Risk Management Scope

for:

Aromatic Amines Group, *specifically:*

Benzenamine, N,N-dimethyl-

(Dimethylaniline)

Chemical Abstracts Service Registry Numbers

(CAS RN 121-69-7)

Environment and Climate Change Canada

Health Canada

August 2020

Summary of Proposed Risk Management

This document outlines the risk management options under consideration for dimethylaniline, which has been proposed to be harmful to human health.

In particular, the Government of Canada is considering the actions below to address the health concerns:

Regulatory and/or non-regulatory measures to help reduce dermal and inhalation exposures to dimethylaniline contained in certain automotive products such as adhesives, sealants, fillers, primers, bonding agents, available to consumers in Canada, for Do-It-Yourself (DIY) projects.

Moreover, because certain data gaps remain, information on the following items should be provided (on or before October 14, 2020) to the contact details identified in section 8 of this document, to inform risk management decision-making: Ranges of concentrations of dimethylaniline in products available to consumers in Canada, for DIY projects.

The risk management options outlined in this Risk Management Scope document may evolve through consideration of assessments and risk management options or actions published for other Chemicals Management Plan (CMP) substances as required to ensure effective, coordinated, and consistent risk management decision-making.

All eight substances in this assessment were identified as having low potential to cause ecological harm, based on the Ecological Risk Classification of organic substances (ERC) approach (ECCC 2016).

Note: The above summary is an abridged list of options under consideration to manage these substances and to seek information on identified gaps. Refer to section 3 of this document for more complete details in this regard. It should be noted that the proposed risk management options may evolve through consideration of additional information obtained from the public comment period, literature and other sources.

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1. Context

The *Canadian Environmental Protection Act, 1999* (CEPA) (Canada,1999) provides the authority for the Minister of the Environment and the Minister of Health (the Ministers) to conduct assessments to determine if substances are toxic to the environment and/or harmful to human health as set out in section 64 of CEPA[1,2], and if so, to manage the associated risks.

As part of the third phase of the Chemicals Management Plan (CMP), the Ministers plan to assess and manage, where appropriate, the potential health and ecological risks associated with approximately 1550 substances (Canada, 2016).

2. Issue

Health Canada and Environment and Climate Change Canada conducted a joint scientific assessment relevant to the evaluation of the aromatic amines, including dimethylaniline, in Canada. A notice summarizing the scientific considerations of the draft screening assessment for these substances was published in the *Canada Gazette*, Part I*,* on August 15, 2020. (Canada 2020). For further information on the draft screening assessment for aromatic amines, refer to https://www.canada.ca/en/environment-climate-change/services/evaluating-existing-substances/draft-screening-assessment-aromatic-amines-group.html.

2.1 Draft Screening Assessment Conclusion

On the basis of the information available, the draft screening assessment proposes that dimethylaniline meets the criteria under section 64c of CEPA because it 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 (Canada, 2020).

[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 are met is based upon an assessment of potential risks to the environment and/or to human health associated with exposures in the general environment. For humans, this includes, but is not limited to, exposures from ambient and indoor air, drinking water, foodstuffs, and products used by consumers. A conclusion under CEPA is not relevant to, nor does it preclude, an assessment against the hazard criteria specified in the *Hazard Product Regulations*, which are a part of the regulatory framework for the Workplace Hazardous Materials Information System for products intended for workplace use. Similarly, a conclusion on the basis of the criteria contained in section 64 of CEPA does not preclude actions being taken under other sections of CEPA or other Acts.

The draft screening assessment also proposes that dimethylaniline meets the persistence criteria but does not meet the bioaccumulation criteria, as set out in the *Persistence and Bioaccumulation Regulations* of CEPA.

The exposure sources of concern, identified in the draft screening assessment, are based on the potential release of dimethylaniline from certain automotive products, such as adhesives, sealants, fillers, primers, bonding agents, available to consumers, for DIY projects. As such, this document will focus on these exposure sources of concern (refer to section 5).

2.2 Proposed Recommendation under CEPA

Based on the findings of the draft screening assessment conducted as per CEPA, the Ministers propose to recommend that dimethylaniline be added to the List of Toxic Substances in Schedule 1 of the Act][3].

The Ministers will take into consideration comments made by stakeholders during the 60-day public comment period on the draft Screening Assessment Report for the Aromatic Amines Group (including dimethylaniline) and its associated Risk Management Scope document.

If the Ministers finalize the recommendation to add dimethylaniline to Schedule 1, risk management instruments must be proposed and finalized within a set period of time as outlined in sections 91 and 92 of CEPA (refer to section 8 for publication timelines applicable to this group of substances).

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.

For dimethylaniline, the proposed objective is focused on addressing the risks and exposure sources of concern outlined in section 5 of this document. As such, the proposed human health objective for dimethylaniline is to decrease exposure of the general population to dimethylaniline to levels that are protective of human health.

[3] When a substance is found to meet one or more of the criteria under section 64 of CEPA, the Ministers can propose to take no further action with respect to the substances, add the substance to the Priority Substances List for further assessment, or recommend the addition of the substance to the List of Toxic Substances in Schedule 1 of the Act.

3.2 Proposed Risk Management Objective

Proposed risk management objectives set quantitative or qualitative targets to be achieved by the implementation of risk management regulations, instruments and/or tools for a given substance or substances.

In this case, the proposed risk management objective for dimethylaniline for the protection of human health is to reduce concentrations of dimethylaniline contained in certain automotive products such as adhesives, sealants, fillers, primers, bonding agents, available to consumers in Canada, for DIY projects.

The proposed risk management objective may be revised in the Risk Management Approach document that will be published concurrently with the screening assessment for these substances, or in subsequent risk management documents (e.g. consultation document on proposed instrument), as the case may be.

3.3 Proposed Risk Management Options under Consideration

To achieve the proposed risk management objective and to work towards achieving the proposed human health objective, the risk management options under consideration for dimethylaniline are:

Regulatory and/or non-regulatory measures to limit the concentrations of dimethylaniline contained in certain automotive products such as adhesives, sealants, fillers, primers, bonding agents, available to consumers in Canada, for DIY projects.

Following the publication of this Risk Management Scope document, additional information obtained from the public comment period and from other sources will be considered, along with the information presented in this document, in the instrument selection and development process[4]. The risk management options 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.

3.4 Risk Management Information Gaps

At this time, the following additional information is being requested from interested stakeholders to help fill any information gaps and to inform risk management decision-making regarding dimethylaniline use in Canada:

- Ranges of concentrations of dimethylaniline in products available to consumers in Canada, for DIY projects.

[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)

- Socio-economic and technical impacts and benefits associated with the proposed risk management options under consideration.

Should stakeholders have such further information, they should provide it ideally on or before October 14, 2020, within the timelines (and to the contact) identified in section 8 of this document.

3.5 Performance Measurement and Evaluation

Performance measurement evaluates the ongoing effectiveness and relevance of the actions taken to manage risks from toxic substances. The aim is to determine whether human health and/or environmental objectives have been met and whether there is a need to revisit the risk management approach for that substance, to ensure that risks are managed effectively over time. To achieve this, the Government of Canada will review, on a regular basis, the effectiveness of the risk management actions for dimethylaniline, by collecting and analyzing relevant data.

The results of performance measurement and evaluation will be used to inform whether further risk management action is warranted and will be made available to Canadians along with recommendations for further action, if applicable.

4. Background

4.1 General Information on the Aromatic Amines Group

Aromatic amines are a family of chemical substances in which an amino group is attached to an aromatic ring system. The following eight substances are identified in the draft screening assessment as the Aromatic Amines Group:

Substance	*Common Name*
Benzenamine, N-nitroso-N-phenyl-	NDPhA
1-Naphthalenamine, N-phenyl-	P1NA
Phenol, 2-amino-	2-aminophenol
4,4' - Methylenebis (2-chlorobenzenamine)	MBOCA
1,4-Benzenediamine, N,N’-bis(1-methylpropyl)-	44PD
Benzenamine, N,N-dimethyl-	Dimethylaniline
Benzenamine, N-phenyl-	Diphenylamine
2-Naphthalenol, 2-aminobenzoyl ester	2-naphthyl anthranilate

These substances do not occur naturally except for diphenylamine which may occur naturally in certain food items.

4.2 Current Uses and Identified Sectors

According to information submitted in response to surveys under section 71 of CEPA, dimethylaniline was reported to be manufactured in Canada in 2008 at a volume of < 100 kg, and reported to be imported into Canada at a volume of 10,000 – 100,000 kg.

In Canada, as reported in the draft Screening Assessment Report (Canada 2020) dimethylaniline has been used as a solvent, hardener or curing agent in consumer and industry (automotive, aircraft) sectors, in adhesives and sealants, paints and coatings, plastic and rubber materials. It may also be used as a component in food packaging materials, specifically as a component in fibreglass reservoirs for holding water used in food processing establishments with the potential for direct food contact but with negligible exposure.

5. Exposure Sources and Identified Risks

The purpose of the Risk Management Scope is to present Environment and Climate Change Canada's and Health Canada's early proposal to manage the risks identified in the screening assessment. As such, the exposure sources of concern are further discussed in this document.

As per the draft Screening Assessment Report (Canada 2020) the exposure of the general population in Canada to dimethylaniline occurs from the use of certain automotive products available to consumers (including a 2-component adhesive, automobile body filler and spray paint primer) for DIY projects. The concentration of dimethylaniline in these three products ranged from 0.1-5%.

According to the draft Screening Assessment Report (Canada 2020), the critical health effects for dimethylaniline are seen in the spleen. A comparison of estimated levels of exposure to dimethylaniline and critical effect levels associated with occasional dermal and inhalation contact with dimethylaniline in automotive products for non-cancer health effects, resulted in margins of exposures that were inadequate to account for uncertainties in the health effects and exposure databases.

6. Risk Management Considerations

6.1 Alternatives and Alternate Technologies

There are other substances which may be used in place of dimethylaniline as a solvent, hardener or curing agent, in products. The ideal alternative substance will depend on the nature of the product and the performance characteristics desired by the manufacturer.

6.2 Socio-economic and Technical Considerations

No information on socio-economic or technical considerations was identified. We ask that stakeholders submit information on these considerations, if known.

Socio-economic factors will be considered in the selection process for a regulation and/or instrument respecting preventive or control actions, and in the development of the risk management objectives. Socio-economic factors will also be considered in the development of regulations, instrument(s) and/or tool(s) as identified in the Cabinet Directive on Regulatory Management (TBS 2012a) and the guidance provided in the Treasury Board document Assessing, Selecting, and Implementing Instruments for Government Action (TBS 2007).

7. Overview of Existing Risk Management

7.1 Related Canadian Risk Management Context

Dimethylaniline is not on Health Canada's List (Hotlist) of substances prohibited or restricted for use in cosmetics. Dimethylaniline is on the National Pollutant Release Inventory (NPRI) and is classified by the Workplace Hazardous Materials Information System (WHMIS).

7.2 Pertinent International Risk Management Context

Internationally, there are related risk management measures and actions as indicated below:

- In the EU, dimethylaniline is prohibited for use in cosmetic products
- The US has designated dimethylaniline a volatile organic compound (VOC) subject to compliance with emission standards, and it is listed as a hazardous air pollutant under the United States Clean Air Act
- The US Occupational Safety and Health Administration (OSHA) has set a permissible exposure limit, and the US National Institute for Occupational Safety and Health (NIOSH) has identified a recommended exposure limit, for dimethylaniline. The American Conference of Governmental Industrial Hygienists (ACGHI) has a threshold limit for dimethylaniline.

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 Scope or other information that would help to inform decision-making. Please submit additional information and comments prior to October 14, 2020.

The Risk Management Approach document, which will outline and seek input on the proposed risk management instrument(s), will be published at the same time as the final Screening Assessment Report. At that time, there will be further opportunity for consultation.

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

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 who have a business interest in dimethylaniline are encouraged to identify themselves as stakeholders. The stakeholders will be informed of future decisions regarding dimethylaniline and may be contacted for further information.

8.2 Timing of Actions

Electronic consultation on the draft Screening Assessment Report and Risk Management Scope: August 15, 2020 to October 14, 2020.

Submission of public comments, additional studies and/or information on Aromatic Amines: On or before October 14, 2020

Publication of responses to public comments on the draft Screening Assessment Report and Risk Management Scope: On or before August 2021

Publication of the final Screening Assessment Report and, if required, the Risk Management Approach document: On or before August 2021

Publication of responses to public comments on the Risk Management Approach, if applicable and if required, the proposed instrument(s): At the latest, 24-month from the publication of the final Screening Assessment Report

Consultation on the proposed instrument, if required: 60-day public comment period starting upon publication of each proposed instrument

Publication of the final instrument, if required: At the latest, 18-month from the publication of each proposed instrument.

9. References

Canada Gazette Part I, vol. 140, no. 9, p. 435-459 (2006). *Canadian Environmental Protection Act*, 1999: Notice with respect to selected substances identified as priority for action [PDF].

Canada. 1999. Canada Gazette. Part III. vol. 22, no. 3. (1999). Canadian Environmental Protection Act, 1999. S.C., 1999, c. 33 [PDF].

Canada. 2000. *Canadian Environmental Protection Act, 1999: Persistence and Bioaccumulation Regulations* [PDF], P.C. 2000-348, 23 March 2000, SOR/2000-107.

Canada. 2015. Treasury Board of Canada Secretariat. *Red Tape Reduction Act.* S.C. 2015, c.12.

Canada. 2016. Third phase of the Chemicals Management Plan.

Canada. 2020. Dept. of the Environment, Dept. of Health. Draft Screening Assessment, Aromatic Amines Group

Environment and Climate Change Canada (ECCC 2016) Ecological Risk Classification of Organic Substances (ERC)

EU (European Union). 2009. Official Journal of the European Union L 342/59 Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products [PDF]

[TBS] Treasury Board of Canada Secretariat. 2007. Assessing, Selecting, and Implementing Instruments for Government Action

[TBS] Treasury Board of Canada Secretariat. 2012a. Cabinet Directive on Regulatory Management

[TBS] Treasury Board of Canada Secretariat. 2012b. Red Tape Reduction Action Plan