



Government
of Canada

Gouvernement
du Canada

Risk Management Scope for

**Thioperoxydicarbonic diamide ($[(\text{H}_2\text{N})\text{C}(\text{S})]_2\text{S}_2$),
tetramethyl-**

[TMTD]

**Chemical Abstracts Service Registry Number
(CAS RN):**

137-26-8

Environment and Climate Change Canada

Health Canada

February 2018

Canada 

Summary of proposed risk management

Under the Third Phase of the Government of Canada's Chemicals Management Plan (CMP), Thioperoxydicarbonic diamide ($[(\text{H}_2\text{N})\text{C}(\text{S})]_2\text{S}_2$), tetramethyl- (CAS RN 137-26-8, also known as TMTD) was included within the scope of the Thiocarbamates Group screening assessment and identified as posing a risk to the environment. The [draft screening assessment](#) proposes to conclude that TMTD meets criteria under paragraph 64(a) of the Canadian Environmental Protection Act, 1999 (CEPA).

This document outlines the risk management options under consideration for the substance TMTD. In particular, the Government of Canada is proposing to consider the implementation of regulatory and non-regulatory controls to minimize release of TMTD to the Canadian environment.

Interested stakeholders are invited to provide information that will help to fill possible information gaps and to inform risk management decision-making regarding TMTD use in Canada. These gaps include information on:

- Latex product manufacturing and uses of TMTD in latex rubber compounding/mixing and/or processing sites;
- Potential release of adhesive and sealants that contain TMTD during automotive manufacturing;
- Details on alternatives to TMTD and/or technologies, and their feasibility as applicable to Canadian manufacturers, importers and users;
- The measures and practices currently implemented by the industrial users, such as rubber product manufacturers, to prevent or minimize releases or environmental risks of TMTD (e.g. from the rubber sector during the raw material weighing, handling, compounding and processing) and the associated costs;
- Changes to use patterns and economic impacts since 2011
- Existing provincial regulations or permits governing the use or handling of TMTD.

Note: The above summary is an abridged list of both options under consideration to manage TMTD and to seek information needed to fill 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 Climate Change 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.

Pursuant to sections 68 and 74 of CEPA, the ministers have conducted a screening assessment of two substances referred to collectively as the Thiocarbamates Group. Substances in this group were identified as priorities for assessment as they either met categorization criteria under subsection 73(1) of CEPA or were considered a priority based on other human health concerns.

Two substances in the Thiocarbamates Group

CAS RN ³	Domestic Substances List name
137-26-8 ^a	Thioperoxydicarbonic diamide ($[(H_2N)C(S)]_2S_2$), tetramethyl- (TMTD, Thiram)
120-54-7 ^b	Piperidine, 1,1'-(tetrathiodicarbonothioyl)bis- (DPTT)

^a Chemical Abstracts Service Registry Number. The Chemical Abstracts Service information is the property of the American Chemical Society and any use or redistribution, except as required in supporting regulatory requirements and/or for reports to the Government of Canada when the information and the reports are required by law or administrative policy, is not permitted without the prior, written permission of the American Chemical Society.

^b This substance has multiple uses associated with different acronyms.

^c This substance was not identified under subsection 73(1) of CEPA, but was included in this assessment as it was considered as a priority based on other human health concerns.

The substance, TMTD, also known as Thiram, has been assessed internationally through a variety of programs including the Cooperative Chemicals Assessment Programme of the Organization of Economic Cooperation and Development

¹ Section 64 [of CEPA]: For the purposes of [Parts 5 and 6 of CEPA], except where the expression “inherently toxic” appears, a substance is toxic if it is entering or may enter the environment in a quantity or concentration or under conditions that

- (a) have or may have an immediate or long-term harmful effect on the environment or its biological diversity;
- (b) constitute or may constitute a danger to the environment on which life depends; or
- (c) constitute or may constitute a danger in Canada to human life or health.

² A determination of whether one or more of the criteria of section 64 of CEPA are met is based upon an assessment of potential risks to the environment and/or to human health associated with exposures in the general environment. For humans, this includes, but is not limited to, exposures from ambient and indoor air, drinking water, foodstuffs, and products available to consumers. A conclusion under CEPA is not relevant to, nor does it preclude, an assessment against the hazard criteria specified in the Hazardous Products Regulations, which are part of the regulatory framework for the Workplace Hazardous Materials Information System for products intended for workplace use. Similarly, a conclusion based on the criteria contained in section 64 of CEPA does not preclude actions being taken under other sections of CEPA or other Acts.

(OECD), the European Chemicals Agency in Europe (ECHA), the European Food Safety Authority (EFSA), the United States Environmental Protection Agency (US EPA), and recently by Health Canada's Pest Management Regulatory Agency (PMRA). These assessments as well as the draft screening assessment described in the section 2.1 below were used to inform this risk management scope.

2. Issue

2.1 Draft Screening Assessment Report conclusion

Health Canada and Environment and Climate Change Canada (ECCC) conducted a joint scientific assessment of TMTD in the Thiocarbamate Group, including information relevant to TMTD in Canada. A notice summarizing the scientific considerations of the draft screening assessment was published in the Canada Gazette, Part I, on February 3, 2018 (Canada 2018). For further information on the draft Screening Assessment Report for the Thiocarbamate Group, refer to the [Canada.ca \(Chemical substances\) website](https://www.canada.ca/chemical-substances).

Based on information examined in the draft screening assessment, it is proposed to conclude that TMTD meets the criteria under paragraph 64(a) of CEPA as it is entering or may enter the environment in a quantity or concentration or under conditions that have or may have an immediate or long-term harmful effect on the environment or its biological diversity. However, it is proposed to conclude that TMTD does not meet the criteria under paragraph 64(b) or 64(c) of CEPA as it is not entering or may not entering the environment in a quantity or concentration or under conditions that constitute or may constitute a danger to the environment on which life depends; and constitute or may constitute a danger in Canada to human life or health (Canada 2017).

According to the draft screening assessment, TMTD does not meet the criteria for persistence or bioaccumulation, as defined in the Persistence and Bioaccumulation Regulations made under CEPA (Canada 2000).

According to the draft screening assessment, DPTT does not meet any of the criteria set out in section 64 of CEPA.

Considering all available lines of evidence presented in the draft screening assessment, there is risk of harm to aquatic organisms from TMTD releases to wastewater during its use in manufacturing rubber products, but not to the broader integrity of the environment (Canada 2017). During rubber compounding/processing, TMTD may be released to wastewater that is generated from industrial operations, such as cleaning, milling, cooling and vulcanizing rubber. TMTD is also used in automotive manufacturing sector as a component in automotive sealants and adhesives and other various automotive

parts. As such, this document will focus on the risk management options for these areas where risk has been identified (refer to section 5).

2.2 Proposed recommendation under CEPA

When a substance is found to meet one or more of the criteria under section 64 of CEPA, the ministers can (1) take no further action with respect to the substance, (2) recommend the addition of the substance to the Priority Substances List for further assessment, or (3) recommend the addition of the substance to the List of Toxic Substances in Schedule 1 of CEPA. Based on the findings of the draft assessment conducted under section 74 of CEPA, the ministers propose to recommend that TMTD (CAS RN 137-26-8) be added to the List of Toxic Substances in Schedule 1 of the Act.

The ministers will consider comments and information provided by stakeholders during the 60-day public comment period on the draft screening assessment and Risk Management Scope. If the final assessment conclusion for TMTD remains the same and the ministers finalize the recommendation to add TMTD to Schedule 1, a risk management instrument 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 substance).

3. Proposed risk management

3.1 Proposed environmental objective

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

In this case, the proposed environmental objective would be to prevent or minimize the presence of TMTD in the aquatic environment to the greatest extent practicable. This objective may be quantitatively defined to achieve and maintain the lowest environmental levels possible. Predicted no-effect concentrations (PNECs) may be used as ultimate goals to work towards but interim levels may also be set, for the media of interest (e.g., water, soil or sediment compartments) or for the affected biota (e.g., aquatic organisms).

Measured environmental concentrations in surface water, soil, sediments and biota for the TMTD substances assessed have not been identified for any medium in Canada. Should more information become available, monitoring results will be considered, when available, to inform risk management decision-making and selection of risk management instrument regarding TMTD, as the case may be. Stakeholders are encouraged to contact ECCC on or before April 4, 2018 to submit information they may have (via the contact details identified in section 8 of this document).

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, instrument(s) and/or tool(s) for a given substance or substances towards meeting the proposed environmental objective.

In this case, the proposed risk management objective (RMO) aims to reduce the releases of TMTD to water to levels that are protective to the environment and that are technically and economically feasible, taking into consideration socio-economic factors. This objective may be quantitatively defined to ensure that practices in place are protective of the environment at existing and new facilities that may be manufacturing rubber products.

3.3 Proposed risk management options

To achieve the proposed risk management objective and to work towards achieving the proposed environmental objective, the proposed risk management options under consideration for TMTD are to consider implementation of regulatory and/or non-regulatory controls to minimize release of TMTD to the Canadian environment.

Note that the proposed risk management options are preliminary and subject to change. Following the publication of this 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 process³. The risk management options outlined in this document will evolve through consideration of assessments and risk management options published for other substances addressed under CMP to ensure effective, coordinated, and consistent risk management decision-making.

3.4 Risk management information gaps

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

- 1) Latex product manufacturing and uses of TMTD in latex rubber compounding/mixing and/or processing sites

³ 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), the Red Tape Reduction Action Plan (TBS 2012b), and in the case of a regulation the Red Tape Reduction Act (Canada, 2015a).

- 2) Potential release of adhesive and sealants that contain TMTD during automotive manufacturing
- 3) Details on alternatives to TMTD and/or technologies, and their feasibility as applicable to Canadian manufacturers, importers and users in:
 - o Various sectors such as: rubber manufacturing (e.g. latex manufacturing, rubber compounding) and automotive.
- 4) The measures and practices currently implemented by the industrial users, such as rubber product manufacturers, to prevent or minimize releases or environmental risks of TMTD (e.g. from the rubber sector during the raw material weighing, handling, compounding and processing) and the associated costs
- 5) Changes to use patterns and economic impacts since 2011
- 6) Existing provincial regulations or permits governing the use or handling of TMTD.

Should stakeholders have further information to help address these gaps, they should provide it ideally on or before April 4, 2018 to inform the risk management decision-making process, within the timelines (and to the contact) identified in section 8 of this document.

4. Background

4.1 General information on TMTD

TMTD is an organic chemical that shares the basic chemical structure of two alkyl groups attached to a nitrogen atom, which in turn is attached to a molecule of carbon disulfide. The two molecules can be linked through one, two, or four sulfur atoms to form the thiuram mono-, di- or tetra-sulfides, respectively. Thiuram sulfides degrade to their respective dithiocarbamates when exposed to heat or alkaline conditions and to carbon disulfide and amine in acid (ACC, 2003). Carbon disulfide is also a common metabolite of these compounds (Zemaitis and Greene, 1979).

4.2 Current uses and identified sectors

Globally, TMTD is used in multiple sectors where it may have varied use patterns. To gather information, TMTD was included in survey pursuant to section 71 of CEPA, such as Domestic Substances List Inventory Update (DSL IU) (Environmental Canada 2009).

TMTD is primarily used as a rapid accelerator for the rubber sector in the vulcanization process. This substance is applied as a component in automotive

sealants and adhesives. TMTD is also included in other various automotive parts (Environment Canada 2009). TMTD is also used in adhesive tape products available to consumers (Environment Canada 2009). TMTD has minor uses in adhesives and sealants, and the manufacture of other rubber products, such as tires and latex gloves (SCA 2015).

4.2.1 Uses of TMTD in Canada

In Canada, TMTD is primarily used as a process regulator (accelerator and curing agent) for the manufacture of rubber products (Environment Canada 2009). As an accelerator, TMTD is added into the rubber compound to increase the speed of vulcanization and allow the process to occur at lower temperature. TMTD was reported to be used by a variety of sectors in Canada, such as automotive manufacturing, adhesives and sealant and in pest control products (Environment Canada 2009). TMTD (known as Thiram) is used in contact protectant fungicides for both food and non-food uses (Health Canada 2016). TMTD is also used as an active ingredient in pesticides in Canada and as such is regulated under the Pest Control Products Act (PCPA). The draft screening assessment (Canada 2017) has focused on releases of this substance from its uses in manufacturing rubber products to the environment.

4.2.2 Manufacture and import quantities in Canada

Based on information obtained through the notice under section 71 of CEPA, a total of 17 companies reported under the survey, including two manufacturers and 17 importers (Environment Canada 2009). There was no report of manufacturing of TMTD above the 100 kg reporting threshold. However, total imports of TMTD into Canada in 2008 ranged from 170 300 kg to 403 100 kg. TMTD was imported either as a pure substance, in rubber compound products, in adhesives, and sealants or as part of final products (as parts ready for installation in vehicles or in vehicles) (Environment Canada 2009).

5. Exposure sources and identified risks

5.1 Environmental presence

TMTD is an organic chemical that is not naturally occurring in the environment. TMTD is not expected to persist in air and water as the substance does not volatilize and could undergo rapid photodegradation and hydrolysis in water. It has low potential to bioaccumulate in aquatic organisms as TMTD transforms rapidly in water and soil and will likely not be accumulated by organisms.

However, empirical effects data suggest that TMTD is highly toxic to aquatic organisms. This means there would be effects at low levels of exposure.

TMTD does not meet the criteria of persistence or bioaccumulation and its potential for long-range transport is low. Current uses of TMTD suggest that there may only be short-term exposure to organisms in local areas. Exposure over a long period of time or in the far field is not expected (Canada 2017). For further information on the proposed screening assessment conclusion for Thiocarbamates, refer to the draft SAR, available on the [Canada.ca \(Chemical substances\)](https://www.canada.ca/chemical-substances).

No monitoring data have been identified for TMTD in any medium, including wastewaters in Canada. TMTD is not a reportable substance under the National Pollutant Release Inventory (NPRI). There are very limited monitoring data reported by other countries on this substance (Canada 2017).

Based on the information presented in the draft screening assessment, the ecological risk characterization for TMTD indicates that releases from current uses of this substance in the manufacturing rubber products may pose a risk to aquatic organisms. This substance is not expected to be of concern to organisms in sediment and soil.

5.2 Rubber manufacturing sector

In the draft screening assessment, the rubber manufacturing sector was identified as a sector with potential releases of TMTD into the aquatic environment. Based on information obtained from follow-ups conducted in 2016 (ECCC 2016) and submissions from previous DSL IUs (Environment Canada 2009) and site visits at rubber compounding/processing facilities, the primary releases are expected to mainly occur during weighing/handling of raw material and during rubber compounding and further processing. Primary releases are expected mainly via the wastewater generated, as this wastewater may go through industrial or publicly owned wastewater treatment plants and ultimately enters surface water. The release to air from product handling (i.e. powder) are also possible but expected to be minor (Canada 2017).

Main releases of TMTD to wastewater occur during industrial operations, such as cleaning, milling, cooling and vulcanizing rubber. For cleaning, releases can come from production lines like tanks/mixers, equipment, filters, floors, storage and transportation containers. A generic approach was selected to simulate releases of this substance from floor cleaning in raw material weighing, handling and compounding area. However, releases from other cleaning activities, mixing, cooling or vulcanizing are not quantified, due to a lack of information. (Canada 2017).

5.3 Other minor sectors

TMTD is also used as a component in automotive sealants and adhesives and in other various automotive parts. During the automotive manufacturing process, there is potential for the uncured sealants and adhesives to have contact with water that can result in minor releases of TMTD to wastewater at their assembly or component sites. However, the substance is expected to transform during these applications and, therefore, releases should be negligible (Canada 2017).

TMTD was also reported by few companies via the DSL IU1 (Environment Canada 2009) to be used in the manufacture of adhesive and sealants products that are available to consumers. During the manufacture of adhesives and sealant products, there may be some releases of this substance via raw material handling and cleaning of formulation vessels. However, TMTD exposure from adhesive tape products is expected to be minimal based on low concentrations of TMTD in adhesives (Canada 2017).

6. Risk management considerations

6.1 Alternative chemicals or substitutes

As there are many groups of accelerators in the market, potential chemicals or substitutes may be found. It should be noted that there are other thiuram rubber accelerators belonging to the chemical class of thiocarbamates. Some of these other thiuram rubber accelerators have similar physical-chemical properties as TMTD and, hence, could be present in similar environmental compartments. These alternatives would not necessarily reduce the risk to the environment. However, the substitution depends on many factors related to the type of rubber used, the final use and health/environmental and socio-economic considerations (Canada 2017).

6.2 Alternative technologies and/or techniques

At this time, there are no alternative technologies and/or alternative techniques that have been identified to minimize the release of TMTD from product handling or cleaning. However, technologies and good engineering practices to reduce or eliminate industrial releases are available. Examples of best practices include material weighing, handling of TMTD, reducing use of contact cooling water, use of closed loop system for direct cooling water and use of dry cleaning and blocking floor drains. Good ventilation systems are equipped with control devices that may also reduce emissions from weighing and handling, which reduce deposition to the floor and then to wastewater (Canada 2017).

6.3 Socio-economic and technical considerations

Socio-economic factors, such as incremental costs associated with adopting mitigation measures to reduce or eliminate industrial releases of the substances, as well as incremental economic benefits associated with environmental improvement, will be considered in the selection process for the regulatory and non-regulatory controls to minimize release of TMTD to the Canadian environment and in refining the risk management objective. Socio-economic factors will also be considered in the development of the instrument(s) as identified in the Cabinet Directive on Regulatory Management (TBS 2012a).

In 2015, there were 381 establishments in the Rubber Products Manufacturing sector (NAICS 3262) (Industry Canada 2015a), which employed 16,385 people (Statistics Canada 2016). The breakdown of establishments by size is as follows: 19% micro-sized (1-4 employees), 67% small (5-99 employees), 11% medium (100-499 employees), and 3% large establishments (Industry Canada 2015b). Provincially, 42% of the establishments were in Ontario, 27% in Quebec, 15% in the Prairies, 12% in British Columbia, and 4% in the Atlantic and Maritime provinces (Industry Canada 2015b).

In 2014, the total revenues in the sector were \$4.9 billion, of which \$ 1.8 billion was value added to the Canadian economy (Industry Canada 2015c). In 2015, total exports from the sector were \$3.8 billion and total imports were \$6.5 billion, resulting in a negative trade-balance of \$2.7 billion (Industry Canada 2015d). The United States was the main trading partner in this sector, with 93% of exports going there and 49% of imports coming from there (Industry Canada 2015d). Canada also imported manufactured rubber products from China (13%) and Japan (8%) (Industry Canada 2015d).

7. Overview of existing risk management

7.1 Related Canadian risk management context

In Canada, there are no specific risk management controls/measures to manage industrial releases for TMTD. However, Canada has some risk management measures aligned with United States and Europe for restrictions on cosmetic products and pest control products. Below are examples of risk management instruments for several products:

- **Drugs and health products** – TMTD is not in any prescription drug, nor is it listed in the Licensed Natural Health Products Database (Health Canada 2015), despite it being listed in the Natural Health Products Ingredients Database (NHPID) with a non-medicinal role (email from Health Product Food Branch, Health Canada to Existing Substances Risk Assessment Bureau, Health Canada, August 2016; unreferenced).

- **Pesticides** – TMTD is registered (under the name Thiram) as an active ingredient in pest control products and managed under PCPA. Health Canada's Pest Management Regulatory Agency (PMRA) published the proposed re-evaluation decision of –TMTD as pesticidal use (e.g. fungicide) on February 29, 2016 (PMRA 2016). Based on an evaluation of available scientific information, the proposed re-evaluation report indicated that current conditions of TMTD as pesticide use pose potential risks of concern to human health and the environment; specifically risks of concern were identified for both workers and the general public in additions to birds, mammals and aquatic organisms. The proposed re-evaluation decision is to cancel all end-use pest control products containing TMTD registered in Canada.
- **Cosmetics** – TMTD (Thiuram, CAS RN 137-26-8) is on Health Canada's Cosmetic Ingredients Hotlist (Canada 2015b) and is described as being prohibited for use in cosmetics in Canada. Thiuram disulfides is described as being prohibited, on Health Canada's Cosmetic Ingredient Hotlist
- **Food and non-food sources**– TMTD is being used a protectant fungicide in Canada for both food and non-food sources. In Canada TMTD is also used in food packaging, in food processing and manufacturing components.

7.2 Pertinent international risk management context

7.2.1 United States

The United States has no environmental regulations or restrictions/prohibitions for TMTD. In the United States, TMTD is not restricted or prohibited as an ingredient in cosmetic products and not risk managed for cosmetics. However, the United States is aligned with Canada in the risk management on the use of TMTD in pesticide applications and pest-control products. The United States Environmental Protection Agency (US EPA) has implemented several mitigation measures (restrictions, prohibitions, mandatory labelling, etc.) to risk-manage TMTD in the environment and to protect/minimize exposure and health risk to field workers and the general population. In the United States, the US Code of Federal Regulations Title 21 (21 CFR) allows TMTD to be safely used as components of adhesives and coating components intended for use in packaging, transporting, or holding food (21 CFR 175.105, 175.300). TMTD is also listed as safe for use as a vulcanization accelerator in rubbers for use in packaging, transporting or holding food (21 CFR 177.2600) (US FDA, 2013).

TMTD has also been registered for use as a fungicide in the field, for crops and as seed protectant to protect harvested crops during transportation/storage since 1948 (US EPA 2004a). Specifically, TMTD is registered by the US EPA as a class II (slightly toxic) general use pesticide and animal repellent to protect vegetables/fruits from rabbits, deer and rodents. TMTD has gone through several re-registration tests by US EPA, occurring in 1991, 1995 and the last one

2004 (US EPA 2004a). In 2004, the US EPA completed its review on human health and environmental risk assessment for TMTD and implemented several mitigation actions on end-of-use products (pest-control products) based on identified human health and ecological risks to the aquatic environment. Although the major agriculture use of TMTD is seed treatment in the United States, it is the foliar (peaches, apples) and turf uses that present the most significant risks to mammals, birds and aquatic organisms (freshwater, marine fish, invertebrates) on acute basis as the application rates to the environment is higher than that for treated seed. To reduce the risk to mammals, birds and aquatic species, the US EPA has developed several mitigation actions necessary to address these risks, such as more requirements for labelling on end-use products, restrictions on TMTD application to turfs, parks and athletic fields and cancellation or restrictions on daily usage rates to apples, strawberries, peaches (US EPA 2004b)

7.2.2 European Union (EU)

The EU has similar risk measures as Canada on the restrictions, prohibitions of TMTD in various applications, products and uses for pesticidal use. The EU has taken several risk measures to prohibit/restrict TMTD in various uses and applications in the final end-use products (cosmetics, pesticides, food uses, and non-food uses). Similar to Canada's regulation and permit of TMTD in pesticidal uses, the European Commission Regulations (EC) No 1107/2009 allows the use of TMTD as an approved active substance in plant protection products until April 30, 2017 (ECHA 2015). Belgium and France are evaluating for renewal of approval under AIR-3 programme (EU Regulations No. 686/2012). In Sweden, TMTD has a harmonized classification Annex VI to Classification, Labelling and Packaging (CLP) Regulation (March 18, 2015). (ECHA 2015) The CLP Regulation ensures that the hazards presented by chemicals are clearly communicated to workers and consumers in the European Union through classification and labelling of chemicals. The CLP Regulation came into force in January 2009 and replaces two previous pieces of legislation, the Dangerous Substances Directive and Dangerous Preparations Directive and there is transition period until 2015.

In Europe, Thiram (TMTD) has similar prohibitions in cosmetic products as Canada. In 2009, The EU has listed TMTD in the "List of Substances prohibited in cosmetic products" under Annex II/162 of the Cosmetics Regulations (EC) No. 1223/2009 (CosIng 2013). Norway, Iceland and Liechtenstein have taken similar mitigation measures as the EU to prohibit TMTD in cosmetic ingredients as part of their Cosmetic Regulations (Health Canada 2014).

Customs Union (EEC) representing Russia, Kazakhstan and Belarus have prohibited TMTD under entry 162 of Appendix 1 of the Technical Regulations TR TC 009/2011 "On the safety of perfumery and cosmetics products."

7.2.3 Other jurisdictions

Internationally, TMTD is widely restricted or prohibited in variety of products available to consumers. The Association of Southeast Asian Nations (ASEAN) have prohibited TMTD (CAS RN 137-26-8) under entry 162 of Annex II Part 1 “List of substance which must not form part of the composition of cosmetic products” of the ASEAN Cabinet Directive (Health Canada 2014)..

Japan has established specific restrictions (application rates) of TMTD to cosmetic products. TMTD has a maximum concentration of 0.50 g per 100 g of cosmetic “to be washed away immediately after use such as soap or shampoo” and 0.30 g per 100 g of cosmetic “other than those washed away immediately after use”, as specified in the Standard for Cosmetics (Japan Ministry of Health and Welfare, 2000).

In New Zealand, TMTD (CAS RN 137-26-8) is prohibited under entry 162 of Schedule 4 “Components Cosmetic Products Must Not Contain” of the Cosmetic Products Group Standard (New Zealand EPA). In Australia, TMTD is listed in Schedule 6 (“Poison”) of the Poisons Standard 2015 except when in paint containing 0.5 percent or less of TMTD (Australian Government, 2015).

In South America, MERCOSUR representing Argentina, Brazil, Paraguay, Uruguay and Venezuela have prohibited disulfiram and TMTD by listing them on the “List of Substances that cannot be used in products of personal hygiene, cosmetics and perfume” (GMC/Res. No. 29/05), entry 162. In addition, Thiuram monosulfides and Thiuram disulfides are also prohibited under entries 353 and 354, respectively (MERCOSUR, 2005).

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, including information that would help to inform decision-making (such as outlined in section 3.3). Please submit additional information and comments prior to April 4, 2018. 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
Chemicals Management Division

Gatineau Quebec K1A 0H3
Tel: 1-888-228-0530 | 819-956-9313
Fax: 819-953-7155
Email: ecccc.substances.ecccc@canada.ca

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

Following the public comment period on the Risk Management Approach document, the Government of Canada will initiate the development of the specific risk management instrument(s), where necessary. Comments received on the Risk Management Approach document will be taken into consideration in the selection or development of these instrument(s). Consultation will also take place as instrument(s) are developed.

8.2 Timing of actions

Electronic consultation on the Risk Management Scope: February 3, 2018 to april 4, 2018.

Submission of additional studies or information on TMTD: on or before April 4, 2018.

Publication of responses to public comments on the draft screening assessment and Risk Management Scope: on or before February 2019.

Publication of the final screening assessment and, if required, the Risk Management Approach document: on or before February 2019.

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(s), if required: 60-day public comment period starting upon publication of each proposed instrument(s)

Publication of the final instrument(s), if required: at the latest, 18-month from the publication of each proposed instrument(s)

9. References

[ACC] 2003. Rubber and Plastic Additives Panel of the American Chemistry Council. Thiuram Category Justification and Testing Rationale, CAS Registry Numbers 97-77-8, 97-74-5 and 137-26-8. US EPA document 201-14587A

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