Government of Canada / Gouvernement du Canada

Risk Management Approach

for

Methylenediphenyl Diisocyanates

(MDIs)

Chemical Abstracts Service Registry Numbers (CAS RN):

101-68-8; 2536-05-2; 5873-54-1;

9016-87-9; 26447-40-5

Environment and Climate Change Canada

Health Canada

June 2017

Canada

Summary of Proposed Risk Management

This document outlines the proposed risk management actions for methylenediphenyl diisocyanates (MDIs). The proposed risk management objective for MDIs is to reduce general population exposure resulting from the use of do-it-yourself (DIY) low-pressure two-component spray polyurethane foam (SPF) consumer products containing MDIs. In particular, the Government of Canada is proposing to develop a Code of Practice under section 55 of the *Canadian Environmental Protection Act, 1999* (CEPA) with implicated industry stakeholders that will meet the risk management objective for MDIs. The code would be used to create standardized information and recommendations regarding the products to inform DIY users about proper personal protective equipment (PPE) and other conditions needed for the safe use of low-pressure two-component SPF consumer products.

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.

Note: The above summary is an abridged list of actions proposed to manage these substances. Refer to section 3 of this document for more complete details in this regard.

Table of Contents

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 harmful or dangerous to human health and/or the environment as set out in section 64 of CEPA[1,2] and, if so, to manage the associated risks.

For the second phase of the CMP, the Ministers had committed to assess and manage, where appropriate, the potential health and ecological risks associated with approximately 500 substances in nine substance groupings. The five substances listed in Annex A and referred to throughout this document as "MDIs" are included in the Methylenediphenyl Diisocyanates and Diamines (MDI/MDA) Substance Grouping of the Substance Groupings Initiative of the Chemicals Management Plan (Canada 2011). Certain MDIs were identified as priorities for action as they met categorization criteria under subsection 73(1) of CEPA and/or were considered as priority substances under the CMP on the basis of other human health concerns.

2. Issue

2.1 Final Screening Assessment Conclusion

Environment and Climate Change Canada and Health Canada conducted a joint scientific assessment relevant to the evaluation of MDI/MDA substances. A notice summarizing the scientific considerations of the final screening assessment was published for MDI/MDA by Environment and Climate Change Canada and Health Canada in the *Canada Gazette*, Part I, on June 10, 2017, under subsection 77(1) and paragraphs 68*(b)* and *(c)* of CEPA. On the basis of

[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 *Hazardous Products Regulations,* which are part of the regulatory framework for the Workplace Hazardous Materials Information System for products intended for workplace use. Similarly, a conclusion based on the criteria contained in section 64 of CEPA does not preclude actions being taken under other sections of CEPA or other Acts.

the information available, it was concluded that MDIs [4,4'-MDI (CAS RN[3] 101-68-8), 2,2'-MDI (CAS RN 2536-05-2), 2,4'-MDI (CAS RN 5873-54-1), mixed MDI (CAS RN 26447-40-5) and polymeric MDI (pMDI) (CAS RN 9016-87-9)] are entering or may enter the environment in a quantity or concentration or under conditions that constitute or may constitute a danger in Canada to human life or health and therefore meet the criteria set out in section 64*(c)* of CEPA.

The final screening assessment concludes that MDIs are not entering the environment in a quantity or concentration or under conditions that have or may have an immediate or long-term harmful effect on the environment or its biological diversity or that constitute or may constitute a danger to the environment on which life depends and therefore do not meet the criteria set out in section 64 *(a)* or *(b)* of CEPA.

The final screening assessment also concludes that MDAs [4,4'-MDA (CAS RN 101-77-9) and polymeric MDA (CAS RN 25214-70-4)] do not meet any of the criteria set out in section 64 of CEPA (Canada 2017b). However, owing to the hazardous properties of these substances, there is concern that new uses or that an increased use of the substances, such as in products available to consumers, may lead to increased exposure of Canadians and the environment, which could lead to these substances meeting the criteria set out in section 64 of the Act. Application of the Significant New Activity Provisions under section 81(3) of the Act is proposed to collect the information required to determine whether increased use or new uses may pose health or environmental concerns.

This document is focused on the proposed risk management of MDIs for the exposure source of concern identified in the final screening assessment, which is the application (i.e., use) of DIY low-pressure two-component SPF consumer products. The proposed risk management actions may be subject to change based on further consultation. For more information on the final screening assessment for MDIs, refer to http://www.ec.gc.ca/ese-ees/default.asp?lang=En&n=3139721E-1

2.2 Recommendation Under CEPA

As a result of screening assessments conducted under sections 68 and 74 of CEPA, substances may be found to meet one or more of the criteria under section 64 of CEPA. The Ministers can then propose to take no further action with respect to the substances, add the substances to the Priority Substances List (PSL) for further assessment, or recommend the addition of the substances

[3] 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.

to the List of Toxic Substances in Schedule 1 of the Act. In this case, the Ministers propose to recommend that MDIs be added to Schedule 1 of the Act.

2.3 Public Comment Period on the Risk Management Scope

The risk management scope document for MDIs, which summarized the proposed risk management actions under consideration at that time, was published on August 16, 2014. Interested stakeholders were invited to submit comments on the document during a 60-day comment period. Comments received have been taken into consideration in the development of this risk management approach document. A summary of responses to public comments received is available from http://www.ec.gc.ca/ese-ees/default.asp?lang=En&n=8BC9294C-1

3. Proposed Risk Management

3.1 Proposed Human Health Objective

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

The proposed human health objective is to minimize the potential for respiratory sensitization of the general population from exposure to MDIs.

3.2 Proposed Risk Management Objective and Actions 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. The proposed risk management objective for MDIs is to reduce general population exposure to MDIs resulting from the use of DIY low-pressure two-component SPF consumer products containing MDIs.

The risk management scope document published with the draft screening assessment indicated that the proposed risk management option being considered for MDIs was to work with retailers, manufacturers and/or importers to minimize access of the general population to DIY two-component SPF consumer products. In response, implicated industry stakeholders expressed support for the risk management objective and have provided limited information on their product stewardship programs, which offer guidance on personal protective equipment, ventilation, safe handling and use, and proper disposal, for these products. Multiple stakeholders suggested building on these existing

programs to create a ‘code of practice’ for the risk management of these products.

The proposed risk management action being considered for MDIs at this time is to work with experts and industry stakeholders involved with these products (e.g., manufacturers of the products and related trade organizations, such as the American Chemistry Council’s (ACC) Center for the Polyurethanes Industry (CPI), the Canadian Plastics Industry Association (CPIA), the Retail Council of Canada (RCC), importers and/or retailers) to develop a code of practice under section 55 of CEPA that will meet the risk management objective.

The proposed code of practice would be used to create standardized information and recommendations regarding the products to inform DIY users about proper personal protective equipment (PPE) and other conditions needed for the safe use of low-pressure two-component SPF consumer products. The following are some proposed actions that may be included in the code of practice, which will be developed through discussions with stakeholders:

- Indication of specific respiratory PPE requirements shown in an image and described on the product outer packaging;
- Improved labelling to provide safety information on the product outer packaging, including cautionary warnings;
- Clear and detailed instructions for safe use of the product;
- Development of a generic respiratory protection plan to be included with the product;
- Product manufacturers to have a plan for training retailers on the potential risks of the products such that proper information would be provided to DIY consumers at the point of sale;
- Product manufacturers and retailers to provide consumers with materials on the potential risks of the products at the point of sale; and
- Proper PPE be made available for sale near the products or at the point of sale.

Currently, these products must meet labelling requirements set out in the *Consumer Chemicals and Containers Regulations, 2001* (CCCR 2001), made under the *Canada Consumer Product Safety Act*. Specifically, they must display labelling in the form of hazard symbols, warning statements, instructions and first-aid treatments in both official languages. The requirements set out in the CCCR 2001 are minimum requirements, and manufacturers and importers are encouraged to add any further information they consider necessary to fully inform users of the hazards of their products as long as it does not disclaim or contradict the required information.

The code of practice aims to increase the level and consistency of safety information provided regarding low-pressure two-component SPF consumer products available in Canada and to strengthen existing industry product

stewardship programs and materials in order to reduce the potential exposure to MDIs by DIY users of these products. If Canadian consumers are provided with consistent and more detailed information on PPE, such as the addition of an image on the packaging showing the need for proper respiratory protection, it is expected that they will be better informed when selecting products for DIY use and will take precautions to use these products safely and to avoid possible inhalation exposure to MDIs.

Following the publication of this risk management approach document, additional information obtained during the public comment period and from other sources will be considered, along with the information presented in this document, in the development of the code of practice.[4] The risk management actions outlined in this document may evolve through consideration of assessments and risk management options published for other CMP substances, to ensure effective, coordinated, and consistent risk management decision-making. Additional regulatory actions may be considered at a later date, depending on the measured success of the code of practice in achieving the risk management objective.

3.3 Risk Management Information Gaps

Additional information is requested to inform risk management decision-making and to help in the early drafting of the proposed code of practice. Where available, information on the following aspects may be submitted during the public comment period for this risk management approach document or during stakeholder outreach activities that are anticipated to occur in the future for development of the code:

- Detailed product stewardship programs, policies or measures put in place by manufacturers, importers and/or retailers in Canada or elsewhere, regarding safe use of low-pressure two-component SPF consumer products available to the general population (i.e., DIY users) or for professional contractors;
- Percentage or quantity of sales of low-pressure two-component SPF consumer products to DIY consumers;
- Percentage or quantity of sales of low-pressure two-component SPF consumer products to professional contractors; and
- Information or options on how air purifying cartridge respirators can be safely and correctly used by DIY users to provide protection from inhalation exposure to MDIs (e.g., sample respiratory protection plans for

[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), Red Tape Reduction Action Plan (TBS 2012b) and the *Red Tape Reduction Act* (Canada 2015).

non-workers or for workers using low-pressure two-component SPF systems).

4. Background

4.1 Current Uses and Identified Sectors

Generally, MDIs are widely used in the production of polyurethanes and as adhesives in the production of engineered wood products. MDIs are increasingly replacing toluene diisocyanates (TDIs) in the production of flexible and rigid foams, particle board and wood binders, paints and coatings, adhesives, sealants, elastomers, casting material, and spandex fibres (ECJRC 2005; US EPA 2011; Björkner et al. 2001; Methner et al. 2010). MDIs are also being used more as a replacement toformaldehyde as a resin binder in the manufacture of oriented strand board products (Environment Canada 2012).

In the case of flexible foams, MDIs are reacted with polyetherols or polyesterols in industrial settings to form flexible slabstock or moulded parts, which are then used to manufacture furniture, such as sofas and mattresses, automotive foam cushions, flooring underlay, and other packaging foam (ECJRC 2005; Hoffman and Schupp 2009). Polyurethanes made from MDIs are also used to make textiles and sports tracks (Booth et al. 2009; Björkner et al. 2001).

Rigid foam and polyurethane coatings, adhesives, sealants and elastomers (CASE) are also made from MDIs, which are then used in the construction, transportation, machinery, packaging and furniture sectors (ECJRC 2005). Manufactured items represent a large commercial use of MDIs. Products containing MDIs also exist in the form of DIY products used by consumers for home improvement projects, such as products in which MDIs are reacted with polyols to form rigid foam or CASE upon application, such as sealants around windows or doors, insulation inside walls, or floor adhesives (ECJRC 2005). SPF products containing unreacted MDIs fall into this category of DIY products available to consumers.

In Canada, both industrial and consumer uses of MDIs were reported in response to a survey conducted under section 71 of CEPA (Canada 2012). Between 10 and 100 million kg were reported for use in Canada, a fraction of which was available for consumer use (Environment Canada 2012).

In Canada, MDIs were reported to be used in the manufacture of polyurethane flexible and rigid foam, elastomers, coatings, adhesives, and sealants, which are then used in other sectors such as furniture, construction and automotive. Other manufactured items, such as oriented strand board, particle board and other wood products, are produced in Canada for further use in construction (Environment Canada 2012). Several Canadian industrial sites use pMDI and

MDI for engineered wood products, often in conjunction, in combined quantities ranging from 400 000 kg/year to close to 6 000 000 kg/year, per site (Environment Canada 2012). MDIs are also used in casting materials by professionals for medical purposes (Environment Canada 2012). In addition, manufactured items containing MDI substances (such as flexible packaging laminate and foam slabs) are imported for use in other sectors (i.e., furniture and automotive) (Environment Canada 2012). Uses of products available to consumers, which include unreacted MDIs, include several DIY products such as adhesives, insulation foam and sealants (HPD 2013; HSDB 1983-2003).

5. Exposure Sources and Identified Risks

General population exposure to unreacted MDIs is expected to occur primarily during the use of DIY products available to consumers in home improvement activities, such as adhesive (e.g., glues containing MDIs) or sealant products (e.g., low-pressure two-component SPF consumer products). SPF products are available to the general population as either one-component or two-component type products. One-component products, which release expandable foam, typically come in a single can with a straw or gun applicator and are used for small, air-sealant applications, such as filling small cracks, holes and gaps. MDIs in these products are considered partially reacted with other chemical ingredients. Safety precautions are needed when using these one-component products to protect the user from exposure to MDIs or other substances, as directed on the labels.

Low-pressure two-component SPF consumer products are available to the general population for DIY use and to professional contractors and are typically used for air sealant applications in the home. These products come with two separate chambers, where the MDIs are in a free, unreacted state in one chamber to keep them separated from other chemicals in the second chamber. During application, the MDIs and the other chemicals are sprayed or dispensed simultaneously through a nozzle to react and form polyurethane foam at the point of application.

The low-pressure two-component SPF consumer products are available through retail stores or distributors in various product sizes and/or brands. These products are used by both DIY users and professional contractors. It is important to note that in Canada, these low-pressure two-component SPF consumer products only meet National Building Code of Canada (NBC)[5] standards and

[5] The National Building Code of Canada (NBC) sets out technical provisions for the design and construction of new buildings and also applies to the alteration, change of use and demolition of existing buildings. The NBC is a model document and must be adopted at the provincial/territorial level to come into effect. The authority having jurisdiction, which is often at the municipal level, enforces provincial/territorial building codes through the building permit process.

related material and installation standards for use as ‘air sealants’ (e.g., to fill cracks and holes) and not for insulation application (e.g., full coverage). In the United States, however, low-pressure two-component SPF consumer products are used for both air sealant and insulation purposes, as one can observe through internet videos and advertising. It is recognized that use of these products by the general population may vary and may not adhere to the NBC. SPF is available for insulation applications to Canadians but only through professional installers who use a high-pressure delivery method of two-component SPF. This form of SPF meets the NBC standards for thermal insulation material (e.g., full coverage).

Taking account of the collective information and classifications by other international regulatory agencies, the critical effects considered for characterization of the risk to human health from exposure to MDI substances are carcinogenicity, respiratory effects including sensitization, and dermal sensitization. Available information from studies with experimental animals, human case studies and epidemiological data were used to establish critical effect levels for risk characterization (Canada 2017b).

Exposure of the general population to MDIs through the use of DIY home improvement consumer products would be short-term and may occur through inhalation and dermal routes. Margins of exposure (MOE) for these scenarios were derived on the basis of an effect level of 0.05 mg/m^3 identified from MDI epidemiological studies. Use of this effect level as a critical endpoint for characterizing the risk from use of consumer products containing MDIs is considered conservative. The effect level is based on observation of effects in workers exposed on a continuous basis throughout an 8-hour work day which represents a higher exposure frequency (repetition over several weeks to several years) and longer exposure duration than for users of DIY consumer products. Therefore, margins of exposure for inhalation were also estimated using an acute respiratory effect level of 0.14 mg/m^3 identified from studies conducted on healthy volunteers exposed to TDIs for a short duration (up to 2 hours). TDIs are considered to be appropriate analogues for MDIs owing to their similar chemical substructures and similar respiratory and sensitization effects observed in humans and animals (Canada 2017b).

Although labels for products containing MDIs may indicate personal protective measures for users (e.g., gloves or respiratory protection), these recommendations are not consistent across products and they may not provide enough detail. Moreover, the proper respiratory protective equipment may not be readily available and it may be difficult to use properly without detailed information or training (i.e., generic recommendations for respiratory protection may not provide users with enough information to be able to select the appropriate respirator and use it properly). In order to be protective of the general population, exposure estimates consider that individuals are not wearing personal protective equipment (Canada 2017b).

When potential exposures of DIY users of low-pressure two-component SPF consumer products were compared to relevant critical health effect levels for respiratory effects, margins were deemed inadequate for inhalation exposures (Canada 2017b).

When potential exposures for other MDI-containing products, such as one-component foam sealant, polyurethane sealant, floor/wall adhesive, construction glue, generic/hobby glue, super glue, and hot melt adhesive, were compared to relevant critical health effect levels for respiratory effects, margins were deemed adequate for inhalation exposure. Sensitized individuals should avoid any exposure to MDIs to prevent allergic reactions (Canada 2017b).

Collective evidence from experimental animal and human case studies and epidemiological data indicate that MDIs are strong skin sensitizers. In addition, evidence in experimental animals suggests that dermal exposure prior to inhalation exposure could trigger respiratory hypersensitivity, highlighting the importance of minimizing dermal contact (e.g., wear appropriate gloves) (Canada 2017b).

Residents in a home who are not applicators could also potentially be exposed to airborne MDI from the presence of aerosols in the air during either DIY or professional use of low-pressure two-component SPF consumer products. In the case of a professional application, homeowners would typically be asked to vacate the premises during installation of the product and to return at a specified time later in the day in order to minimize exposure to MDIs (Canadian Urethane Foam Contractors Association). Some of the two-component products indicate re-entry times in the product materials; however, there are various factors that are used to make this determination (e.g., size of project, volume of product being used, ventilation, temperature, etc.). Available data indicates that levels of MDIs in the air drop rapidly once the foam starts curing (Canada 2017b).

6. Risk Management Considerations

6.1 Alternatives and Alternate Technologies

The final screening assessment identified DIY low-pressure two-component SPF consumer products as the primary source of concern for potential exposure of the general population to MDIs.

The selection and installation of air sealant and related insulation products for home improvement is a decision that must take into consideration the material and design characteristics of the specific building or task. There are materials and products that do not contain unreacted MDIs available to the DIY user for the purpose of air sealing, such as caulking, tape and sheeting; however, some of these options may not achieve the same performance qualities or desired effects as SPF.

If a homeowner selects SPF for air sealant purposes, a viable alternative to the homeowner using a low-pressure two-component SPF consumer product is to have a professional install the SPF. Similarly, when SPF is desired for home insulation (e.g., full coverage) that meets the NBC, a homeowner should hire a professional to install this product using a high-pressure two-component system.

6.2 Socio-economic Considerations

Socio-economic factors will be considered in the selection and development of regulations, instrument(s) and/or tool(s) 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).

The risk management scope document noted information gaps in the socio-economic impact of risk managing low-pressure two-component SPF consumer products containing unreacted MDIs, and information was received from stakeholders.

Low-pressure two-component SPF consumer products come in various sizes and are manufactured in Canada as well as imported by a small number of small to large companies. Overall, it is not known what proportion of these products is sold to the general population (i.e., DIY users) versus professional contractors.

7. Overview of Existing Risk Management

7.1 Related Canadian Risk Management

Existing risk management actions targeting MDIs in Canada are mostly related to presence in ambient air and tracking releases to the environment. Measures are also in place for 4,4'-MDI when present in workplace chemicals.

Federal Measures

4,4'-MDI and polymeric MDI are reportable to the National Pollutant Release Inventory (Environment Canada 2013).

4,4'-MDI is regulated by the *Hazardous Products Regulations* (HPR) established under the *Hazardous Products Act* (HPA) to protect workers from potential exposure to the substance in occupational settings. The HPR modified the Workplace Hazardous Materials Information System (WHMIS) to incorporate the Globally Harmonized System of Classification and Labelling of Chemicals (GHS), an internationally consistent approach to classifying chemicals and communicating hazard information through labels and safety data sheets (SDS). Although still applicable through a transition period, the *Controlled Product Regulations* (CPR) (Canada 1988) and the Ingredient Disclosure List have been repealed. More information on WHMIS 2015 may be found at this Health Canada website: http://hc-sc.gc.ca/ewh-semt/occup-travail/whmis-simdut/ghs-sgh/index-eng.php.

Low-pressure two-component SPF consumer products are regulated under the *Consumer Chemicals and Containers Regulations*, *2001* (CCCR 2001), issued under the authority of the *Canada Consumer Product Safety Act* (CCPSA). The CCCR 2001 use a criteria-based system by which consumer chemical products are regulated on the basis of the scientifically assessed acute hazards that they pose to users. Scientific data is used to identify the types of inherent hazards and the possible routes of exposure to the product in order to appropriately classify the product and its container. These regulations address acute (short-term) exposure situations resulting from reasonably foreseeable use of the product; however, sensitization is not within the scope of these regulations. To help Canadians make informed choices about the products they buy, the label on consumer chemical products must display hazard symbols, warning statements, instructions, and first-aid treatment(s), in both official languages. The label must also disclose all hazardous ingredients present at a concentration of one percent or greater. The CCCR 2001 sets out minimum requirements, and manufacturers and importers are encouraged to add further information they consider necessary to fully inform the users of the hazards associated with their products as long as it does not disclaim or contradict the required information.

Provincial Measures

Employers in Canada are required by provincial or territorial occupational health and safety legislation to develop and implement a worker education program that informs workers on how to work safely with hazardous chemicals. These programs involve instruction on requirements for labels and data sheets (where applicable); information on health and safety risks associated with a product, and training in safe work procedures. Each province and territory has legislation that specifies the requirements for worker education programs, which may vary slightly among jurisdictions (CCOHS 2015).

Some provincial and/or territorial governments have set exposure limits or contamination limits for either 4,4'-MDI or mixed MDI in an occupational setting (BC 2015; Quebec 2007; Saskatchewan 2007, 2010).

4,4'-MDI is subject to drinking water and soil standards under British Columbia's *Contaminated Sites Regulation* (B.C. Reg. 375/96) (BC MOE 2013).

4,4'-MDI and polymeric MDI are subject to limits for contaminants in air under Ontario Regulation 419/05 *Air Pollution – Local Air Quality* (Ontario MOE 2011) and Ambient Air Quality Criteria (Ontario MOE 2012).

MDI mixed isomers is subject to an Ontario Jurisdictional Screening Level (JSL) value, which is used as a screening tool for local air quality (Ontario MOE 2008).

"MDI" (isomer unspecified) is subject to limits under Manitoba's Ambient Air Quality Criteria (Government of Manitoba 2005).

7.2 Pertinent International Risk Management Context

Internationally, measures related to MDIs in products available to consumers have been identified as either in place or underway, specifically in the United States and the European Union, as listed below.

United States

The US Environmental Protection Agency (EPA) developed an action plan on MDI and related compounds in 2011 (US EPA 2011). The plan identifies a range of actions the EPA is considering under the authority of the *Toxic Substances Control Act* (TSCA). It intends to address potential health effects that may result from exposures to the consumer or self-employed worker while using products containing unreacted MDI and its related polyisocyanates or incidental exposures to the general population. The EPA provides information on SPF and how to use it more safely on its website. A multi-agency partnership for the safer use of SPF containing MDI and related compounds is ongoing (US EPA 2011).

SPF systems containing unreacted diisocyanates (including MDIs) were proposed as initial priority products under California's *Safer Consumer Products Regulations* due to health concerns (California EPA 2014). The priority product profile was revised in September 2014 to focus on low-pressure two-component SPF systems containing MDIs. The profile is designed to provide a rationale for identifying a product as a priority and may be used in future decision-making.

4,4'-MDI (HSDB 2012) and polymeric MDI (HSDB 2002) are subject to section 8*(d)* of the US *Toxic Substances Control Act,* under which manufacturers, importers and processors are required to provide the EPA with unpublished health and safety studies (40 CFR 716.120).

4,4'-MDI is subject to the section 8*(a)* of the US *Toxic Substances Control Act* which requires manufacturers of this chemical substance to report preliminary assessment information concerned with production, exposure, and use (40 CFR 712.30) (HSDB 2012).

4,4'-MDI is a designated a hazardous air pollutant (HAP) under the US *Clean Air Act* (HSDB 2012), which sets air quality standards for certain substances. As a designated HAP, 4,4'-MDI is also a reportable substance under the US *Comprehensive Environmental Response, Compensation, and Liability Act* (40 CFR 302.4) (HSDB 2012), which provides a fund for cleanup of uncontrolled or abandoned hazardous-waste sites as well as accidents, spills, and other emergency releases of pollutants and contaminants into the environment.

4,4'-MDI, produced as an intermediate or final product, is subject to performance standards for equipment leaks of volatile organic compounds in the synthetic organic chemical manufacturing industry (40 CFR 60.489) (HSDB 2012).

Europe and other jurisdictions

2,4'-MDI, 4,4'-MDI and MDI mixed isomers are on the Danish List of Undesirable Substances (Danish EPA 2009). The list is intended for manufacturers, product developers and others to help identify which substances may be candidates for substitution or which should be used less in the long term or which should be completely phased out..

2,2'-MDI, 2,4'-MDI, 4,4'-MDI and mixed MDI are classified by the Swedish Chemicals Agency (KEMI) as priority risk reduction substances (KEMI 2013). KEMI provides guidelines for decision-making to reduce risk from these substances.

Mixed MDI is subject to Annex XVII of the EU's REACH Regulation, under which mixtures sold to the general population must not contain greater than 0.1% by weight unless the package contains gloves that comply with Council Directive

89/686/EEC and is marked with specific warning labels (does not apply to hot melt adhesives) (European Commission 2009).

4,4'-MDI is undergoing an assessment under the European Union Community Rolling Action Plan (CoRAP) program, led by Estonia (ECHA 2015).

4,4'-MDI is reportable to the National Pollutant Inventory in Australia (Australian Government 2013).

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 approach or other information that would help to inform decision making. Please submit comments prior to August 9, 2017.

Comments and information submissions on the risk management approach should be submitted to the address provided below:

Program Development and Engagement Division
Environment and Climate Change Canada
Gatineau, Quebec K1A 0H3
Telephone: 1-800-567-1999 (in Canada) or 819-938-3232
Fax: 819-938-5212
Email: eccc.substances.eccc@canada.ca

Companies with a business interest in low-pressure two-component SPF consumer products containing MDIs available to consumers are encouraged to identify themselves as stakeholders. Stakeholders will be informed of future decisions regarding MDIs 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 proposed risk management instrument (i.e., code of practice). Comments received on the approach will be taken into consideration in the selection or development of this instrument. Consultation will also take place as the instrument is developed.

8.2 Timing of Actions

Electronic consultation on the risk management approach: June 10, 2017 to August 9, 2017

Publication of responses to risk management approach document: on or before June 10, 2019

Publication of the proposed instrument(s): No later than June 10, 2019

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

Publication of the final instrument(s): No later than December 10, 2020.

9. References

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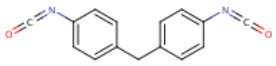
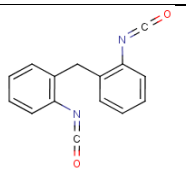
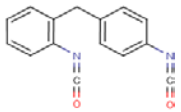
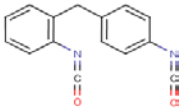
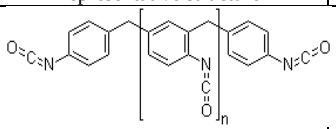
10. ANNEX A: List of Targeted Substances

CAS RN	Substance Name	Acronym	Chemical Structure	Molecular Weight (g/mol)	Chemical Formula
101-68-8	Benzene, 1,1'-methylenebis[4-isocyanato-	4,4'-MDI		250.3	$C_{15}H_{10}N_2O_2$
2536-05-2	Benzene, 1,1'-methylenebis[2-isocyanato-	2,2'-MDI		250.3	$C_{15}H_{10}N_2O_2$
5873-54-1	Benzene, 1-isocyanato-2-[(4-isocyanatophenyl) methyl]-	2,4'-MDI		250.3	$C_{15}H_{10}N_2O_2$
26447-40-5	Benzene, 1,1'-methylenebis[isocyanato-	Mixed MDI	 Representative structure	250.3	$C_{15}H_{10}N_2O_2$
9016-87-9	Isocyanic acid, polymethylenepolyphenylene ester	pMDI	 Representative structures n = 0-4	250.3 - 774.8	$C_{15}H_{10}N_2O_2$ •$[C_8H_5NO]_n$