Government of Canada / Gouvernement du Canada

PROPOSED RISK MANAGEMENT APPROACH

for

Hexanedioic acid, bis(2-ethylhexyl) ester

DEHA

Chemical Abstracts Service Registry Number (CAS RN):
103-23-1

Environment Canada
Health Canada

September 2011

Canada

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This proposed risk management approach document builds on the previously released risk management scope document for DEHA, and outlines the proposed control actions for this substance. Stakeholders are invited to submit comments on the content of this proposed risk management approach or provide other information that would help to inform decision making. Following this consultation period, the Government of Canada will initiate the development of the specific risk management instrument(s) where necessary. Comments received on the proposed risk management approach will be taken into consideration in developing the instrument(s). Consultation will also take place as instrument(s) are developed.

SUMMARY OF RISK MANAGEMENT

1. The Government of Canada plans to develop a control instrument under the *Canadian Environmental Protection Act, 1999* (CEPA 1999) to address releases to the environment from the manufacturing and industrial use of DEHA, as appropriate.
2. The Government of Canada plans to implement Significant New Activity (SNAc) provisions under CEPA 1999 to DEHA.
3. The Government of Canada will work with stakeholders to further quantify sources of releases of DEHA to the environment throughout its lifecycle and will develop risk management control actions under CEPA 1999 to address these releases as required.
4. The Government of Canada will add DEHA to the CMP monitoring and surveillance program to further quantify levels of this substance that may be found in the environment.
5. The Government of Canada will investigate a suitable health protective restriction for DEHA on the Health Canada Cosmetic Ingredient Hotlist.
6. The Government of Canada will perform targeted surveys of DEHA in foods and food packaging materials and consider adding DEHA to the Total Diet study to better define Canadian exposure to DEHA through dietary intake.

Note: This summary is an abridged list of the instruments and tools proposed to risk manage this substance. Please see section 9.1 of this document for a complete explanation of risk management.

1. ISSUE

1.1 Categorization and the Challenge to Industry and Other Interested Stakeholders

The *Canadian Environmental Protection Act, 1999* (CEPA 1999) (Canada 1999) requires the Minister of the Environment and the Minister of Health (the Ministers) to categorize substances on the *Domestic Substances List* (DSL). Categorization involves identifying those substances on the DSL that, in accordance with the criteria at section 73 of the Act, a) are considered to be persistent (P) or bioaccumulative (B), based on the criteria set out in the *Persistence and Bioaccumulation Regulations,* and "inherently toxic" (iT) to humans or other organisms, or b) may present, to individuals in Canada, the greatest potential for exposure (GPE). In addition, the

Act requires the Ministers to conduct screening assessments of substances that meet the categorization criteria. The assessment further determines whether the substance meets one or more of the criteria set out in section 64 of the Act[1].

In December 2006, the Challenge identified 195 chemical substances through categorization which became high priorities for assessment due to their hazardous properties and their potential to pose risks to human health and the environment. In February 2007, the Ministers began publishing, for industry and stakeholder comments, profiles of batches containing 12 to 19 high-priority substances. New batches are released for comments every three months.

Information-gathering authority in section 71 of CEPA 1999 is being used under the Challenge to gather specific information where it is required. The information that is collected through the Challenge is used to make informed decisions and appropriately manage any risks that may be associated with these substances.

The substance Hexanedioic acid, bis(2-ethylhexyl) ester, Chemical Abstracts Service Registry Number (CAS RN)[2] 103-23-1, referred to throughout this document as "DEHA", is included in Batch 11 of the Challenge under the Chemicals Management Plan.

1.2 Final Screening Assessment Report Conclusion for DEHA

A notice summarizing the scientific considerations of a final screening assessment report was published by Environment Canada and Health Canada in the *Canada Gazette*, Part I, for DEHA on September 10, 2011, under subsection 77(6) of CEPA 1999. The final screening assessment report concluded that DEHA is entering or may be entering the environment in a quantity or a 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 it is entering or may be entering the environment in a quantity or a concentration or under conditions that constitute or may constitute a danger in Canada to human life or health.

The critical effect for characterization of risk to human health for DEHA is developmental toxicity (increased postnatal deaths observed in rats). Based on a comparison of estimated exposures to DEHA in Canada to the critical effect levels for developmental effects, and taking into account the uncertainties in the databases on exposure and effects, it is considered that the resulting margins of exposure resulting from daily use of certain cosmetics and personal care products are potentially inadequate. Based on the available information, it is concluded that DEHA is entering the environment in a quantity or concentration or under conditions that constitute or may constitute a danger in Canada to human life or health.

[1] A determination of whether one or more of the criteria of section 64 are met and whether risk management may be required 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 exposures from ambient and indoor air, drinking water, foodstuffs and the use of consumer products. A conclusion under CEPA 1999 on the substances in the Chemicals Management Plan (CMP) Challenge Batches 1-12 is not relevant to nor does it preclude an assessment against the hazard criteria specified in the Workplace Hazardous Materials Information System [WHMIS] *Controlled Products Regulations* for products intended for workplace use. Similarly, a conclusion based on the criteria contained in section 64 of CEPA 1999 does not preclude actions being taken under other sections of CEPA or other Acts.

[2] CAS RN: 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.

The final screening assessment report also concluded that DEHA does not meet the criteria for persistence or bioaccumulation, as defined in the *Persistence and Bioaccumulation Regulations* made under CEPA 1999. The presence of DEHA in the environment results primarily from human activity.

For further information on the final screening assessment report conclusion for DEHA, refer to the final screening assessment report, available at http://www.chemicalsubstanceschimiques.gc.ca/challenge-defi/batch-lot-11/index-eng.php

1.3 Proposed Measure

As a result of a screening assessment of a substance under section 74 of CEPA 1999, the substance may be found to meet one or more of the criteria under section 64 of CEPA 1999. The Ministers can propose to take no further action with respect to the substance, add the substance to the Priority Substances List (PSL) for further assessment, or recommend the addition of the substance to the List of Toxic Substances in Schedule 1 of the Act. Under certain circumstances, the Ministers must make a specific proposal to recommend the implementation of virtual elimination. In this case, the Ministers proposed to recommend the addition of DEHA to the List of Toxic Substances in Schedule 1. As a result, the Ministers will develop a regulation or instrument respecting preventive or control actions to protect the health of Canadians and the environment from the potential effects of exposure to this substance.

DEHA is not subject to the virtual elimination provisions under CEPA 1999 and will be managed using a lifecycle approach, to prevent or minimize its release into the environment.

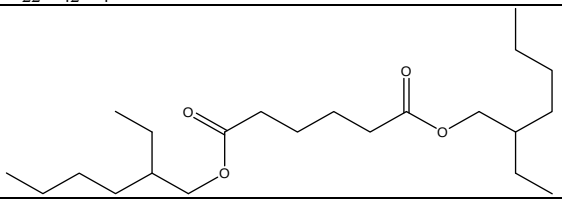
2. BACKGROUND

2.1 Substance Information

DEHA is part of the chemical grouping discrete organics and the chemical sub grouping alkyl adipates.

Table 1 presents other names, trade names, chemical groupings, the chemical formula, the chemical structure and the molecular mass for DEHA.

Table 1. Identity of DEHA

Chemical Abstracts Service Registry Number (CAS RN)	103-23-1
DSL name	**Hexanedioic acid, bis(2-ethylhexyl) ester**
National Chemical Inventories (NCI) names[1]	*Hexanedioic acid, bis(2-ethylhexyl) ester* (AICS, ASIA-PAC, ENCS, PICCS, SWISS, NZIoC, TSCA) *Bis(2-ethylhexyl) adipate* (EINECS, PICCS) *Hexanoic acid bis(2-ethylhexyl) ester* (ECL) *Adipate, di (2-ethylhexyl)* (PICCS) *Dioctyl adipate* (PICCS)
Other names	*Adimoll DO; Adipic acid, bis(2-ethylhexyl) ester; Adipol 2EH; ADO; ADO (lubricating oil); Arlamol DOA; Bisoflex DOA; Crodamol DOA; Dermol DOA; Di(2-ethylhexyl) adipate; Diacizer DOA; Diethylhexyl adipate; DOA; Effomoll DA; Effomoll DOA; Ergoplast AdDO; Flexol A 26; Hatcol 2908; Hexanedioic acid, 1,6-bis(2-ethylhexyl) ester; Hexanedioic acid, bis(2-ethylhexyl) ester; Jayflex DOA 2; K 3220; Kodaflex DOA; Lankroflex DOA; Monoplex DOA; NSC 56775; Octyl adipate; Plasthall DOA; Plastomoll DOA; Reomol DOA; Sansocizer DOA; Sicol 250; SP 100; SP 100 (solvent); Truflex DOA; USS 700; Vestinol OA; Vistone A 10; Wickenol 158; Witamol 320*
Chemical group (DSL Stream)	Discrete organics
Major chemical class or use	Esters
Major chemical sub-class	Alkyl adipates
Chemical formula	$C_{22}H_{42}O_4$
Chemical structure	
SMILES[2]	O=C(OCC(CCCC)CC)CCCCC(=O)OCC(CCCC)CC
Molecular mass	370.58 g/mol

[1] National Chemical Inventories (NCI). 2007: AICS (Australian Inventory of Chemical Substances); ASIA-PAC (Asia-Pacific Substances Lists); ECL (Korean Existing Chemicals List); EINECS (European Inventory of Existing Commercial Chemical Substances); ENCS (Japanese Existing and New Chemical Substances); NZIoC (New Zealand Inventory of Chemicals); PICCS (Philippine Inventory of Chemicals and Chemical Substances); SWISS (Swiss Giftliste 1 and Inventory of Notified New Substances); and TSCA (Toxic Substances Control Act Chemical Substance Inventory).

[2] Simplified Molecular Input Line Entry System

3. WHY WE NEED ACTION

3.1 Characterization of Risk to Human Health

Evaluation of risk to human health involves consideration of data relevant to estimation of exposure (non-occupational) of the general population, as well as information on health hazards.

Analysis of the literature and assessments by other international agencies (US EPA, OECD) confirmed that the critical effects of exposure to DEHA were developmental. Carcinogenicity was considered in the health effects assessment for DEHA, as the substance had been classified as a possible human carcinogen by the US EPA (1994). Although a mode of action has not been fully elucidated, reviews on rodent tumours suggest that the increased incidence of liver tumours in female mice following treatment with DEHA results from a mechanism that does not operate in humans, i.e. a mechanism based on enhanced activation of peroxisome proliferators (Cattley et al. 1998; Klaunig et al. 2003). Consideration of the available information on genotoxicity indicates that DEHA is not likely to be genotoxic. Based on this evidence, as well as the fact that mouse liver tumours were observed only at high doses, a threshold approach is used to assess risk to human health.

The lowest LOAEL (lowest observable adverse effects level) for developmental toxicity is 400 mg/kg-bw per day based on a dose-related increase in postnatal deaths. This LOAEL is based on mortality, which implies that there would be other, less severe effects due to treatment occurring below this dose prior to death that were not measured in this or any other study identified (Dalgaard et al. 2003). Based on the lack of reported effects in foetuses and/or developing rats at lower doses than 400 mg/kg-bw per day, the NOAEL (no observable adverse effects level) of 200 mg/kg-bw per day is used for the characterization of risk to human health in this assessment.

A total daily intake of the general population was estimated based on exposure from food, beverages, drinking water and air inhalation, and the main contributor in this estimate is expected to be food for most age groups. Comparison between the lowest NOAEL for developmental effects at 200 mg/kg-bw per day with the highest upper-bounding intake estimate (0.14 mg/kg-bw per day) results in an MOE (margin of exposure) of 1400. This MOE is considered to be adequately protective of human health, taking into account the uncertainties in the databases on exposure and effects.

The general population may also be exposed to DEHA during use of consumer products containing this substance. The principal route of such exposure is considered to be dermal contact based on its physical and chemical properties as well as the types of products containing this substance. Comparison between the NOAEL for developmental effects of 200 mg/kg-bw per day with the estimate of potential internal dose from daily use of cosmetic and personal care products (0.06 – 2.18 mg/kg-bw per day) results in MOEs ranging from 91 to 3300. MOEs in the lower end of the range are not considered to be adequately protective of human health, taking into account the uncertainties in the health effects and exposure databases.

Use of other cosmetic and personal care products which are not used on a daily basis (i.e., bath salts, nail polish, body shimmer, etc.) resulted in exposure estimates ranging from 0.0007 to 7.15 mg/kg-bw per application. A two-week dermal study on rabbits was used as a surrogate for acute critical effects in the absence of an acute dermal study. Comparing the short-term (two weeks) dermal LOAEL from this study (2060 mg/kg-bw per day) to the exposure estimates from

infrequent use of cosmetic and personal care products resulted in MOEs of 300 to 2 900 000. These MOEs are considered to be adequately protective of human health, taking into account uncertainties in the health effects and exposure databases.

Use of other consumer products such as auto protectants and heavy-duty hand cleanser resulted in exposure estimates ranging from 0.004 to 0.43 mg/kg-bw per application. Comparison of the LOAEL from the rabbit dermal study (2060 mg/kg-bw per day) to the upper-bound estimates of the range of exposure estimates during the use of the consumer products containing DEHA resulted in MOEs ranging from 4800 to 515 000. Thus, based on a "per event" use of these consumer products, the resulting MOEs are considered to be adequately protective of human health, taking into account the uncertainties in the databases on exposure and effects (Canada 2010).

3.2 Characterization of Risk to the Environment

The approach taken in the ecological portion of the screening assessment was to examine various supporting information and develop conclusions based on a weight-of-evidence approach and using precaution as required under CEPA 1999. Lines of evidence considered include results from risk quotient calculations, as well as information on persistence, bioaccumulation, toxicity, sources and fate of the substance (Canada 2010).

DEHA does not meet the criteria for persistence and bioaccumulation as set out in the *Persistence and Bioaccumulation Regulations.* There is, however, concern over the potential for chronic toxicity to aquatic organisms as both experimental and modelled data indicate that adverse effects may occur at chronic exposure levels near or below the water solubility limit for DEHA.

Potential for occurrence and widespread, continual release into the Canadian environment are indicated by

- High Canadian manufacture and importation volumes of DEHA;
- Information on the uses of DEHA;
- Evidence for environmental releases reported in the National Pollutant Release Inventory (NPRI);
- Data submitted under section 71 Notices (Environment Canada 2010), and
- Its presence in sewage treatment plant (STP) effluents in Canada.

Once released into the environment, this substance will partition mainly to sediment and soil, but will also be found in the water column either dissolved or as an emulsion (Canada 2010).

To determine whether there is potential for ecological harm in Canada, a risk quotient analysis, integrating realistic estimates of exposure with toxicity information, was performed for the water and sediment media which are the main environmental media receiving releases of DEHA.

Furthermore, a site-specific exposure analysis was conducted for the aquatic compartment at 8 industrial sites which are identified as being involved with the highest quantities of DEHA based on the information collected from the CEPA section 71 survey (Environment Canada 2010). These 8 sites include two DEHA manufacturers, five DEHA industrial users and one DEHA

container cleaning operation. Each site consists of one or two facilities and involves a quantity of this substance in the range of 10 000 to 10 000 000 kg per year. The selection of these sites is based on a general assumption that the quantity released is proportional to the quantity used, manufactured or transported and that these sites represent sites with the highest potential for risk.

Predicted Environmental Concentrations (PEC) were estimated using measured and modeled concentrations of DEHA in effluent (in the range of 0.01 to 73.13 µg/L for these 8 industrial scenarios). A Predicted No Effect Concentration (PNEC) was derived from the chronic toxicity value (the most sensitive valid experimental value) for *D. magna* (0.0035 mg/L). The resulting risk quotients (PEC/PNEC) range from 0.0003 to 21. Four sites have a risk quotient (RQ) above the level of concern (> 1); therefore, harm to aquatic organisms is possible at these sites (Canada 2010).

Based on this information, DEHA has the potential to cause ecological harm in Canada (Canada 2010).

4. CURRENT USES AND INDUSTRIAL SECTORS

According to information submitted under section 71 of CEPA 1999 (Canada 1999), 1 – 10 million kg of DEHA were manufactured in Canada in 2006 (Environment Canada 2010). The total quantity imported into Canada in the same reporting year (above the reporting threshold of 100 kg/year) was approximately 250,000 kg. The majority of DEHA imported to Canada in 2006 was for use as a plasticizer (Environment Canada 2010).

Globally, DEHA is used primarily as a plasticizer in the flexible vinyl industry and may be used in flexible polyvinylchloride (PVC) food film (Bizzari et al. 2009). The main uses of PVC films packaging in Canada are: the packaging of beef products (ground beef, etc.), poultry in processing plants, selected vegetables and fruits (produce), repackaging of cheese in supermarkets; prepared delicatessen products; and in fast food outlets and miscellaneous food distributors such as food caters and cafeterias in institutional facilities and retail establishments (2010 Personal communication from the Food Directorate, Health Canada, to the Existing Substances Risk Assessment Bureau, Health Canada; unreferenced). Other than its possible use in food industry, DEHA is used as a plasticizer, emollient or solvent in cosmetic products (Gottschalck and McEwen 2004). In Canada, approximately 300 products containing DEHA have been reported in a mandatory product formulations notification to Health Canada. The use of DEHA was reported in skin moisturizer and cleanser, facial makeup, and bath preparation products (CNS 2010).

DEHA is a formulant (non-active ingredient) found in pesticides, which are regulated under the *Pest Control Products Act* in Canada (PMRA 2005). Recent reassessment of DEHA, a List 1 formulant, concluded it is acceptable for a specific use within the approved concentration range. Proposed uses outside this use pattern would require additional data (April 2010 Personal communication from Pest Management Regulatory Agency, Health Canada, to Risk Management Bureau, Health Canada; unreferenced).

DEHA is also used as a plasticizer in the manufacture of rubber and thermoplastics, as a solvent and as a component of functional (hydraulic) fluid and aircraft lubricants (IUCLID 2000), in the

processing of nitrocellulose and synthetic rubber, and in plasticizing polyvinyl butyral, cellulose acetate butyrate, polystyrene and dammar wax (IARC 2000). Reported uses submitted under section 71 of CEPA 1999 besides its use as a plasticizer include, but are not limited to, adhesives and sealants for automobile manufacturing (Environment Canada 2010). Based on the available information, consumer products containing DEHA in Canada also include auto interior protectants, heavy-duty hand cleansers, and lubricants.

International data indicate that due to concerns over plasticizer migration into foods, typical DEHA concentrations in cling wrap formulations have decreased from up to 22% down to 8 – 10% over the past several years. DEHA has been replaced mainly with bio-based plasticizers in conjunction with adipic acid-based polymeric plasticizers. Such combinations have been used in special food-grade PVC film, as well as in other food applications including tubes, hoses and conveyor belts used in the food industry (Bizzari et al. 2009; Cadogan and Howick 2000; OECD 2005).

DEHA may be found in heat-seal ink system intended to be used on the exterior of laminated structures of food packaging materials. It is also found in one polystyrene product used in the middle of a laminate structure and in one lubrication product. No food contact is expected from these uses.

In the US, DEHA is approved as an indirect food additive as a component of adhesives, cellophane food wrap, closures with sealing gaskets for food containers, cellulose film and plasticizers in polymeric substances (US CFR 2007a,b,c,d,e).

5. PRESENCE IN THE CANADIAN ENVIRONMENT AND EXPOSURE SOURCES

5.1 Releases to the Environment

According to the information submitted under section 71 of CEPA 1999 and NPRI, the majority of DEHA released to the environment from industry (manufacturing of DEHA and its use as plasticizer) was to air and a small fraction to water via releases from the manufacture of DEHA (Environment Canada 2010).

Air emissions and off-site disposal are also reported to the NPRI in 2006 with total on-site releases of 1,800 kg and total off-site disposals of 6,900 kg (Environment Canada 2008) although DEHA is not expected to persist for long periods in air, sediment, or soil.

Monitoring data provide evidence that DEHA is being released to WWTPs and subsequently to the aquatic environment (Canada 2010). Overall industrial contributions to influents of the WWTPs were estimated and industrial exposure models used to compliment the empirical concentration data available, with realistic worst-case assumptions being made when determining potential releases. Overall, four sites were identified as having the potential to cause ecological harm from the release of DEHA. However, there was insufficient information on quantities of DEHA-containing consumer products being used to develop a quantitative consumer release modelling scenario during the assessment and it is not known to which degree

DEHA concentrations in effluents can be attributed to either industrial activities or consumer use of products containing DEHA.

5.2 Exposure Sources

Based on the available information, sources of exposure of the general population of Canada are expected to be food (as a result of migration from food packaging), consumer products containing DEHA in Canada (including cosmetics and personal care products, auto interior protectants, heavy-duty hand cleansers, and lubricants) and environmental media (Canada 2010).

6. OVERVIEW OF EXISTING ACTIONS

6.1 Existing Canadian Risk Management

- Food packaging materials are regulated under Division 23 of the *Food and Drug Regulations*. Section B.23.001 prohibits the sale of foods in packages that may impart harmful substances to their contents.
- The Foods Directorate has set an Acceptable Daily Intake (ADI) for DEHA of 0.5 mg/kg-bw per day.
- *Pest Control Products Act:* DEHA is a formulant (non-active ingredient) found in pesticide products (PMRA 2005). Recent reassessment of DEHA, a List 1 formulant, concluded it is acceptable for use as a specific use within the approved concentration range. Proposed uses outside this use pattern would require additional data (April 2010 Personal communication from Pest Management Regulatory Agency, Health Canada, to Risk Management Bureau, Health Canada; unreferenced).
- Therapeutic Products Directorate's internal Non-Medicinal Ingredients Database: DEHA is listed as a non-medicinal ingredient present in a sunscreen product that is regulated as a therapeutic product (March 2010 Personal communication from Therapeutic Products Directorate, Health Canada, to Risk Management Bureau, Health Canada; unreferenced).
- Natural Health Products Ingredients Database: DEHA is listed as an acceptable non-medicinal ingredient for use as a plasticizer or skin-conditioning emollient or solvent in natural health products (NHPID 2010).
- DEHA is a reportable substance to the NPRI (NPRI 2006).

6.2 Existing International Risk Management

United States

- DEHA is part of the High Production Volume (HPV) Challenge (US EPA 2010).
- Under US EPA CFR 40 141, National Primary Drinking Water Regulations prescribe the maximum contaminant level for DEHA in drinking water as 0.4 mg/L.

- Under US FDA Code of Federal Regulations Title 21; 21CFR 165.110 with an allowable level of 0.4 mg/L DEHA in bottled water.
- Under US FDA Code of Federal Regulations Title 21, DEHA is approved as an indirect food additive, as a component of adhesives, cellophane food wrap, closures with sealing gaskets for food containers, water-insoluble hydroxyethyl cellulose film and plasticizers in polymeric substances (US CFR 2007a,b,c,d,e).

European Union

- DEHA is on the European Inventory of Existing Commercial Chemical Substances (ESIS c1995–2010) with a Tolerable Daily Intake (TDI) of 0.3 mg/kg-bw.

The World Health Organization established a drinking water guideline for DEHA of 80 µg/L.

7. CONSIDERATIONS

7.1 Alternative Chemicals or Substitutes

There are alternatives besides DEHA to plasticize food wraps currently on the market. Industry is gradually refining these alternatives already on the shelves for consumer use and the use of DEHA in plasticized food wrap is considerably less than it was a decade ago. While there are alternatives to DEHA as a plasticizer and emulsifier in cosmetic products they generally do not possess the same properties as DEHA, may emit undesirable odours and may not be as cost-effective.

It is important to note that these substitutes have not undergone an assessment to determine whether they meet the criteria under section 64 of CEPA 1999.

7.2 Alternative Technologies and/or Techniques

There are a number of technologies and techniques that can be used to reduce the releases of DEHA in air and water. Secondary wastewater treatment or certain physical treatment systems can be used to remove DEHA in effluents. For example, a facility that uses DEHA in the production of plastic food wrap reported using carbon filters to treat their effluents, thereby reducing their DEHA releases to water. Other facilities that manufacture DEHA and that produce plastic food wrap indicated using scrubber systems or Brinks filter systems to control their air emissions of DEHA. These facilities also reported applying best management procedures and practices to prevent spills or other releases of DEHA during their operation.

7.3 Socio-economic Considerations

Socio-economic factors have been considered in the selection process for a regulation and/or instrument respecting preventive or control actions, and in the development of the risk management objective(s). Socio-economic factors will also be considered in the development of regulations, instrument(s) and/or tool(s) as identified in the *Cabinet Directive on Streamlining Regulation* (Treasury Board of Canada Secretariat 2007) and the guidance provided in the

Treasury Board document *Assessing, Selecting, and Implementing Instruments for Government Action*.

7.4 Children's Exposure

The Government of Canada considered, where available, risk assessment information relevant to children's exposure to this substance. As part of the Challenge, the Government asked industry and interested stakeholders to submit any information on the substance that may be used to inform risk assessment, risk management and product stewardship. In particular, stakeholders were asked through a questionnaire if any of the products containing the substance were intended for use by children. Given the information received, it is proposed that no risk management actions to specifically protect children are required for this substance at this time.

8. PROPOSED OBJECTIVES

8.1 Human Health Objective

A human health objective is a quantitative or qualitative statement of what should be achieved to address environmental or human health concerns identified during a risk assessment.

The proposed human health objective for DEHA is to reduce exposure of the general population to DEHA to levels that are adequately protective of human health.

8.2 Environmental Objective

An environmental objective is a quantitative or qualitative statement of what should be achieved to address environmental concerns identified during a risk assessment.

The proposed environmental objective for DEHA is to prevent or minimize releases of the substance to the environment.

8.3 Risk Management Objectives

A risk management objective is a target expected to be achieved for a given substance by the implementation of risk management regulations, instrument(s) and/or tool(s).

The proposed risk management objectives for DEHA are to prevent or minimize releases of DEHA to the aquatic environment to the greatest extent possible throughout its lifecycle and to prevent increases in exposure to Canadians.

9. PROPOSED RISK MANAGEMENT

9.1 Proposed Risk Management Instrument and Tool

As required by the Government of Canada's *Cabinet Directive on Streamlining Regulation*[3] and criteria identified in the Treasury Board document entitled *Assessing, Selecting, and Implementing Instruments for Government Action*, the proposed risk management was selected using a consistent approach, and took into consideration the information that was received through the Challenge and other information available at the time.

As the final screening assessment report did not conclude that DEHA meets the conditions set out in subsection 77(4) of CEPA 1999, DEHA will not be subject to the virtual elimination provisions under CEPA 1999 and will be managed using a life-cycle approach to prevent or minimize its release into the environment.

It has been concluded that the estimated margins of exposure associated with the use of certain cosmetics and personal care products are potentially not adequately protective of human health (Canada 2010). Aside from cosmetics and personal care products the total daily intake of DEHA for Canadians in general was estimated based on exposure from food, beverages, drinking water and air inhalation, and the main contributor in this estimate is expected to be food for most age groups. Comparison between the lowest NOAEL for developmental effects with the highest upper-bounding intake estimate results in an MOE that is considered to be adequately protective of human health, taking into account the uncertainties in the databases on exposure and effects.

This substance will be considered for inclusion in the Domestic Substances List inventory update initiative. In addition and where relevant, research and monitoring will support verification of assumptions used during the screening assessment.

In order to achieve the risk management objective and work towards achieving the environmental and human health objectives, the Government of Canada is proposing the following actions for DEHA:

1. Environmental initiatives

   (a) Addressing releases from the manufacturing and industrial use of DEHA by developing a control instrument under CEPA 1999, as appropriate.

   (b) Implementing Significant New Activity (SNAc) provisions under CEPA 1999 for DEHA.

   (c) Working with stakeholders to further quantify sources of releases of DEHA to the environment throughout its lifecycle and developing risk management control actions under CEPA 1999 to address these releases as required.

[3] Section 4.4 of the *Cabinet Directive on Streamlining Regulation* states that "Departments and agencies are to: identify the appropriate instrument or mix of instruments, including regulatory and non-regulatory measures, and justify their application before submitting a regulatory proposal".

(d) Adding DEHA to the CMP monitoring and surveillance program to further quantify levels of this substance that may be found in the environment.

2. Health initiatives

(a) Investigating the uncertainties related to risk to human health (such as dermal absorption) to determine appropriate health protective restrictions for DEHA on the Health Canada Cosmetic Ingredient Hotlist, which is an administrative tool to help manufacturers satisfy the cosmetic safety provisions of section 16 of the *Food and Drugs Act*. Compliance with the provisions of section 16 are monitored, in part, through the mandatory notification provisions of section 30 of the Cosmetic Regulations of the *Food and Drugs Act*, which requires that all manufacturers and importers provide a list of the cosmetic's ingredients to Health Canada.

(b) Although the margin of exposure from food and beverages is considered to be adequately protective, the Government of Canada will perform targeted surveys of DEHA in foods and food packaging materials and consider adding DEHA to the Total Diet Study to better define Canadian exposure to DEHA through dietary intake. The findings of the surveys will be used to determine whether further risk management actions under the *Food and Drugs Act* and *Regulations* are warranted.

9.2 Implementation Plan

The proposed regulation or instrument respecting preventative or control actions in relation to DEHA will be published in the *Canada Gazette*, Part I, no later than September 2013, as per the timelines legislated in CEPA 1999.

10. CONSULTATION APPROACH

The risk management scope document for DEHA, which summarized the proposed risk management under consideration at that time, was published on October 2, 2010. 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 proposed risk management approach document.

Consultation for the proposed risk management approach document will involve publication on September 10, 2011, and a 60-day public comment period.

The primary stakeholders include

- Plastics and chemical manufacturers, importers and distributors
- Cosmetics and fragrance manufacturers, importers and distributors
- Pesticides manufacturers, importers and distributors
- Municipal wastewater treatment sector
- Food and food packaging industry sector

- Non-governmental organizations
- Provincial/territorial and municipal governments

11. NEXT STEPS / PROPOSED TIMELINE

Actions	Date
Electronic consultation on proposed risk management approach document	September 10, 2011 to November 9, 2011
Response to comments on proposed the risk management document	No later than the time of publication of the proposed instrument
Consultation on the draft instrument	Spring/ Summer 2012
Publication of the proposed instrument	No later than September 2013
Formal public comment period on the proposed instrument	No later than Fall 2013
Publication of the final instrument	No later than March 2015

Industry and other interested stakeholders are invited to submit comments on the content of this proposed risk management approach or provide other information that would help to inform decision making. Please submit comments prior to November 9, 2011, since the risk management of DEHA will be moving forward after this date. During the development of regulations, instrument(s) and tool(s), there will be opportunity for consultation. Comments and information submissions on the proposed risk management approach should be submitted to the address provided below:

Chemicals Management Division
Gatineau Quebec K1A 0H3
Tel: 1-888-228-0530 / 819-956-9313
Fax: 819-953-7155
Email: Substances@ec.gc.ca

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