Government of Canada | Gouvernement du Canada

PROPOSED RISK MANAGEMENT APPROACH

for

Benzene, 1,3-diisocyanato-2-methyl-
(TDI)
(2,6-Toluene Diisocyanate)
Chemical Abstract Service (CAS) Registry Number:
91-08-7

Benzene, 2,4-diisocyanato-1-methyl-
(TDI)
(2,4-Toluene Diisocyanate)
Chemical Abstract Service (CAS) Registry Number:
584-84-9

Benzene, 1,3-diisocyanatomethyl-
(TDI)
(Mixture of 2,6-Toluene Diisocyanate and 2,4-Toluene Diisocyanate)
Chemical Abstract Service (CAS) Registry Number:
26471-62-5

Environment Canada
Health Canada

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Canada

TABLE OF CONTENTS

This proposed risk management approach document builds on the previously released risk management scope document for benzene, 1,3-diisocyanato-2-methyl-; benzene, 2,4-diisocyanato-1-methyl-; and benzene, 1,3-diisocyanatomethyl- and outlines the proposed control actions for this group of substances. 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.

1. ISSUE

1.1 Categorization and the Challenge to Industry and Other 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 all substances on the *Domestic Substances List* (DSL). Categorization involves identifying those substances on the DSL that a) are considered to be persistent (P) and/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) 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 the definition of "toxic" set out in section 64 of CEPA 1999.

In December 2006, the Challenge identified 193 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 comment, profiles of batches containing 15 to 30 high-priority substances. New batches are released for comment every three months.

In addition, the mandatory information–gathering provisions under section 71 of CEPA 1999 are being used under the Challenge to gather specific information where it is required. The information that is collected through the Challenge will be used to make informed decisions and appropriately manage any risks that may be associated with these substances.

The substances benzene, 1,3-diisocyanato-2-methyl-; benzene, 2,4-diisocyanato-1-methyl-; and benzene, 1,3-diisocyanatomethyl-, Chemical Abstract Service (CAS) Registry Numbers 91-08-7, 584-84-9 and 26471-62-5 respectively, referred to collectively throughout this document by "TDI," were included in Batch 1 of the Challenge under the Chemicals Management Plan.

1.2 Final Screening Assessment Report Conclusion for TDI

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 TDI on

July 5, 2008, under subsection 77(6) of CEPA 1999. The final screening assessment report concluded that TDI 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 final screening assessment report also concluded that TDI does not meet the criteria for persistence and does not meet the criteria for bioaccumulation, as defined by the *Persistence and Bioaccumulation Regulations* (Canada 2000) made under CEPA 1999. The presence of TDI in the environment results primarily from human activity.

For further information on the final screening assessment report conclusion for TDI, refer to the final screening assessment report, available at http://www.chemicalsubstanceschimiques.gc.ca/challenge-defi/batch-lot_1_e.html.

1.3 Proposed Measure

Following a screening assessment of a substance under section 74 of CEPA 1999, a substance may be found to meet 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 CEPA 1999. Under certain circumstances, the Ministers must make a specific proposal either to recommend addition to the List of Toxic Substances or to recommend the implementation of virtual elimination (or both). In this case, the Ministers proposed to recommend the addition of TDI to the List of Toxic Substances in Schedule 1 of CEPA 1999. 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.

The final screening assessment report did not conclude that TDI meets the conditions set out in subsection 77(4) of CEPA 1999. As a result, TDI will not be 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.

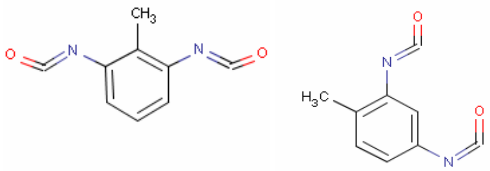
2. BACKGROUND

2.1 Substance Information

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

Table 1: Identity of TDI

CAS Registry Numbers and names	CAS RN 584-84-9: benzene, 2,4,-diisocyanato-1-methyl- (2,4-TDI) CAS RN 91-08-7: benzene, 1,3,-diisocyanato-2-methyl- (2,6-TDI)

	CAS RN 26471-62-5: benzene, 1,3,-diisocyanatomethyl- (TDI mixed isomers)
Other names CAS RN 584-84-9	1,3-Diisocyanato-4-methylbenzene; 2,4-Toluene diisocyanate (2,4-TDI); Isocyanic acid, 4-methyl-m-phenylene ester
CAS RN 91-08-7	1,3-Diisocyanato-2-methylbenzene; 2,6-Toluene diisocyanate (2,6-TDI); Isocyanic acid, 2-methyl-m-phenylene ester
CAS RN 26471-62-5	Crude tolylene diisocyanate; 1,3-Diisocyantomethylbenzene ; Toluene diisocyanate (80% 2,4-TDI; 20% 2,6-TDI)
Chemical formula	$C_9H_6N_2O_2$
Chemical structure	2,6- toluene diisocyanate 2,4- toluene diisocyanate 
Molecular mass	174.16
TDI is most commonly sold as an 80:20 mixture of 2,4- and 2,6- isomers. A mixture that is 65:35 is also in commerce and a crude TDI mixture with an undefined isomer ratio is also sold commercially.	

3. WHY WE NEED ACTION

Based principally on weight of evidence based assessments by several international and national agencies, as well as an independent review by a multinational group of experts, the available human epidemiological data and the experimental inhalation animal data are equivocal and thus inadequate to determine the carcinogenic risk of inhalation exposure to TDI in humans. Mixed results have been obtained for TDI in *in vivo* and *in vitro* genotoxicity assays. TDI is considered to be carcinogenic, since oral dosing in animals was associated with the appearance of tumours at multiple sites.

For non-cancer effects, TDI has been classified as a dermal and respiratory sensitizer by the European Union. With respect to non-cancer effects, comparison of the critical effect level for chronic non-neoplastic effects via inhalation in humans (i.e., 14 µg/m^3) and the conservative

upper-bounding exposure estimate via inhalation for TDI (1.06 μg/m^3), in the vicinity of a plant using TDI, results in a margin of exposure of approximately 13.

Comparison of the critical effect levels for acute non-neoplastic effects via inhalation in sensitized humans (i.e., 7–70 μg/m^3) and the conservative upper-bounding exposure estimate via inhalation for TDI from consumer products (i.e., 24 μg/m^3) results in margins of exposure of <1 to 2.9.

Comparison of the critical effect levels for short-term to subchronic non-neoplastic effects via inhalation in the general population (i.e., 70–140 μg/m^3) and the conservative upper-bounding exposure estimate via inhalation for TDI from consumer products (i.e., 24 μg/m^3) results in margins of exposure of 2.9–5.8.

Thus, the margins of exposure for non-neoplastic effects and exposure via inhalation to the general population and for consumer product exposure scenarios (although conservative in nature), are not adequate to account for uncertainties in the databases on exposure and effects.

On the basis of the carcinogenicity of TDI, for which there may be a probability of harm at any level of exposure, as well as the potential inadequacy of the margins between estimated exposure to the general population or exposure from products and critical effect levels for non-cancer effects, it is concluded that TDI be considered as a substance that may be 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.

4. CURRENT USES AND INDUSTRIAL SECTORS

Toluene diisocyanate (TDI) is an industrial chemical which was not manufactured by any company in Canada in a quantity above the reporting threshold of 100 kg in 2006, but which is imported into the country. Submissions made under section 71 of CEPA 1999, indicate that, in 2006, more than 10 million kilograms of TDI were imported into Canada. This includes TDI imported in mixtures and in consumer products if the quantity of TDI imported was equal to or greater than 100 kg in 2006.

Mixtures of 2,4- and 2,6- toluene diisocyanate isomers dominate industrial use of TDI. The pure 2,4- toluene diisocyanate isomer is used in some specialty elastomer applications. The pure 2,6- toluene diisocyanate isomer is not a commercial industrial chemical. Based on an end-use market survey by IAL Consultants (IAL 2007), about 86% of TDI was used in the manufacture of flexible polyurethane foam (PUF) in Canada in 2006.

Flexible PUF is used extensively in household furniture and automotive upholstery, and in mattresses, pillows, packaging and carpet underlay. Semi-flexible and semi-rigid PUF are used in automotive panels, padding and bumpers. TDI or a TDI derivative is used in polyurethane-modified alkyd paints and coatings, including automotive and marine paint, wood varnish, floor treatment, wire and powder coating. TDI or a TDI derivative is used in sealants, adhesives and elastomers. Poly(urethane urea)-cast elastomers based on TDI may be used in wheels, rollers and conveyors. TDI is used in the production of coatings for textiles for durability and waterproofing and in other textile applications. TDI-based coatings are also used in paper

production. Biomedical applications of polyurethanes based on TDI have been reported elsewhere; however, in Canada, no medical devicese were identified that are currently manufactured using TDI as a starting material.

5. PRESENCE IN THE CANADIAN ENVIRONMENT AND EXPOSURE SOURCES

5.1 Releases to the Environment

Industrial releases of TDI are expected to be mainly to air, where photolytic degradation is expected to yield a half-life of less than 2 days. TDI has a transient existence in water, moist soils and sediments due to rapid hydrolysis. The long-range atmospheric transport potential of TDI is considered to be low. The majority of TDI on-site releases reported to the National Pollutant Release Inventory were to air. The highest releases were for the isomer mixture and ranged from 700 to 5000 kg over the years 1994 to 2006. The 2,4-TDI isomer releases ranged from 2 to 148 kg over the same time period. Only 1 kg of the 2,6-TDI isomer was released in 2003 (NPRI 2007).

5.2 Exposure Sources

There are no known natural sources of TDI. Potential sources of TDI include industrial releases during manufacture and/or processing and releases from the use or disposal of finished products containing TDI. Toluene diisocyanate may be emitted to the environment from industrial processes that use TDI as a reactive intermediate, for example, during the manufacture of flexible polyurethane foam. TDI is highly volatile (Canada 2007) and emissions from industrial activities are principally to air. Another potential source of TDI emissions to the environment is incineration of waste containing TDI or waste that may degrade to TDI during the incineration process. TDI is a reactive chemical; therefore, long-range transport of TDI is not expected to contribute significantly to human exposure in Canada.

Toluene diisocyanate may be emitted during the use of some consumer products. Examples include specialty polyurethane-based paints, varnishes and coatings, polyurethane adhesives, sealants and mastic. There is experimental evidence that TDI residuals in polyurethane foam are not volatilized in measurable quantities after an initial curing period of several days. Estimates of oral exposure to TDI from infant mouthing of polyurethane foam consumer products (e.g., pillows) were less than 0.1% of the intake estimate from ambient and indoor air in the vicinity of a plant using TDI and therefore negligible. The use of TDI in food packaging is restricted to specific applications where migration is not expected in order for food contamination to be avoided. TDI residues in food have not been identified.

Short-term exposures to TDI may result from inhalation of indoor air and dermal contact during non-occupational use of non-foam consumer products (e.g., polyurethane sealer). Chronic exposures to TDI may result from non-occupational inhalation of indoor and outdoor air in the vicinity of industries releasing TDI (e.g., foam manufacture).

While the general population would likely have very low exposures to TDI, several subpopulations have been identified in the risk assessment which may have higher exposures,

notably people living in the vicinity of industries releasing TDI and people using non-foam consumer products which may release TDI.

5.2.1 Emissions from industrial activities

The use of toluene diisocyanate in adhesives, coatings manufacture, elastomers, and flexible and semi-rigid foams may result in its release to the environment through various waste streams from industry sites. Based on data submissions in response to the section 71 survey, approximately 97% of TDI consumption in Canada is located within the flexible foam production sector. The most likely environmental emission scenario for TDI is its release in stack exhaust from plants using TDI in the manufacture of these products.

According to the screening assessment report, the estimated annual average concentration of TDI in air in the vicinity of a foam manufacturing facility is 1.06 $\mu g/m^3$ based on estimated annual TDI stack releases of 1400 kg. The focus of risk management will be on addressing industrial releases of TDI emissions within the foam production sector.

5.2.2 Emissions from waste incineration

Of all the municipal solid waste (MSW), 96.8% goes to landfills and 3.2% is thermally treated (incineration). Polyurethane foams which contain trace amounts of TDI would fall in the furniture / bulky items category, which represents about 1.77% of the total MSW, and the foam itself would only represent a small percentage of that (approximately 10%).

The screening assessment report identified possible emissions of TDI from incineration at a temperature of 300°C. Municipal incinerators operate at temperatures of 900°C, which destroys 99% of the chemicals present, including TDI. Based on these findings, TDI is very unlikely to be released to the environment (air) through incineration.

In conclusion, releases to air from incineration of TDI containing products would not be a significant exposure source to Canadians.

5.2.3 Emissions from non-foam consumer products

TDI may be released to air during the use of certain products such as specialty polyurethane-based paints, varnishes and coatings, polyurethane adhesives, sealants and mastic. Based on data submissions in response to the section 71 survey, these products account for less than 3% of the total TDI consumption in Canada. Due to the small number of products identified which are available to the general public and the expected infrequency of the use of these products, the potential for exposure to TDI from consumer products is expected to be low.

5.2.4 Emissions from foam-based consumer products

Foam-based consumer products were not indicated as a major source of exposure for TDI in the assessment and thus were not a focus of the risk management scope document**.** Based on the assessment, the estimate of potential oral exposure to TDI from consumer products containing

foam was less than 1% of the estimate of exposure to TDI from the air in the vicinity of a foam plant and was therefore considered to be negligible.

5.2.4 Emissions from the wood and pulp and paper sector

Although wood products and pulp and paper are not considered to be a major source of exposure for TDI and thus were not a focus of the risk management scope document, further information has been obtained on this sector. It is unlikely that the public is exposed to TDI through the disposal of paper recycling sludge, because any residual TDI in paper coatings will rapidly react with the large volume of water used in the de-inking and pulping processes. Releases of TDI to the environment from pulp and paper recycling would not be a significant source of exposure to TDI for Canadians.

6. OVERVIEW OF EXISTING ACTIONS

6.1 Existing Canadian Risk Management

6.1.1 Air

Air quality criteria for TDI in ambient air have been set by the Province of Ontario: the Ontario Ministry of the Environment (MOE) has two kinds of standards to protect air quality. Ambient air quality criteria are used to assess the general quality of the air, while "point of impingement" limits control air emissions from individual sources of pollution, such as factories, and can be used directly as enforcement tools. For TDI, the 24-hour ambient air quality criterion is 0.2μg/m^3. The half-hour point of impingement guideline is 0.6 μg/m^3 (Ontario MOE 2005). Air quality criteria for TDI in ambient air have also been set by the Province of Newfoundland and Labrador. The 24-hour ambient air quality criterion is 0.8μg/m^3 and the half-hour point of impingement guideline is 0.5 μg/m^3 (Ontario MOE 2005).

6.1.2 Waste

The *Export and Import of Hazardous Waste and Hazardous Recyclable Material Regulations* under CEPA 1999 specify that the definition of hazardous waste and hazardous recyclable material includes specific residues from TDI production.

6.1.3. Products/Occupational

The *Controlled Products Regulations* established under the *Hazardous Products Act* (HPA) provides that any supplier who imports or sells a product that contains a listed substance in a concentration that is equal to or greater than the concentration denoted on the Ingredient Disclosure List (IDL) must supply a Material Safety Data Sheet disclosing that information. TDI is listed on the IDL with a concentration of 0.1% weight/weight. The IDL applies only to occupational settings with workplace chemicals and does not include consumer products available to the general public.

Consumer products which contain TDI may be controlled under the *Consumer Chemicals and Containers Regulations, 2001* under the HPA. These Regulations use a criteria-based classification system by which products are regulated on the basis of the scientifically assessed

acute (short-term) hazards posed during foreseeable consumer use and exposure. Scientific data are used to identify the types of inherent acute hazards and the possible routes of exposure to the product in order to appropriately classify it and determine whether any labelling or packaging requirements need to be met. Only ingredients in a concentration of 1% or greater are considered in the classification process, and those ingredients with a concentration of 1% or greater that contribute to the classification results must also be listed in the first aid treatment portion of the product label.

The Pest Management Regulatory Agency (PMRA) lists 2,6-TDI and 2,4-TDI as List 2 formulants**.** A formulant is any component of a pest control product that is added intentionally to the product and that is not an active ingredient. List 2 is a list of formulants which are considered "potentially toxic based on structural similarity to List 1 formulants or on data suggestive of toxicity" (PMRA 2007).

TDI-based products are regulated under the general provisions of Division 23 of the *Food and Drugs Act*, which includes regulations that prohibit the sale of foods in packages that may impart harmful substances to their content. Health Canada conducts safety evaluations of food packaging materials, with the goal of ensuring that the use of these materials does not result in a health risk to consumers.

The *Transportation of Dangerous Goods Regulations* classify TDI as Class 6.1 toxic substances based on human experience and specify how TDI may be packaged and shipped (Transport Canada 2006).

The Ontario *Occupational Health and Safety Act* Regulation 842 indicates that isocyanates are considered a designated substance, and that certain procedures including training, medical surveillance and occupational exposure standards must be followed by every employer and worker at a workplace where isocyanates are produced, used, handled or stored and at which the worker is likely to inhale isocyanates or where isocyanates may come into contact with the worker (Ontario Ministry of Labour 1990).

6.1.4. Releases

The National Pollutant Release Inventory (NPRI) was established in 1992 and legislated under CEPA 1999. The NPRI requires companies to report information on releases and on-site and off-site disposal of pollutants to the Government of Canada on an annual basis. Environment Canada makes the information available to Canadians in an annual public report, and maintains a detailed inventory that can be accessed and searched through an on-line database. Through this system, TDI releases have been reported by industry annually (NPRI 2007).

6.1.5. Accidental releases

TDI is regulated by the *Environmental Emergency Regulations* (SOR/2003-307) under CEPA 1999. These Regulations state that anyone who owns or has the charge, management or control of the substance in a quantity equal to or exceeding 4500 kg or stored in a container that has a maximum capacity equal to or exceeding 4500 kg must provide information on the substance. If both the substance quantity and the maximum container capacity are equal to or

exceed 4500 kg, an environmental emergency plan must be prepared, implemented and annually tested (Canada 2002).

6.1.6. Provincial permits and approvals to operate

Permitting is used by the provinces for managing emissions to the environment. Permits established for industrial activities specify source emission limits according to the environmental regulations of the province. These approvals can also require regular stack testing and ambient monitoring, as well as dispersion modelling to predict maximum concentrations for various air pollutants.

The facilities are generally asked to provide the expected (calculated) ground level concentrations of all air contaminants that may be released. TDI emissions will generally be managed in the provinces that have set air quality standards regarding TDI (see information under the heading “Air” in section 6.1.1 of this risk management approach).

6.2 Existing International Risk Management

6.2.1 United States

Clean Air Act (CAA): TDI has a threshold quantity of 10 000 lbs which triggers the requirement for risk management programs for accidental releases. The United States Environmental Protection Agency (US EPA) has developed national emission standards and regulations for the release of hazardous air pollutants (HAPs) from fugitive, stack and storage sources for major stationary sources. TDI is included on the U.S. HAPs list, and national emissions standards for TDI include those for wood furniture manufacturing, polyurethane foam manufacturing, coating of automobiles and light-duty trucks, synthesis of organic chemical manufacturing, and mobile sources (US EPA 2007).

Emergency Planning and Community Right-to-know Act (EPCRA): Releases above 100 lbs (2,4-TDI and 2,6-TDI) require reporting to state and local governments. Emergency planning activities are required if the presence of TDI is above the threshold planning quantity of 500 lbs (2,4-TDI) or 100 lbs (2,6-TDI). Emissions, transfers and waste management data must be reported annually for substances listed (US EPA 2001).

Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA): Releases above 100 lbs (2,4-TDI and 2,6-TDI) require reporting to national governments (US EPA 2001).

Food and Drug Act (FDA): TDI isomers are listed as indirect additives used in food contact substances. The isomer mixture is listed under polyurethane resins. The 2,6-TDI isomer is listed under adhesives. The 2,4-TDI isomer is listed under adhesives, reverse osmosis membranes and as a component of paper or paperboard in contact with aqueous or fatty food with a limit for the polymer of 0.1% by weight as a surface sizing agent (US FDA 2007).

Toxic Substances Control Act (TSCA): This act requires copies of unpublished health and safety studies to be submitted to the U.S. Environmental Protection Agency (EPA) for the TDI isomer mixture (HSDB 2003).

Resource Conservation and Recovery Act (RCRA): This act specifies that when TDI becomes a waste, it must be managed according to federal and/or state hazardous waste regulations (HSDB 2003).

6.2.2 Other National Legislation

The United Kingdom (UK) has a stack emission limit for industrial sites of 0.1 mg/m^3 for total reactive isocyanate groups (stated to be equivalent to 0.2 mg/m^3 TDI) (Allport et al. 2003).

The *Control of Major Accident Hazards Regulations* in the UK state that facilities storing 10 000 kg of TDI or more must have a safety management plan and facilities storing 100 000 kg or more must have plans for supplying information to the public and notifying the European Commission of major accidents (OPSI 1999).

The *Merchant Shipping Regulations* prohibit the release of TDI into specified waters (OPSI 1997).

The *Plastic Materials and Articles in Contact with Food Regulations* state that the maximum quantity of residual TDI in the plastic material is 1 mg/kg (OPSI 2003).

The *Volatile Organic Compounds in Paints, Varnishes and Vehicle Refinishing Products Regulations* limit the amount of VOC which can be used and sets labelling requirements. TDI is not specifically listed (OPSI 2005).

The *Environmental Protection Regulations* outline which processes using TDI must request authorization. The enforcing authority must seek to ensure that the best available techniques not entailing excessive cost are employed to prevent or minimize the release to air (OPSI 1991).

7. CONSIDERATIONS

7.1 Alternative Chemicals or Substitutes

No information on potential substitutes for TDI was brought forward in the voluntary Challenge questionnaire submissions. In discussions with industry, it was mentioned that methylenediphenyl diisocyanate (MDI) has replaced or is replacing TDI in some applications (e.g., carpet underlay and foam-in-place caulking). It is important to note that this potential substitute has not undergone an assessment to determine whether it would meet the criteria under section 64 of CEPA 1999.

7.2 Alternative Technologies and/or Techniques

Releases of TDI from industrial sites may be decreased by the use of abatement technology. Neutral and alkali aqueous scrubbing and carbon adsorption methods have proved to be both practically and economically viable (Alliance for the Polyurethanes Industry 2005).

7.3 Socio-economic Considerations

Where information was available, socio-economic factors have been considered, at least in a qualitative manner, in the selection process for an 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 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

In screening assessments, potential exposure of the general population, including infants and children, is estimated. To the extent possible, based on available data, exposure to TDI from multiple routes (i.e., inhalation, ingestion and contact on the skin) and possible sources (ambient air, indoor air, drinking water, food, beverages—including breast milk and formula for infants—soil, and in some instances consumer products) is estimated. Infants and children's exposure is characterized by their unique physiology (e.g., intake of air, food, and water relative to body size) and generally known behaviour characteristics (e.g., crawling versus walking, mouthing activity).

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, and other data considered, it is proposed that no additional risk management actions to specifically protect children are required for this substance at this time.

8. PROPOSED OBJECTIVES

8.1 Environmental or Human Health Objective

An environmental or 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 TDI is to minimize human exposure to the greatest extent practicable.

8.2 Risk Management Objective

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

objective for TDI is to achieve the lowest level of release to the environment that is technically and economically feasible.

In order to achieve the risk management objective and to work towards achieving the human health objective, the risk management described below is being considered for TDI.

9. PROPOSED RISK MANAGEMENT

9.1 Proposed Risk Management Instrument(s) and/or Tool(s)

As required by the Government of Canada's *Cabinet Directive on Streamlining Regulation,*[1] and criteria identified in the Treasury Board document entitled *Assessing, Selecting, and Implementing Instruments for Government Action*, the proposed risk management regulations, instruments and/or tools were selected using a consistent approach, and took into consideration the information that has been received through the Challenge and other information available at the time.

In order to achieve the risk management objective and to work towards achieving the human health objective, the risk management being considered for TDI is an instrument that prescribes maximum TDI concentrations at air stack exhaust to control and reduce TDI releases to the environment from the foam industry. Additional actions being considered are the investigation of the management of non-foam consumer products and the addition of TDI to the Cosmetic Ingredient Hotlist.

9.1.1 Plastics and Plasticizers Sector

Based on NPRI reports in 2006, the conservative upper-bounding exposure estimate via inhalation for TDI in the vicinity of a plant using TDI is 1.06 $\mu g/m^3$ for annual TDI releases of approximately 1400 kg. It is also understood that a facility reporting TDI emissions to the NPRI in 2006 has since installed a device to reduce air emissions. This device would reduce annual TDI releases and therefore the exposure to the substances in the vicinity of the facility.

Over the past 25 years, a wide range of technical devices to reduce TDI emissions have been tested and selected versions have been used commercially. Some of them have been installed on flexible polyurethane foam plants in the UK, Holland and Belgium, and data are now available from these units in terms of efficiency, life and cost per tonne of TDI treated.

A study by Allport et al. (2003) has indicated that, where technical devices were installed, concentrations of TDI, post abatement, were below 20 $\mu g/m^3$ in the stack exhaust. This value would be equivalent to an annual TDI release of approximately 10 kg and a non-detectable TDI level in the vicinity of a foam manufacturing facility.

Technical devices could also be used in other Canadian facilities to reduce TDI emissions from the flexible and rigid and foam industry.

[1] 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".

An instrument that prescribes maximal TDI concentrations at air stack exhaust will be considered to control and reduce TDI releases to the environment. The most appropriate type of instrument, whether regulations or release guidelines, will be determined through consultation with stakeholders.

9.1.2 Waste Management Sector

Based on recent results and findings, no potential exposure from releases due to incineration of polyurethane foam products is assumed, hence no control instrument is proposed from the waste management sector.

9.1.3 Consumer Products and Paints and Coatings Sectors

The need for risk management of non-foam consumer products containing TDI will be further investigated.

9.1.4 Food Packaging Sector

Although food packaging is not considered to be a major source of exposure for TDI and thus was not a primary focus of the risk management scope document, Health Canada is continuing to investigate this potential source of exposure. A letter has been sent to the single manufacturer whose TDI-based materials are listed on the Canadian Food Inspection Agency's Reference Listing of Accepted Construction Materials, Packaging Materials and Non-Food Chemical Products. This letter requests data on residual levels and potential migration of TDI. Health Canada is planning to conduct limited testing of TDI levels in specified foods. In addition, future submissions for the use of TDI in food packaging materials will be scrutinized by Health Canada so that residual levels in finished materials are as low as possible or there is a functional barrier between the packaging material and food to prevent contact and therefore minimize the potential migration into food.

9.1.5 Cosmetics Sector

Issues pertaining to TDI isomers and mixtures in cosmetics fall under the regulatory area of the *Food and Drugs Act*. Section 16 of the Act states that no person shall sell a cosmetic product that has in it any substance that may injure the health of the user when the cosmetic is used according to its customary method. To help cosmetic manufacturers satisfy this requirement, Health Canada has developed the Cosmetic Ingredient Hotlist—a list of substances which are restricted and prohibited in cosmetics. Although no data were available on TDI and mixture application in cosmetics, Health Canada will propose that TDI be added to the Cosmetic Ingredient Hotlist so that these substances will not be used in cosmetic products in the future.

9.2 Implementation Plan

The proposed instrument will be published in the *Canada Gazette*, Part I, no later than July, 2010, as per the timelines legislated in CEPA 1999.

Releases of TDI will continue to be monitored under the National Pollutant Release Inventory. Other monitoring will be considered in order to assess the performance of the risk management regulation or instrument and to determine whether further action needs to be taken with respect to TDI.

10. CONSULTATION APPROACH

The risk management scope for TDI, which summarized the proposed risk management under consideration at that time, was published on January 19, 2008, and is available at www.ec.gc.ca/TOXICS/EN/detail.cfm?par_substanceID=236&par_actn=s1. Industry and other interested stakeholders were invited to submit comments on the risk management scope 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 risk management approach will involve publication on July 5, 2008, and a 60-day public comment period.

The primary stakeholders include

- polyurethane and other foam industries
- importers of TDI
- environmental non-governmental organizations

11. NEXT STEPS / PROPOSED TIMELINE

Actions	Date
Electronic consultation on proposed Risk Management Approach	July 5, 2008 to September 3, 2008
Response to comments on the Risk Management Approach	At time of publication of proposed instrument
Consultation on the draft instrument	Winter 2008–2009
Publication of the proposed instrument	No later than July 2010
Formal public comment period on the proposed instrument	No later than summer 2010
Publication of the final instrument	No later than January 2012

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 September 3, 2008, since the Government of Canada will be moving forward with the risk management of TDI after this date. Pursuant to section 313 of CEPA 1999, any person who provides information to the Minister under CEPA 1999 may submit with the information a request that it be treated as confidential. During the development of the risk management instrument(s) and/or tool(s), there will be opportunity for consultation on the proposed instrument(s). Comments and information submissions on the proposed risk management approach should be submitted to the address provided below:

Existing Substances Division
Place Vincent Massey, 20th Floor
351 Saint Joseph Boulevard
Gatineau QC K1A 0H3
Tel: 1-888-228-0530 / 819-956-9313
Fax: 1-800-410-4314 / 819-953-4936
Email: Existing.Substances.Existantes@ec.gc.ca

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