



Government  
of Canada

Gouvernement  
du Canada

**Risk Management Approach**  
**for**  
**Thioperoxydicarbonic diamide ( $[(\text{H}_2\text{N})\text{C}(\text{S})]_2\text{S}_2$ ),**  
**tetramethyl-**  
**(TMTD)**  
**in the Thiocarbamates Group**  
**Chemical Abstracts Service Registry Number**  
**(CAS RN):**  
**137-26-8**

Environment and Climate Change Canada

Health Canada

January 2021

**Canada**



# Summary of Proposed Risk Management

This document outlines the proposed risk management actions for Thioperoxydicarbonic diamide ( $[(\text{H}_2\text{N})\text{C}(\text{S})]_2\text{S}_2$ ), tetramethyl- (TMTD) of the Thiocarbamates Group, which has been found to be harmful to the environment.

In particular, the Government of Canada is considering:

- implementing a Code of Practice under section 54 of the *Canadian Environmental Protection Act, 1999* (CEPA); and
- applying the significant new activity (SNAc) provisions under section 81 the *Canadian Environmental Protection Act, 1999* (CEPA) to be notified of new manufacturing activities related to TMTD.

The main industrial sector with exposure sources of concern is the rubber products manufacturing sector; therefore, the proposed Code of Practice would be applicable to this sector.

To inform risk management decision-making, information on the following topics should be provided (ideally on or before March 10, 2021), to the contact details identified in section 8 of this document:

- Measures and practices currently implemented by the industrial users, such as rubber products manufacturers, to prevent or minimize releases or environmental risks of TMTD (e.g. from the rubber sector during the raw material weighing, handling, and compounding) and the associated costs;
- Details on alternatives to TMTD and/or technologies, and their feasibility as applicable to Canadian manufacturers, importers and users in the rubber products manufacturing sector;
- Changes to use patterns since 2011, other than rubber manufacturing;
- Existing provincial regulations or permits governing the use or handling of TMTD;
- Information on latex product manufacturing and uses of TMTD in latex rubber compounding/mixing and/or processing sites within Canada.

The risk management actions outlined in this Risk Management Approach document may evolve through consideration of assessments and risk management options published for other Chemicals Management Plan

substances as required to ensure effective, coordinated, and consistent risk management decision-making.

**Note:** The above summary is an abridged list of actions proposed to manage this substance 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 action(s) 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<sup>1,2</sup>, and if so to manage the associated risks.

The substance thioperoxydicarbonic diamide ( $[(\text{H}_2\text{N})\text{C}(\text{S})]_2\text{S}_2$ ), tetramethyl-, Chemical Abstracts Service Registry Number (CAS RN<sup>3</sup>) 137-26-8, referred to throughout this document as TMTD, is included in the third phase of the Chemicals Management Plan (Canada 2016) as part of the Thiocarbamates Group.

## 2. Issue

Health Canada and Environment and Climate Change Canada conducted a joint scientific assessment of TMTD in the Thiocarbamates Group. A notice summarizing the scientific considerations of the Screening Assessment for these substances was published in the *Canada Gazette*, Part I, on January 9, 2021 (Canada 2021). Refer to the final [Screening Assessment for the Thiocarbamates Group](#) for further information.

### 2.1 Screening Assessment Report Conclusion

On the basis of the information presented in the screening assessment, it is concluded that TMTD is toxic 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

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<sup>1</sup> 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.*

<sup>2</sup> 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.

<sup>3</sup> CAS RN: Chemical Abstracts Service Registry Number. The Chemical Abstracts Service information is the property of the American Chemical Society and any use or redistribution, except as required in supporting regulatory requirements and/or for reports to the Government of Canada when the information and the reports are required by law or administrative policy, is not permitted without the prior, written permission of the American Chemical Society.

or its biological diversity. However, it is concluded that this substance does not meet the criteria under paragraphs 64(b) or 64(c) of CEPA as it is 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 it is not 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 (ECCC, HC 2021).

The screening assessment also concludes that TMTD does not meet the criteria for persistence or bioaccumulation, as defined in the *Persistence and Bioaccumulation Regulations* made under CEPA (Canada 2000).

The exposure sources of concern identified in the Screening Assessment are based on the release of TMTD to wastewater during its use in manufacturing rubber products. During rubber compounding, TMTD may be released to wastewater that is generated from industrial operations, such as cleaning, milling, and cooling, ultimately reaching surface waters. This document will focus on this exposure source.

## **2.2 Recommendation under CEPA**

On the basis of the findings of the screening assessment conducted under CEPA, the Ministers recommend that thioperoxydicarbonic diamide ( $[(\text{H}_2\text{N})\text{C}(\text{S})]_2\text{S}_2$ ), tetramethyl- (CAS RN 137-26-8) be added to the List of Toxic Substances in Schedule 1 of the Act<sup>4</sup>.

The Ministers have taken into consideration comments made by stakeholders during the 60-day public comment period on the draft screening assessment for TMTD and its associated Risk Management Scope document.

As the Ministers finalize the recommendation to add thioperoxydicarbonic diamide ( $[(\text{H}_2\text{N})\text{C}(\text{S})]_2\text{S}_2$ ), tetramethyl- (CAS RN 137-26-8) to Schedule 1, risk management instruments must be proposed within 24 months from the date of the recommendation, and finalized within 18 months from the date on which risk management instruments are proposed, as outlined in sections 91 and 92 of CEPA (refer to section 8 for publication timelines applicable to this substance).

## **2.3 Public Comment Period on the Risk Management Scope**

The draft screening assessment for TMTD and its associated Risk Management Scope document summarizing the proposed risk management options under consideration at that time, were published on February 3, 2018 (ECCC, HC 2018).

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<sup>4</sup> 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.

Industry and other interested stakeholders were invited to submit comments on both documents during a 60-day comment period.

Comments received on the Risk Management Scope document were taken into consideration in the development of this document. A summary of responses to public comments received is available from [here](#).

## **3. Proposed Risk Management**

### **3.1 Proposed Environmental Objective**

Proposed environmental objectives are quantitative or qualitative goals to address environmental concerns.

For TMTD, the proposed objective addresses the exposure sources of concern outlined in section 5 of this document. The proposed environmental objective for TMTD is to reduce the concentration of TMTD in the aquatic environment to levels below the predicted no-effect concentration (PNEC) of 190 ng/L.

### **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 (RMO) is 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.

### **3.3 Proposed Risk Management Actions**

To achieve the proposed risk management objective and to work towards achieving the proposed environmental objective, the proposed risk management action being considered for TMTD is the development of a Code of Practice under section 54 of CEPA in order to reduce releases of TMTD from its use in the rubber products manufacturing sector.

Key considerations for the design of the Code of Practice may include recommended operating procedures and best practices. Additionally, regulatory and non-regulatory instruments (e.g., Environmental Performance Agreements (EPAs), pollution prevention planning notices, etc.), which could include use thresholds (e.g., daily, monthly or annual use volumes) and release limits, are being investigated as part of a sector-wide approach.

Also, in order to be notified of any new manufacturing activities in Canada associated with the substance TMTD, the application of SNAc provisions<sup>5</sup> under CEPA is being considered.

Note that the proposed risk management actions 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 also be considered in the instrument selection and development process<sup>6</sup>. The risk management actions may also 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 Performance Measurement and Evaluation

Performance measurement evaluates the ongoing effectiveness and relevance of the actions taken to manage risks from toxic substances<sup>7</sup>. 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 TMTD.

The Government of Canada plans to measure the effectiveness of the risk management actions by collecting and analyzing data such as data on compliance rate and concentrations of TMTD in industrial waste water effluent to measure progress towards meeting the risk management objective.

In addition, the Government of Canada plans to collect and analyze data, including monitoring data obtained from the Monitoring and Surveillance Program

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<sup>5</sup> A significant new activity is an activity that could result in a significantly greater quantity or concentration of the substance in the environment, or that could lead to a significantly different manner or circumstances of exposure to the substance. The SNAc provisions trigger an obligation for a proponent to notify and the government to assess, information about a substance when a proponent proposes to use the substance in a significant new activity. The assessment is completed by the Ministers, based on information provided by the notifier and other information available to them. If, based on the outcome of the assessment, the proposed new activity could pose a risk to the environment or human health, then the Ministers may consider further risk management action(s), if warranted.

<sup>6</sup> The proposed risk management regulations, instruments or tools are 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 Regulation (TBS 2018), the Red Tape Reduction Action Plan (TBS 2012), and in the case of a regulation the *Red Tape Reduction Act* (Canada 2015).

<sup>7</sup> Performance measurement can be performed at two levels:

- Instrument-based performance measurement evaluates the effectiveness of an individual instrument in meeting the specific risk management objectives that were set out when the risk management tool was designed. The results of performance measurement will help determine if additional risk management or assessment is needed (*i.e.*, evaluate whether risk management objectives have been met); and
- Substance-based performance measurement considers performance of all final risk management instruments applied to a chemical substance and relevant data or indicators of exposure to the environment or human health (*i.e.*, evaluate whether human health and/or environmental objectives have been met).

on the presence of TMTD in municipal wastewater influent and effluent from waste water treatment plants receiving effluent from rubber products manufacturing facilities that use TMTD. Collected data will be used to establish a baseline environmental presence and to measure progress towards meeting the environmental objective following implementation of risk management actions.

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

### **3.5 Risk Management Information Gaps**

Interested stakeholders can provide further information to inform risk management decision-making regarding TMTD, including:

- 1) Measures and practices currently implemented by the industrial users, such as rubber products 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;
- 2) Details on alternatives to TMTD and/or technologies, and their feasibility as applicable to Canadian manufacturers, importers and users in the rubber products manufacturing sector;
- 3) Changes to use patterns since 2011, other than rubber manufacturing;
- 4) Existing provincial regulations or permits governing the use or handling of TMTD;
- 5) Information on latex product manufacturing and uses of TMTD in latex rubber compounding/mixing and/or processing sites within Canada.

Stakeholders that have information to help address these gaps, should provide it on or before March 10, 2021 to the address identified in section 8.

## **4. Background**

### **4.1 General Information on TMTD**

TMTD (CAS RN 137-26-8) is an organic thiocarbamate substance and possesses moderate water solubility. It does not occur naturally in the environment. If released to the environment, this substance will degrade via

hydrolysis reaction in aqueous environments and photosynthetic reactions when exposed to light (ECCC, HC 2021).

## **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 a survey issued in 2009 pursuant to section 71 of CEPA (Domestic Substances List Inventory Update (DSL IU) (Environment Canada 2009); follow-ups with stakeholders were also conducted in 2016 and 2018 to confirm the current uses (ECCC 2016; ECCC 2018).

### **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 solid 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 temperatures. Currently there is no indication that TMTD is used as a process regulator for the manufacture of latex rubber products in Canada (ECCC 2018); however, it is used for this purpose in other jurisdictions such as the United States and the European Union.

TMTD is also used as a component in automotive parts and in sealants and adhesives, and is also used in adhesive tape products available to consumers. The substance also may be used in the manufacture of a limited number of food packaging materials. It is registered as an active ingredient in pest control products in Canada (where it is known as thiram).

The screening assessment (ECCC, HC 2021) has determined that releases of this substance to the environment from its uses in manufacturing of rubber products is a source of concern; however, other identified TMTD uses are not of concern under current conditions. Therefore this document is focused on releases of this substance to the environment from its uses in rubber products manufacturing.

### **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 spanning multiple sectors reported under the survey, including two companies that manufactured and imported TMTD and 15 importers of TMTD (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 were in the range of 170 300 kg to 403 100 kg 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

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

Empirical effects data suggest that TMTD is highly toxic to aquatic organisms. It has the potential to cause acute adverse effects at very low exposure levels, even if there is only short-term exposure for organisms in areas near points of release.

The exposure of concern for TMTD is associated with its release to surface water. The aquatic exposure was estimated based on estimated quantities released from industrial facilities to receiving waters via wastewater treatment systems as described in the screening assessment for the Thiocarbamates Group (ECCC, HC 2021).

### 5.1 Environmental Presence

TMTD does not meet the criteria of persistence or bioaccumulation as defined under the *Persistence and Bioaccumulation Regulations* made under CEPA (Canada 2000). It is not subject to long-range transport. Current uses of TMTD suggest that there may only be short-term exposure to organisms in local areas near points of discharge to the environment. Exposure over a long period of time or at more remote locations is not expected (ECCC, HC 2020). For further information on the screening assessment conclusion for substances in the Thiocarbamates Group, refer to the [Screening Assessment for the Thiocarbamates Group](#).

In 2017-2018, limited surveillance was conducted in surface water at eight sites upstream and downstream of wastewater treatment plant discharge points, with some sites receiving wastewater from rubber products manufacturers. No samples contained TMTD above the method detection limit. 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 (ECCC, HC 2021).

Based on the information presented in the screening assessment (ECCC, HC 2020), the ecological risk characterization for TMTD indicates that releases from current uses of this substance in the manufacture of rubber products may pose a risk to aquatic organisms. Wastewater generated from rubber compounding facilities is considered to be the main source of potential releases of TMTD to the

environment. This substance is not expected to be of concern to organisms in sediment and soil.

TMTD is also used as a component in automotive sealants and adhesives and in various other automotive parts. The substance is expected to be transformed during these applications and therefore, releases of the unreacted substance are not expected. 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 (ECCC, HC 2021). These minor releases are not expected to be of concern.

TMTD was also reported by a few companies via the Domestic Substances List Inventory Update (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 and sealants is expected to be minimal based on low concentrations of TMTD in adhesives (ECCC, HC 2021). These releases of TMTD are not expected to be of concern.

## **5.2 Rubber Products Manufacturing Sector**

In the screening assessment, the rubber products manufacturing sector was identified as the main 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 Domestic Substances List Inventory Updates (Environment Canada 2009) and site visits at rubber compounding/processing facilities, the primary losses of TMTD to wastewater are expected to mainly occur during weighing/handling of raw material and during rubber compounding. Primary releases are expected mainly via the wastewater generated; this wastewater will go through industrial or publicly owned wastewater treatment plants before being discharged into surface waters. Releases to air from product handling (i.e. powder or pellets) are also possible but are expected to be minor (ECCC, HC 2021).

The main releases of TMTD to wastewater occur during industrial operations such as cleaning, milling, and cooling. Equipment and floor cleaning operations in raw material weighing/handling and compounding areas are the most significant source of substance aquatic release to the environment. A representative scenario was developed to simulate releases of this substance from floor cleaning in raw material weighing, handling and compounding areas. Based on the total import quantities of TMTD and an estimation of possible daily use quantities of this substance, the number of use days per year was calculated, considering both batch and continuous production processes. However, facilities examined to make this estimation are not necessarily dedicated to using only TMTD as their process regulator. Therefore, use of

TMTD was assumed to be non continuous and the releases of this substance to the environment were estimated accordingly. Quantification of the environmental exposure is discussed in detail in the final screening assessment (ECCC, HC 2021).

## **6. Risk Management Considerations**

### **6.1 Alternatives and Alternate Technologies**

Some of the potential alternatives presented in this section have not been evaluated to determine whether they are safe for human health and the environment.

There are other rubber accelerators belonging to the chemical class of thiocarbamates that may be available on the market. Some of these other rubber accelerators have similar physical-chemical properties to TMTD and, hence, could be present in similar environmental compartments. Available empirical data suggests that these substances may also be toxic to organisms. (ECHA c2007-2017).

There are also other groups of rubber accelerators. For example, benzothiazoles, such as 2-mercaptobenzothiazole (MBT), may be used as alternatives to TMTD in certain applications. This group of chemicals is currently under assessment under the CMP; depending on the outcome of the screening assessment, benzothiazoles may not be considered suitable alternatives.

The potential for substitution will depend on many factors related to the type of rubber used, the final use or end-product as well as health, environmental, and socio-economic considerations.

Technologies and good engineering practices to reduce or eliminate industrial releases in the rubber manufacturing sector are available. In addition, a number of best practices could be used to reduce or eliminate releases, including effective weighing and handling of TMTD, reducing the use of contact cooling water, using closed loop systems for direct cooling water, dry cleaning, and blocking floor drains. Efficient ventilation systems that are equipped with control devices may also capture TMTD particles during weighing and handling, which will reduce deposition to the floor and in turn limit releases to wastewater from floor cleaning (ECCC, HC 2020).

### **6.2 Socio-economic and Technical Considerations**

Socio-economic factors have been considered in the selection process for a regulation respecting preventative or control actions, and in the development of the risk management objective as per the guidance provided in the Treasury

Board document [Assessing, Selecting, and Implementing Instruments for Government Action](#) (TBS 2007). In addition, socio-economic factors will be considered in the development of the regulations, instrument(s) or tool(s), to address risk management objective(s), as identified in the [Cabinet Directive on Regulation](#) (TBS 2018), [Red Tape Reduction Action Plan](#) (TBS 2012) and the [Red Tape Reduction Act](#) (Canada 2015).

In 2015, there were 381 establishments in the Rubber Products Manufacturing sector in Canada (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). Companies that reported using TMTD in section 71 surveys are medium to large establishments. 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 the 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 listed in the Natural Health Products Ingredients Database (NHPID) (Health Canada 2019a) with a non-natural health product role as it is not a naturally occurring substance falling under Schedule 1 of the *Natural Health Products Regulations* (Canada 2003). As such, it is not listed in the Licensed Natural Health Products Database (LNHPD) (LNHPD [modified 2018]) as being present in currently licensed natural health products in Canada. Previously, TMTD was listed as an ingredient in a product in Health Canada's Drug Product Database, however this product (True Test, DIN 02271885) was discontinued in 2013. Currently, there is no pharmaceutical product or veterinary drug with marketed,

approved or dormant status in Canada containing TMTD either as a medicinal or non-medicinal ingredient in the final formulation (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 (fungicide) and managed under the Pest Control Products Act. Based on an evaluation of available scientific information conducted by Health Canada’s Pest Management Regulatory Agency (PMRA), Thiram products pose potential risks of concern to human health and the environment under current conditions of use. Risks of concern were identified for both workers and the general public in addition to birds, mammals and aquatic organisms. On the basis of a final re-evaluation, pest control products registered for animal repellent uses and seed treatment uses (except for seed treatment of grasses, dry bulb onion, and alfalfa grown for forage) are acceptable for continued registration with the implementation of new mitigation measures and label amendments. The following registered uses will be cancelled: all foliar and dip applications; seed treatment of grasses, dry bulb onion, and alfalfa grown for forage in Canada and importation of these treated seeds into Canada; on-farm hopperbox/seed drill seed treatment; and commercial seed treatment (wheat, barley, oats, canola, mustard, rapeseed, rye, triticale, corn). All maximum residual limits for Thiram, including those established for imports, will be revoked (Health Canada 2018).
- **Cosmetics** – TMTD (Thiram, CAS RN 137-26-8) is described as being a restricted ingredient on Health Canada’s Cosmetic Ingredient Hotlist, to be used only in latex products to a maximum concentration of 14% (Health Canada 2015).
- **Food sources** –In Canada, TMTD may be used as a component in the manufacture of certain food packaging materials. The safe use of TMTD in food packaging materials is subject to section 4(1)(a) of the *Food and Drugs Act* (Canada 1985) and Division 23 of the *Food and Drug Regulations* (Canada 1978).

## 7.2 Pertinent International Risk Management Context

### 7.2.1 The United States

The United States has no environmental regulations or restrictions/prohibitions for TMTD with respect to non-pesticide uses of the substance. The United States Environmental Protection Agency (US EPA) has implemented several mitigation measures (restrictions, prohibitions, mandatory labelling, etc.) to risk-manage TMTD-containing pesticides 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 a component of adhesives intended for use in packaging, transporting,

or holding food (21 CFR 175.105). 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. 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. 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, strawberries) 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 restrictions on daily usage rates to apples, strawberries, and peaches, as stated in 40 CFR 180.132 (US EPA 2004).

### **7.2.2 The European Union (EU)**

The EU has taken several risk measures to prohibit/restrict TMTD in various uses and applications in the final end-use products (cosmetics, pesticides and non-food uses). European Commission Implementing Regulation 2018/1500 prohibits the use of TMTD in all pesticide products, including for seed treatments (EC 2018). 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.

TMTD is also regulated in cosmetic products. In 2009, The EU 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 2015b).

### **7.2.3 Risk Management Alignment**

There is partial risk management alignment between actions undertaken in Canada, and those undertaken in the United States and the European Union. As discussed earlier, there are actions in all three jurisdictions that partially or fully restrict the use of TMTD as a pesticide. Additionally, both Canada and the European Union have restrictions or measures in place to reduce TMTD use in cosmetics. However there is no evidence that any jurisdiction has taken specific action on the release of TMTD to the environment from solid rubber product manufacturing activities. If the Government of Canada moves forward with the development of a Code of Practice under section 54 of CEPA, it would be the first to take federal level action to protect aquatic organisms from TMTD exposure from this industry.

## **8. Next Steps**

### **8.1 Public Comment Period**

Industry and other interested stakeholders are invited to submit comments on the content of this Risk Management Approach or other information that would help to inform decision-making (such as outlined in section 3.5). Please submit additional information and comments prior to March 10, 2021.

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

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

Companies who have a business interest in TMTD are encouraged to identify themselves as stakeholders. The 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 instruments, where necessary. Comments received on the Risk Management Approach document will be taken into consideration in the selection or development of these instruments. Consultation will also take place as instruments are developed.

### **8.2 Timing of Actions**

Electronic consultation on the Risk Management Approach: January 9, 2021 to March 10, 2021

Publication of responses to public comments on the Risk Management Approach document: Concurrent to the publication of the proposed instrument(s).

Publication of the proposed instrument(s): At the latest, 24-months from the date on which the Ministers recommended that thioperoxydicarbonic diamide ( $[(\text{H}_2\text{N})\text{C}(\text{S})]_2\text{S}_2$ ), tetramethyl- be added to Schedule 1 of CEPA

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

Publication of the final instrument(s): At the latest, 18-months from the publication of each proposed instrument.

These are planned timelines, and are subject to change. Please consult the [schedule of risk management activities and consultations](#) for updated information on timelines.

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