Methylenediphenyl Diisocyanates (MDIs) and Methylenediphenyl Diamines (MDAs) Public Comments Summary Table

Comments on the draft screening assessment report (screening assessment) for MDIs and MDAs to be addressed as part of the Chemicals Management Plan (CMP) were submitted by the Canadian Network for Human Health and Environment, Canadian Vehicle Manufacturers' Association, American Chemistry Council's Center for the Polyurethanes Industry, American Chemistry Council Diisocyanates Panel, Clayton Corporation, Dow Chemical Canada, Fomo Products Canada, Lord Corporation, Children's Hospital of Eastern Ontario Research Institute, and Retail Council of Canada.

A summary of comments and responses is included below, organized by topic:

Topic	Rolled up comment	Response
Methodology	Reconsider the critical toxicity value (CTV) for assessing ecological effects of methylenediphenyl diamine (MDA) in soil, preferably using a no observed effects concentration (NOEC) or a median effective concentration (EC_{50}) with a notable impact, rather than an effects concentration at 10%.	The 56-day EC_{10} for reproduction of earthworm (*Eisenia fetida*) of 11.2 mg/kg (dry soil) was the most sensitive valid experimental ecotoxicity value available for 4,4'-MDA. EC_x values are preferred over NOECs or other unbound values because they are statistically based and use the full available dataset. An EC_{10} value was applied in this study rather than an EC_{50} because it was closer to a true no effects value.
	Discuss or summarize the European Chemicals Agency study (ECHA c2007-2013A) that refers to the CTV of 3.75 mg/kg for MDA in the sediment compartment.	This study is discussed in association with Table 6d, along with additional study details. A more thorough summary of the study is not needed, as the CTV of 3.75 mg/kg is not used in the quantitative risk quotient analysis.
	Provide a rationale for the extrapolation and application of the results from the empirical mammalian toxicity studies on MDA to other mammals.	Although standardized mammalian toxicity data may be used as surrogates for wildlife, no anticipated routes were identified in the screening assessment where wildlife would be potentially exposed to MDAs. Therefore, a PNEC for wildlife was not developed for MDAs.
	The emission rate of 0.027% for release of MDIs from the oriented strand board facilities appears to be incorrect. Based on the figures provided, a lower value (0.023%) was calculated.	The correct maximum emission level of 920 kg MDI/year is now applied in the assessment, and provides the correct emission factor of 0.027%.
	The statement regarding methylenediphenyl diisocyanate (MDI) fully (100%) converting to MDA upon contact with water is both chemically impossible and conservative. It likely leads to an overestimate of the environmental exposure and risk. A discrepancy in the information regarding the rate of hydrolysis reactions of MDI in the atmosphere also needs to be addressed.	A conservative approach (assumption of 100% conversion of MDI to MDA) was used, because accurate data on the conversion rate from MDIs to MDAs in the vapour phase are not available. In condensed phases (e.g., rain drops, fog or clouds) toluene diisocyanate (TDI) and MDI could form toluenediamine (TDA) and MDA residuals (Yakabe et al. 1999) that could be deposited in soil or surface waters. Vapour phase MDIs would also be subject to relatively quick reactions with hydroxyl radicals in the atmosphere. Two statements on slow or no gas-phase hydrolysis for MDI (Tury et al. 2003) were removed because they did not accurately describe the fate of atmospheric MDIs.
	The hobby glue scenario may be an overestimation and should be revisited and revised.	The estimate of dermal load following use of hobby glue was based on the Rijksinstituut voor Volksgezondheid en Milieu (RIVM) study that measured the actual dermal load of glue after being spread on a surface with fingers. The selected default value of 80 mg was combined with the weight fraction of MDI in hobby glue (0.56) to give a conservative estimate of dermal load. This hobby glue scenario was not found to be associated with a concern for human health in the screening assessment and the estimate of dermal load was not considered to require refinement.

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	Consider adding a dermal uptake of 30% described in Hamada et al. (2012) to applicable scenarios.	The Hamada et al. (2012) study investigates dermal sensitization and does not estimate dermal absorption. The study included only two test subjects and did not report the exact dermal uptake. The estimates of dermal exposure to MDIs in the screening assessment are considered protective and do not require refinement.
	Rodent asthma model and mouse Local Lymph Node Assay (LLNA) models continue to demonstrate that thresholds exist for chemical sensitization (whether dermal or respiratory).	Available information suggests there may be a threshold in humans to respiratory or dermal sensitization through exposures to MDIs. Validated animal testing models are not available to characterize respiratory sensitization in humans and it is not clear whether the dose-response relationship observed in animals can be extrapolated to humans. These uncertainties are reflected in the final screening assessment.
	Use of TDI as an MDI analogue is a conservative assumption for an acute respiratory effect level due to differing physicochemical properties of TDI and MDI, such as vapour pressure.	Differences in physicochemical properties between MDIs and TDIs are described in appendix A of the screening assessment. There is uncertainty in using a study on humans exposed to TDI vapours to characterize potential health risk associated with inhaling MDIs in the air likely present as aerosols. This is reflected in the final screening assessment.
	Based on case studies and epidemiological reports, diisocyanates do not have a history of causing significant skin sensitization cases. Although a number of chemical allergens appear to correlate well between animal studies and human test results, human experience does not seem to support this correlation for diisocyanates.	Dermal sensitization is considered to be a critical health effect of MDIs, based on a volunteer study, case studies, epidemiological reports, animal studies (mouse lymph node assays, mouse ear swelling tests, guinea pig maximization studies) and classifications by other regulatory agencies. The final screening assessment reflects new case studies on skin sensitization associated with occupational exposures to MDIs.
	The characterization of risk to human health effects of MDIs should be presented in the order of importance to the assessment and to the conclusions. Specifically, put cancer risk into a more appropriate order.	MDIs were selected for assessment based on categorization criteria under section 73 of CEPA for their high hazard classification (namely carcinogenicity) by international regulatory agencies. CMP screening assessments address the health effects identified as criteria for categorization first, as reflected in the final screening assessment.
	Grouping MDIs and MDAs in one assessment is commended.	Noted.
	Separate MDA and MDI into two separate screening assessments for clarity.	MDA and MDI substances have a similar core structure, but are functionally different. MDI substances are very reactive due to the presence of the isocyanate groups. MDAs are often used to make MDIs, and MDAs are formed as MDIs hydrolyze (react with water). MDIs and MDAs were assessed separately. They will remain together in one screening assessment.

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Additional Information and Data	The National Pollutant Release Inventory data on MDI may overestimate industrial releases since facilities are conservative to ensure compliance. In addition, individual MDI isomers may be reported more than once.	Noted.
	Change the statement that MDI does not react with water vapour to state that MDI does not react to any appreciable extent with water vapour in the atmosphere.	The statement was removed from the screening assessment. It is noted that condensed phases may still lead to reaction to polyurea and residual amines.
	Clarify why study data on the ECHA website are used for ecotoxicity and bioaccumulation, but not for the most recent studies of biodegradation in sediment and water.	Information available from other sources, including regulatory authorities, is considered in screening assessments under the CMP. Factors involved in determining use of data include: level of detail provided; whether the original data are published elsewhere; and transparency of the data source. Additional relevant studies are referenced within the final screening assessment.
	Provide more information to rationalize and operationalize the read-across approach for substances with structural similarities.	Use of the read-across approach for substances with structural similarities is discussed at the end of section 6.2.2 (for persistence) and in the second paragraph of section 6.3.2.2 (for bioaccumulation). A detailed rationale for its use in human health and ecological effects is included at the end of section 7.1 and in Appendix A.
	Provide the vapour pressure used in modeling for 4,4'-MDA, as well as missing density information for other MDIs.	Vapour pressure for 4,4'-MDA was corrected and new density information was added for other MDIs.
	Reflect in the screening assessment that two-component spray polyurethane foam (SPF) products containing MDIs can be formulated for either high or low pressure applications and for either 'insulation' or 'air sealant' applications. The method and purpose of application of two-component SPF products will affect application time and volume of product applied, which in turn will influence the exposure potential of the applicator. MDI emission data for low pressure applications of two-component SPF products for both sealant and insulation purposes were submitted for consideration.	All stakeholder data and information submitted during the public consultation period were considered in the final screening assessment. The distinction between high and low pressure delivery of two-component SPF was made in the draft and final screening assessments, and only measurements of MDI concentrations during application of low pressure two-component products were used to estimate homeowner exposure and risk. The distinction between 'insulation' versus 'sealant' use of the low pressure two-component SPF products is acknowledged in the final screening assessment.

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	Consider additional submitted data that show MDI emissions during application of low pressure two-component spray foam products to be near or below the identified short term critical effect level in the screening assessment.	All MDI emission data submitted by stakeholders during information gathering and the public comment period are considered in the final screening assessment. Based on these data, the margins between the estimate of exposure to MDI substances from use of low pressure two-component SPF products, and critical effect levels are inadequate.
	In the draft screening assessment the MDI emission level (0.16 mg/m^3) for estimating inhalation exposure during application of low pressure two-component spray foam was three times greater than all other available concentrations measured during both sealant and insulation applications submitted. It is unclear why this MDI emission level was the same for two different ventilation schemes. Additional data was submitted.	All new data that was received during the public consultation period were taken into consideration in the final screening assessment. Uncertainties regarding the concentration of 0.16 mg/m^3 during application of a two-component spray foam product were acknowledged in the final screening assessment.
	There are low to non-detectable area concentrations of MDI during spraying and non-detectable area concentrations within one hour of spraying low pressure two-component SPF.	Data on concentrations of MDI in the general area at the application site during and after low pressure application of two-component SPF, and personal air concentrations in the breathing zone of the applicator were included in the screening assessment.
	To reflect the most accurate characterization of potential risk, the final screening assessment should consider recently submitted data that indicate non-detectable airborne concentrations for MDI during the use of one-component foams. Clarify if the value presented in the assessment of exposure from use of one-component foam products (based on the EU RAR – 0.0061 mg/m^3) is based on actual measured values or on a corresponding detection limit.	The final screening assessment considers the three studies submitted by stakeholders where MDI concentrations in the air were all below the detection limit of 0.0065 mg/m^3 during application of one-component foam products. This detection limit is considered to be an upper-bounding estimate for general population exposure to MDI from use of a one-component foam sealant and was used to characterize risk in the final screening assessment. Margins of exposure between this upper-bounding estimate and the critical effect levels are considered adequate. The value 0.0061 mg/m^3 is a detection limit based on data submitted by industry to the European Union (EU) where MDI concentration in the air was below the detection limit during use of one-component foam products by consumers. The EU used this value as a worst case estimate of short-term inhalation because it reflects occupational exposure and consumer use (ECJRC 2005).
	It is agreed that exposure of the general population to MDI from manufactured items is minimal. Add references indicating negligible exposure to TDI from flexible foam.	Noted. However, only information directly related to the risk to human health from exposure to substances in the MDI/MDA grouping are included in the screening assessment.

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	Describe chronic obstructive lung disease (COPD) caused by isocyanates in the screening assessment.	COPD was not found to be associated with MDIs.
	Clearly articulate the discrepancies between the European Union classification (Category 2) and the International Agency for Research on Cancer (IARC) classification (Group 3).	Additional information on the IARC findings based on the Reuzel et al. (1994a) study was added to the health effect section of the screening assessment.
	Consider using a single acute critical effect level for MDI. The effect level of 0.14 mg/m^3 based on acute respiratory effect level for TDI is more representative of do-it-yourself (DIY) product assessment.	Both critical effect levels (0.05 mg/m^3 from MDI epidemiological studies and 0.14 mg/m^3 from TDI acute study) are considered in the risk characterization due to uncertainties in the health effect database, the severity of health effects, and the complexity of the health endpoint (respiratory sensitization) for which a mechanism of action is largely unknown.
	Discuss the technical procedure used by Reuzel et al. to generate the respirable aerosol of MDIs used in their bioassay and its impact on human health risk.	A brief description of the technical procedure used by Reuzel et al. was added to the final screening assessment. Studies conducted with aerosols of MDIs were considered relevant in this screening assessment given that the use of MDI containing consumer products may result in exposure to both vapours and aerosols.
Use and Exposure	Revise the parameters used for estimating human exposure to a floor adhesive.	The description of the surface area of hands in contact with MDI has been clarified in the final screening assessment. The exposure scenario is considered protective and was not refined.
	Low pressure two-component SPF products/kits may be used by consumers, although they are intended for professional use only.	Some low pressure two-component SPF products on the Canadian market are readily accessible and/or are marketed to the general population. Exposure to MDIs from use of these products by consumers has been assessed in the screening assessment.

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Environmental Fate, Degradation and Persistence	Clarify how MDI polyurea particles would be transported into the adjacent water and air when formed in soil. MDI polyureas are biologically inert and resistant to degradation.	The statement regarding transport of polyureas was removed from the final screening assessment.
	Hydrolysis half-lives are for heterogeneous reactions of MDIs with water, and not as dissolved MDI with water. Where half-lives for release of MDA from polymeric-MDA-polyurea (pMDA-polyurea) are expressed in years to millions of years, this is extreme and should simply be represented as extraordinarily stable.	The description of the half-lives for release of MDA from pMDA-polyurea has been revised to indicate that polyureas are extremely stable.
	Activated sludge toxicity values from Organisation for Economic Co-operation and Development (OECD) TG 209 should not be directly translated to an expected toxic concentration under more dilute conditions in the various biodegradation screening tests. Environment Canada has misinterpreted the toxicity/inhibition of MDA which occurs in some screening tests as indication that microorganisms require adaptation to MDA before degrading it.	The OECD 209 test measured toxicity of MDA to activated sludge with no effects observed up to 100 mg/L, the maximum concentration tested. In biodegradation tests with MDA, inhibition may thus occur at higher concentrations (Kim et al. 2002). Low biodegradation results obtained from lower concentrations (i.e., <100 mg/L) are not likely due to inhibition of sludge microorganisms.
	The respiration inhibition of pMDI determined as greater than 100 mg/L should be described as the median respiration inhibition concentration (EC_{50}).	The pMDI test results indicate no inhibition of respiration at concentrations of 1, 10 or 100 mg/L. The assessment was updated to clarify inhibition results that show pMDI was not toxic.
	The 2009 CO_2 evolution study conducted according to OECD 301B which reported 53% degradation after 63 days should be recognized as evidence of ultimate biodegradation, not primary inherent degradation.	In the CO_2 evolution study a significant amount of biodegradation occurred after 63 days. The standardized testing timeframe is 28 days. Within this timeframe, MDI did not break down enough to be considered rapidly biodegradable in the environment.
	The statement that inherent biodegradation of 4,4'-MDA only occurs where adapted industrial inoculum is used is not correct. The available studies indicate MDA to exhibit primary biodegradability and potential for ultimate biodegradation in	Available biodegradation test results and modelling data show that 4,4'-MDA biodegrades at a low to moderate rate in the environment. The potential for primary inherent biodegradation of this substance is acknowledged in the final screening assessment conclusion.

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	various environments without a requirement of adaptation.	
	Address the contradictory conclusions in two different sections of the assessment on ready biodegradability of MDA when added as the sole carbon source. Both sections reference the same study by Kim et al. (2002).	The statement in section 6.2.1.3 referencing the Kim et al. (2002) study was removed.
Precaution and Uncertainty	Consider adding an adjustment factor in the exposure scenario that acknowledges that the amount of free MDI released to the air during application of certain one-component DIY products would likely be lower than estimated by ConsExpo, due to limitations of the model.	No data providing a value for such a factor were identified. The final screening assessment reflects refinements to the ConsExpo model where applicable and includes a discussion of uncertainties.
	Include public health consequences in the screening assessment, in addition to uncertainties in epidemiological studies.	The screening assessment describes the significant uncertainties in using an endpoint based on epidemiological studies of occupational settings for the purpose of assessing the risk associated with non-occupational exposure.
Risk Assessment	Any assessment should consider providing the rationale as to why a given data set or MOE is considered adequate (or not) to cover the uncertainty.	Determination of whether or not a margin is considered adequately protective relates to uncertainties in the exposure and hazard datasets specific to the substance. There is no absolute “cut off” for interpretation of this margin. Factors considered in interpretation of the MOE include uncertainties in the available information on exposure and hazard, quality and quantity of the data, the nature or severity of the effect(s) considered critical in the assessment and other effects associated with exposure to the substance, and information on differences in sensitivity between species and across the human population.
	The MOE for two-component DIY SPF insulation containing MDIs is close to the "tipping point."	
	Consult with stakeholders to refine knowledge and data then review the risk characterization to determine a MOE of higher certainty. Consider that a full assessment might be needed for a conclusion with greater certainty.	Based on the substantial number of stakeholder engagement activities throughout the assessment process for the MDI/MDA Substance Grouping, the final screening assessment concludes that there is inadequacy of the margins between the estimate of exposure to MDI substances from use of low pressure two-component SPF products by DIY users and critical effect levels. All substances remain subject to future evaluation if warranted by new, substantive information.

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	The assessment should account for potential synergistic effects of substances and other co-ingredients to accurately estimate the overall risks with MDI/MDA mixtures.	Consideration of synergistic effects is not precluded from a screening assessment if sufficient information is available. Under the Substance Grouping Initiative of CMP, the information typically available allows for assessment of adverse effects of individual substances only. For this reason, effects of co-ingredients in all possible products containing these substances were not considered.
	The Government of Canada is commended for taking a risk-based approach that generated a relatively balanced and science-based assessment.	Noted.
Consultation	The Government of Canada is applauded for continuing engagement with the stakeholders and having a transparent process throughout its evaluation.	Noted.
	Reach out to stakeholders on the substances to be included in any given Substance Grouping Initiative, at the beginning and throughout as issues arise. This is strongly recommended as a way to informally build knowledge.	Extensive stakeholder engagement activities included consideration of how the Groupings are structured. As a result, pMDA was added to the MDI/MDA Grouping for assessment under the CMP. Uretonimine was not included in the assessment of the MDI/MDA Grouping because it is not part of the remaining CMP priorities and has a sufficiently different structure than MDI. If assessed, uretonimine would require a separate assessment. Stakeholders were informed of this decision. Ongoing dialogue is mutually beneficial and encouraged.
	Working with all parties in the supply chain is a positive suggestion. Key stakeholders should be brought into the discussions as they can share important data/information and play an integral role in the development and implementation of risk management actions.	Stakeholders were invited to provide comments on the draft screening assessment and risk management scope document published in August 2014. The desire for earlier stakeholder engagement in the process is noted. Stakeholder engagement is welcome at all levels of the supply chain. Meetings were held with key stakeholders to discuss the published draft screening assessment and the risk management scope. Feedback from these meetings informs the final assessment, risk management approach and path forward. Information submitted during the 60-day comment period is used to refine and update the scope and approach. Meetings with industry stakeholders are planned to discuss low pressure two-component SPF products.
	The scope of the screening assessment should specifically state the potential risk management action or instrument being proposed to solicit stakeholder feedback earlier in the process, which would result in a better end product.	
	Publish a letter to inform stakeholders of a SNAc "consideration." Make this a routine step in Government of Canada protocol for the creation and publication of a SNAc and	Environment and Climate Change Canada and Health Canada propose SNAc provisions for 4,4'-MDA and pMDA requiring pre-market notification for uses above a proposed amount. Stakeholders with commercial interests will continue to be meaningfully engaged and given the opportunity to

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	requests to be on the "List of Interested Stakeholders" for MDAs regarding any communication on this proposed regulatory action and any related actions.	comment on approaches. The request for publication of a letter is acknowledged.
Conclusions	Substantiate the conclusion that MDA does not biodegrade quickly in soil and that co-metabolism/adaption is required for such biodegradation. Available empirical information suggests that the fraction of substance which is not otherwise covalently bound with soil organic matter is rapidly and ultimately biodegraded to CO_2, resulting in degradation half-lives that are shorter than the Environment Canada criterion for persistence in soil.	The reference to co-metabolism was removed. Based on the available empirical data, 4,4'-MDA binds to humic substances in soil and does not biodegrade quickly in soil, thereby reducing its bioavailability and bioaccessibility. However, it may biodegrade faster in the presence of degradable organic substances mixed-in with the soil substrate. However, binding to solid media generally results in a decrease in bioavailability and increase in persistence. Under the CMP, the evaluation of persistence in a screening assessment determines how long the substance is expected to remain in each medium, and the significance regarding overall environmental fate and potential environmental effects of the substance.
	Review the overall conclusions of MDA persistence in the environment and consider all factors that affect biodegradation (i.e., concurrent biodegradation, humification reactions).	Conclusions related to criteria set out in the Persistence and Bioaccumulation Regulations were updated to reflect new persistence studies for water and sediment (OECD 309 and 308 tests). These conclude that 4,4'-MDA will have a low to moderate biodegradation rate in water and that it is expected to bind to sediment/soil and therefore be unavailable for biodegradation. The OECD 309 study findings indicate that MDA is not highly biodegradable in water.
	Include a statement in the synopsis that concludes the inherent toxicity of MDIs.	No separate conclusion on "inherent toxicity" is applicable during the assessment of substances under CEPA.
	Include a recommendation on which of the five MDIs should be considered separately toxic depending on their application. Only those substances involved in the application that compelled the CEPA toxic finding should be declared toxic or be listed on CEPA Schedule.	All five MDIs were identified in the screening assessment as priorities for assessment. Based on product composition information, pMDI, mixed MDI and 4,4'-MDI can all be present as a mixture in low pressure two-component SPF products; 2,2'-MDI and 2,4'-MDI are potentially present as residues. The estimate of exposure from use of these products was based on measured concentration of MDIs in the air during application and on overall concentrations of MDIs in available studies. Data are not available to allow for quantification of the risk to human health from exposure to individual MDIs.
	Provide a more balanced concluding paragraph for observations on mode of action for respiratory tract tumours in animals exposed to MDIs.	Additional information was added to the concluding paragraph of the carcinogenicity discussion in the health effects section of the final screening assessment.

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	The draft risk assessment was very well done. It is risk based and utilizes science to drive conclusions.	Noted.
Risk Management	Ensure that there is complete data regarding manufacturing, importation and use of MDI- and MDA-containing mixtures, and other toxic chemicals.	MDAs are not manufactured in Canada and are used only in a very limited number of industrial operations; they were not found in consumer products in Canada. Information on the manufacture, use, and importation of MDI and MDA substances were collected (including through a mandatory section 71 survey), considered and summarized in the screening assessment (http://ec.gc.ca/ese-ees/default.asp?lang=En&n=14B737B2-1). Information on substances is collected through a variety of methods to inform risk assessment and risk management activities. Note that additional information is requested to inform risk management decision-making and to help in the development of a proposed Code of Practice for MDIs. More information on requested data can be found in the Risk Management Approach document for MDIs ().
	Provide in the scope document an accurate summary of alternatives. Do not recommend that professionals install insulation. Address the hazards, exposure, and costs associated with health effects related to use of products containing MDIs in an occupational setting, in addition to the assessment for the general population.	The risk management approach has been revised to provide an accurate summary of alternatives; however, there are currently no alternatives to replace using isocyanates in SPF. As such, recommending that professionals install the low pressure two-component SPF product/kits instead of the homeowner is a viable alternative. When SPF is installed by professionals, it is industry-wide practice to tell building occupants to vacate the building during installation of the foam and to wait for a period of time before re-occupancy. This action reduces the risk of building occupant exposure to MDIs during application of SPF. Hazards, exposure, and costs associated with health effects related to use of products containing MDIs in an occupational setting were not addressed since screening assessments conducted under CEPA as part of the CMP do not apply to exposures in workplace settings. Hazards related to chemicals used in the workplace are defined within the *Workplace Hazardous Materials Information System* (WHMIS).

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	Eliminate all uses of MDI- and MDA- containing products where there are viable alternatives, such as in packaging. Encourage and support the use and development of less toxic alternatives (i.e. use green chemistry) to eliminate or prevent hazards.	Although it is recognized that there are no alternatives to using isocyanates in SPF, other products that do not contain unreacted MDIs for the purpose of air sealing are available for DIY use. The summary of alternatives in the risk management approach has been revised. Exposure from MDIs in flexible foam used in furniture or mattresses, or as a component in food packaging materials (MDI does not migrate into food) was considered to be negligible. The final screening assessment conclusions and the risk management process for those substances declared to meet CEPA section 64 criteria indirectly supports using alternatives by encouraging technological improvements and investments in research, marketing and incentive programs. Environment and Climate Change Canada and Health Canada are aware of the California DTSC program, the US Environmental Protection Agency (EPA) Action Plan on MDI substances, and the European Union ongoing evaluation of 4,4'-MDI under the Community Rolling Action Plan (CoRAP) program of REACH, led by Estonia. Actions taken to manage risks in other jurisdictions are considered in risk management decision making.
	Work with green chemistry groups and building researchers in Canada and internationally to identify and deploy superior alternative strategies and products, recommend and support research to fill data gaps including on alternatives, and consider action taken by the State of California Department of Toxic Substances Control (DTSC) where these products are identified as a high priority for substance substitution, and consult with the European Union.	
	Although the draft screening assessment conclusions are supported, the government should broaden coverage of risk management to all isocyanates and limit their use in all products.	Not all isocyanates are included in the screening assessment. However, proposed risk management actions address the exposure of concern associated with the general population using DIY low pressure two-component SPF products, which contain unreacted MDIs. Risk management actions apply to the substances that were assessed. Other products containing MDI substances such as the one-component products, adhesives, and glues, were assessed and the margins between the critical effect (respiratory sensitization) and the exposure were considered adequate (i.e., these products were not identified as a concern to human health at current levels of exposure). Therefore, the use of MDIs in these products would not be subject to risk management. Risk management actions for other isocyanates (TDIs) have been proposed and implemented.

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		Information regarding these actions can be found at the following links: 1. Proposed RM actions for TDIs: http://www.chemicalsubstanceschimiques.gc.ca/challenge-defi/summary-sommaire/batch-lot-1/action-tab-eng.php 2. Implemented RM actions for TDIs: http://www.ec.gc.ca/ese-ees/default.asp?lang=En&n=B68C1BAF-1
	Assess accurately and address the incomplete reaction of spray foam products.	Studies monitoring MDI concentrations in air during and after application of spray foam were used in the screening assessment. These studies indicated a quick decline of MDI concentrations in the air over a short period of time once application is terminated. Study results were considered in the screening assessment.
	Industry-led practices and product stewardship programs already address the objective to reduce exposure to unreacted MDIs during the DIY application of low pressure two-component SPF products. There is openness to improving or building on current programs (e.g., messaging, labeling, practices) to further enhance safe use and handling of these DIY products. The implementation of a core product stewardship program could be done by developing a Canadian Code of Practice.	It is acknowledged that industry stakeholders are open to working with Environment and Climate Change Canada and Health Canada on achieving this risk management objective. The Government will work with industry stakeholders to develop a Code of Practice which through implementation, will serve to meet the proposed risk management objective, including with: manufacturers of these products and related trade organizations (such as the American Chemistry Council Center for the Polyurethanes Industry); the Canadian Plastics Industry Association; the Retail Council of Canada; and importers and/or retailers. The Code will increase the consistency of safety information provided across products and strengthen existing industry-led product stewardship for the DIY applicator to reduce potential exposure to MDIs. Comments on restricting access at the retail level are noted. Although a prohibition is not considered for these DIY products at this time, Environment and Climate Change Canada and Health Canada are proposing additional measures for safe use, particularly from exposure through inhalation. Actions proposed are primarily for manufactures, and future actions at the retail level may also be necessary. Further engagement with all industry stakeholders in developing a Code of Practice will be valuable. The risk management approach document is subject to a 60-day public comment period. Further engagement and discussion with industry stakeholders on the detailed actions to be included in a Code of Practice is anticipated after comments are received.
	Restricting access to the products at the retail level is not viable and would not be effective. It is recommended that risk management be tailored to the beginning of the supply chain.	

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	Consider an adjustment factor to account for the use of personal protective equipment.	Exposure estimates do not assume that users are wearing personal protective equipment, since such equipment may not be readily accessible to consumers, or may not be properly handled by consumers.
	Low pressure two-component SPF products/kits only meet the requirements of the National Building Code (NBC) of Canada when used for air sealant applications (not for full coverage insulation applications). The only SPF product that meets the NBC for a thermal insulation application (i.e., full coverage) in Canada is the high-pressure two-component SPF, which is only available through professional installers (e.g., those using high-pressure systems).	It is acknowledged that in Canada low pressure two-component SPF products only meet the National Building Code (NBC) of Canada and related standards for 'air-sealant' applications, and not for full-coverage insulation. However, it is recognized that use of these products by the general population may vary and may not be subject to or adhere to NBC and other related standards. The proposed risk management addresses the exposure source of concern, which is the DIY use of these products.
	It is agreed that no further risk management activities are needed for any application of MDIs beyond the low pressure two-component SPF products for general population use.	Noted. The exposure source of concern in the final screening assessment is specific to the low pressure two-component SPF products/kits that contain unreacted MDIs, used by the general public (i.e., DIY products) rather than SPF applied by professionals in high-pressure systems. Proposed risk management only targets products that may be used by the general public.
	SPF is a valuable product and an acceptable use may be developed in the future. The creation of a regulatory instrument may stigmatize (potentially even impacting current professional use) or create a regulatory hurdle that cannot be overcome.	

Topic	Rolled up comment	Response
	MDA applications described in the assessment do not pose the unacceptable risk required to drive a significant new activity (SNAc) provision. Justify the SNAc provision for 4,4'-MDA and pMDA, consider a number of factors in determining when to apply them and define the threshold at which a SNAc is necessary. SNAcs create challenges and administrative burden for industry even when current uses are not of concern. Use a "market surveillance" mechanism or the Domestic Substance List 'Inventory Update' (DSLIU) to track use of MDA rather than creating a SNAc.	Tracking the use pattern of 4,4'-MDA and pMDA is required because these substances have health effects of concern based on potential carcinogenicity and they exhibit a high to moderate toxicity to aquatic organisms. Existing MDA uses were not identified as a concern at current levels of exposure. However, new activities that have not been identified or assessed (e.g., potential uses of MDAs in uncured consumer products or use in large-scale industrial activities) could pose a potential unacceptable risk as described by criteria set out in section 64 of CEPA. A SNAc was chosen as the most appropriate tool in this case. In consultation with stakeholders, Environment and Climate Change Canada and Health Canada developed a policy outlining the circumstances under which SNAcs are considered for use, available at: http://www.ec.gc.ca/ese-ees/default.asp?lang=En&n=5CA18D66-1. Other tracking options for information gathering are being explored (such as the DSLIU) or a market surveillance mechanism. For MDAs, additional factors related to exposure and use were considered, such as known historic uses and existing activities with MDAs in Canada and other jurisdictions.