, we are asking for specific information related to DEHP. If your company undertakes an activity listed below, ECCC invites you to submit the information identified below within the timelines and to the contact identified in section 8 of this document.

Activity	Information Needs
Import, use, sale, and/or offer for sale of DEHP or a product containing it for use in applications including: • plastic products such as plastic materials; • medical devices; • floor coverings; • building construction materials; • electrical and electronic products; • wire and cable; and • food packaging materials	• Description of the specific use of DEHP in your activity, including its quantity and concentration. • Known alternatives to DEHP suitable to the specific use/function. • Achievable timeline for your company to complete a phase out of DEHP, explaining significant challenges, cost estimates and efficiency or suitability of alternatives.

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 2020). 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).

4.2 Current Uses and Identified Sectors

DEHP has been used in a variety of sectors in Canada, according to submissions made under section 71 of CEPA (Canada 2013, 2017a), including automotive/aircraft manufacturing, chemical manufacturing, pharmaceutical formulation, medical equipment and supplies manufacturing, paint formulation, coating and adhesive manufacturing, plastic and rubber product manufacturing, building and construction material manufacturing, computer and equipment manufacturing, major appliance manufacturing, as well as merchant wholesaling,

such as those for professional machinery, equipment and supplies, and home entertainment equipment.

A variety of products, mixtures or manufactured items containing DEHP were reported in the section 71, these include: flexible PVC, plastic compounding, rubber compounding, surgical drains, tubes, syringes, flooring tiles, table coverings, shower curtains, wire and cable, computer and electronic equipment, major home appliances, paints and coating, automotive parts, building and construction materials and food packaging materials.

In response to a survey on phthalates conducted in 2013 under section 71 of CEPA, a total of 47 companies reported involvement with DEHP, including 2 manufacturers, 31 importers, 23 users and 9 exporters. The survey conducted in 2013 did not take into account the import of finished products containing DEHP. In a similar survey conducted in 2017 for DEHP, there were a total of 30 respondents. Of these 30 companies, 1 identified as a manufacturer, 8 as importers (3 of DEHP and 5 of products or manufactured items containing DEHP), and 9 as users. Additionally, under the 2017 survey, 14 companies reported the import of manufactured items containing DEHP. In 2017, DEHP was not surveyed for export data. In certain cases, in both the 2013 and 2017 surveys, companies identified under multiple categories.

According to submissions made under section 71 of CEPA (Canada 2013, 2017a), the total quantity of DEHP that was reported to be used in Canada was in the range of 1,000 – 10,000 tonnes in both the 2013 and 2017 submissions, however total reported usage of DEHP between the two submissions has decreased by almost 50%.

According to surveys conducted under section 71 of CEPA (Canada 2013, 2017a) the total quantity of DEHP manufactured in Canada in 2012 was in the range of 1,000 – 10,000 tonnes and in 2016 was in the range of 100 – 1,000 tonnes, a decrease of approximately 70%. The total quantity of DEHP imported into Canada was in the range of 100 – 1,000 tonnes in 2012 and 2016, however total reported import also decreased by approximately 70%. The total quantity exported from Canada in 2012 was in the range of 10 – 100 tonnes.

5. Exposure Sources and Identified Risks

Anthropogenic activities are the major source of DEHP entering the environment. Releases may occur during the manufacture and processing of DEHP, including transportation and storage, as well as during production, use and disposal of products that contain DEHP. DEHP is not chemically bound into polymer matrices during manufacturing/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 potential widespread release into the Canadian environment. Releases of phthalates to the environment are expected to occur primarily to air and water (Canada 2017b).

Information on releases of phthalates in Canada is limited. DEHP is reportable to the National Pollutant Release Inventory (NPRI), where all reported releases were to air.

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

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 2017b).

On the basis of 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 2017b).

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 in 2014-2017. Samples of influents and effluents of on-site WWTS from five

[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, aboriginal, 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”.

industrial facilities involved in the manufacture or use of phthalates were collected and analyzed, along with samples of influents and effluents of the off-site WWTS that receive treated wastewater from these industrial facilities. In addition to these five industrial sites and corresponding WWTS, the influents and effluents of 21 other Canadian WWTS were sampled and analyses were conducted. This monitoring data was used to generate 46 predicted environmental concentrations (PECs)[6] for DEHP in the receiving waters near the discharge points: 7 PECs were calculated for industrial sites and 39 were calculated for WWTS sites (Canada 2017b).

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

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., industrial facilities which manufacture plastic products) may be a potential source. However, based on the measured concentrations of phthalates in WWTS that receive both domestic and industrial wastewaters, the contribution of these industrial activities may not be the main source of phthalates in most cases.

An analysis of the locations where both industrial and municipal monitoring data were available suggests that 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 most 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 s.71 survey reporting requirements, or landfill leachate (Canada 2017b). Several phthalates were measured in leachate samples collected from four landfill sites in 2017 and these phthalates were also present in the influents of WWTS receiving the leachates.

[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.

6. Risk Management Considerations

6.1 Alternatives and Alternate Technologies

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, 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 consumer products, 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), diisononyl 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 alternatives (TURI 2006).

TURI also studied alternatives for 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 in medical device applications 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).

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[7] In the SAR, DINP is 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 SAR indicates that certain short-chain and medium-chain phthalates that are not expected to pose a risk at current exposure levels could represent a concern for the environment or human health, due to their high hazard potential, if exposure to these substances were to increase. DINP is included in this group of phthalates.

[8] DEHA was found to meet the criteria for s.64(*c*) of CEPA. [DEHA]

In 2014, the United States Consumer Product Safety Commission Chronic Hazard Advisory Panel (CPSC CHAP) completed a cumulative hazard assessment of phthalates to study the effects of phthalates and phthalate alternatives as used in children's toys and child care articles. As part of the study, the CHAP assessed the risks of 6 phthalate alternatives, including 2,2,4-trimethyl-1,3 pentanediol diisobutyrate (TPIB), DEHA, di(2-ethylhexyl) terephthalate (DEHT), acetyl tributyl citrate (ATBC), diisononyl hexahydrophthalate (1,2-cyclohexanedicarboxylic acid, diisononyl ester) (DINX), and TOTM. The study indicated that there is no evidence that any of the alternatives considered by the CHAP presents a hazard to infants or toddlers from mouthing toys or child care articles. However, the CHAP recommends 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 plasticizers to DEHP have been identified, including diisononyl adipate (DINA), di-isononyl-cyclohexane-1,2-dicarboxylate (DINCH), DEHT, ATBC and sulfonic acids, C10 – C18-alkane, phenylesters (ASE). The study indicated that some of the assessed alternative plasticizers have a broad application scope, others are more specialized (Denmark 2010).

The Swedish government has assigned the Swedish Chemicals Agency (KEMI) to push for a phase-out 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 indicated that many Swedish companies have replaced DEHP with the phthalates DIDP, DINP or DPHP or completely different plasticizers that are not phthalates (Sweden 2014).

It should be noted that some of the alternatives identified for DEHP have been assessed in Canada. For example, DEHA was found to meet the criteria for s.64(c) of CEPA, toxic to human health, and the SAR for the phthalates grouping found that while exposure of the general population or the environment to certain phthalates (including DBP, BBP, DINP and DIHepP) is not of concern at current levels, these substances are associated with human health and ecological effects of concern. Increased manufacture, use and import of these substances or products containing them should be avoided, as there could be a concern for human health and the environment if exposure levels were to increase. A complete list of these substances can be found in Annex A.

6.2 Socio-economic and Technical Considerations

There are some sources of information available about the current state of industry transition to alternative substances. Socio-economic factors will be considered in the development of the risk management objectives. Socio-economic factors will also be considered in the development of regulations, instruments and/or tools respecting preventative or control actions, as identified in the *Cabinet Directive on Regulatory Management* (TBS 2018) 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 the Government of Canada in 1994 under the Priority Substances Assessment Program and determined to present a risk to human health in Canada. DEHP was therefore 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 freshwater (CCME 1993). Based on Environment and Climate Change Canada's current analytical methods, the detection limit for DEHP is 1.2 µg/L at 99% confidence interval. Presence of DEHP in blanks is the limiting factor in 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.

Under the *Canada Consumer Product Safety Act*, Health Canada developed the *Phthalates Regulations* to limit the concentration of six phthalates, including DEHP, in soft vinyl children's toys and 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 a selection of child care articles and toys with the *Phthalates Regulations* (Canada 2018).

DEHP is included on the List of Prohibited and Restricted Cosmetic Ingredients (Cosmetic Ingredients Hotlist) and is described as prohibited for use in cosmetic products 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 *Medical Devices Regulations* do not prohibit DEHP in medical devices above 0.1%, but manufacturers are asked to report its presence as part of their licence applications. A wide variety of medical devices are currently made of PVC that has been softened by the addition of DEHP. Approximately 10 000 medical devices (currently licensed in Canada) have been identified as containing ≥0.1% by weight DEHP.2016a).

The safety of chemicals used in food packaging materials is subject to section 4(1)(a) of the *Food and Drugs Act* and division 23 of the *Food and Drugs Regulations.* Any food packaging assessments of DEHP as a component in food packaging materials have determined that dietary exposures do not represent a risk to human health.

The Government of Canada is actively leading and participating in national and international initiatives that support the effective management of plastics over their full life cycle and keeping plastic waste in the economy and out of landfills and the environment. Further information on these initiatives is available on the Canada.ca website, Toward zero plastic waste.

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 (U.S.) banned DEHP at a concentration >0.1% by weight in children's toys and child care articles (CPSIA 2008) and has confirmed that it will maintain this ban based on assessments of phthalates in a cumulative context (CHAP 2014; CSPC 2017).

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 (IRIS) 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).

The *Consumer Product Safety Improvement Act of 2008* (CPSIA) directed the U.S. Consumer Product Safety Commission (CPSC) to convene a Chronic Hazard Advisory Panel (CHAP) to study the effects of all phthalates and phthalate alternatives as used in children’s toys and child care articles. In 2014, the CPSC CHAP completed a cumulative hazard assessment of phthalates. The CHAP recommends no further action by CPSC on DBP, BBP, or DEHP at this time because they are already permanently banned in children’s toys and child care articles at levels greater than 0.1%. However, the CHAP recommends that U.S. agencies responsible for dealing with DBP, BBP, and DEHP exposures from

food and other products conduct the necessary risk assessments with a view to supporting risk management steps (CHAP 2014).

7.2.2 European Union

The EU Phthalates Directive on phthalates (2005/84/EC) prohibits the use of certain categories of phthalates in the manufacture of toys and childcare articles intended for children. The Directive entered into force in 2006 and restricts the use of seven phthalates, including DEHP (EU 2005).

The Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food restricts the use of DEHP in food packaging materials, where it can only be used as a plasticiser in repeat use materials and articles contacting non-fatty foods, as a technical support agent in concentrations up to 0.1% in the final product (EU 2011).

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, has adopted Regulation (EU) 2018/2005 to replace entry 51 to Annex XVII of REACH to restrict various indoor/outdoor articles which contain four phthalates, including DEHP, in concentrations equal to or greater than 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).

In 2016, the European Commission published a decision to authorize 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 children’s toys and childcare articles. The authorization's review period expires on 21 February 2019 (EU 2016).

Since 1999, DEHP has been prohibited in Denmark to manufacture, import and sell toys and certain childcare articles containing phthalates for children under the age of 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 prohibits the use of tubes containing DEHP above 0.1% in pediatrics, neonatology and maternity wards in

hospitals, with some exemptions (France 2012). The prohibition came into effect on 1 July 2015.

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 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, and other consumer products such as eating vessels and utensils) containing more than 1% DEHP (Australia 2011).

8. Next Steps

8.1 Public Comment Period

Companies who have a business interest in DEHP are encouraged to identify themselves as stakeholders. These companies, along withother interested stakeholders are invited to submit comments on the content of this Risk Management Approach or other information that would help to inform decision-making (such as outlined in sections 3.2 or 3.3). In particular, all interested stakeholders are invited to provide additional information on their current use of DEHP and/or alternatives in plastic products such as plastic materials, medical devices, floor coverings, building construction materials, electrical and electronic products, wire and cable, and food packaging materials, all of which are proposed to be subject to the risk management outlined in this document. Please submit additional information and comments prior to February 3, 2021.

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

Environment and Climate Change Canada
Chemicals Management Division
Gatineau Quebec K1A 0H3
Tel: 1-800-567-1999 | 819-938-3232
Fax: 819-938-3231
Email: eccc.substances.eccc@canada.ca

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

Publication of responses to public comments on the Risk Management Approach document: On or before December 2022.

Publication of the proposed instrument(s): On or before December 2022.

Consultation on the proposed instrument(s): 60-day public comment period starting upon publication of each proposed instrument(s).

Publication of the final instrument(s): On or before June 2024.

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ANNEX A. List of Phthalates that would be a concern should exposure levels increase

DEHP is one of twenty-eight substances addressed in the Phthalates Substance Grouping of the Substance Groupings Initiative of the CMP (Canada 2011).

Of these twenty-eight substances, there are twenty substances for which exposure to the general population or the environment to these substances is not of concern at current levels; however, these substances are associated with human health or ecological effects of concern. These twenty substances are

- 1,2-Benzenedicarboxylic acid, dimethyl ester (DMP)
- 1,2-Benzenedicarboxylic acid, diethyl ester (DEP)
- 1,2-Benzenedicarboxylic acid, dipropyl ester (DPrP)
- 1,2-Benzenedicarboxylic acid, bis(2-methylpropyl) ester (DIBP)
- 1,2-Benzenedicarboxylic acid, butyl cyclohexyl ester (BCHP)
- 1,2-Benzenedicarboxylic acid, dicyclohexyl ester (DCHP)
- 1,2-Benzenedicarboxylic acid, bis(phenylmethyl) ester (DBzP)
- 1,2-Benzenedicarboxylic acid, benzyl C7-9-branched and linear alkyl esters (B79P)
- 1,2-Benzenedicarboxylic acid, bis(methylcyclohexyl) ester (DMCHP)
- 1,2-Benzenedicarboxylic acid, isooctyl phenylmethyl ester (BIOP)
- 1,2-Benzenedicarboxylic acid, dibutyl ester (DBP)
- 1,2-Benzenedicarboxylic acid, butyl phenylmethyl ester (BBP)
- 1,2-Benzenedicarboxylic acid, dihexyl ester (DnHP)
- 1,2-Benzenedicarboxylic acid, di-C8-10-branched alkyl esters, C9-rich; 1,2-Benzenedicarboxylic acid, diisononyl ester (DINP)
- 1,2-Benzenedicarboxylic acid, dioctyl ester (DnOP)
- 1,2-Benzenedicarboxylic acid, diisooctyl ester (DIOP)
- 1,2-Benzenedicarboxylic acid, (C7,C9) ester, branched and linear (79P)
- 1,2-Benzenedicarboxylic acid, cyclohexyl 2-methylpropyl ester (CHIBP)
- 1,2-Benzenedicarboxylic acid, 2,2-dimethyl-1-(1-methylethyl)-3-(2-methyl-1-oxopropoxy)propyl phenylmethyl ester (B84P)
- 1,2-Benzenedicarboxylic acid, di-C6-8-branched alkyl esters, C7-rich (DIHepP)

Follow-up actions identified for each of these substances can be found in the phthalates information sheet.