Approach for a Subset of Organic and Inorganic Substances Prioritized Under the Chemicals Management Plan

Environment and Climate Change Canada

Health Canada

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1. Introduction

As a part of the Chemicals Management Plan (CMP), the Government of Canada assesses and manages, where appropriate, the potential health and ecological risks associated with substances prioritized for action under the *Canadian Environmental Protection Act, 1999* (CEPA) (Canada 1999). The substances in this document were identified as priorities for assessment as they met categorization criteria under subsection 73(1) of CEPA or were considered a priority on the basis of other human health concerns (ECCC, HC [modified 2017a]).

Some of the substances on the *Domestic Substances List* (DSL) that were identified as priorities for assessment through previous prioritization processes were found to already fall within the scope of existing Government of Canada regulatory or non-regulatory initiatives. For example, in the Approach for a Subset of Substances Prioritized during Categorization That Have Already Been Addressed document (ECCC 2015), a number of substances were identified as not requiring further assessment at this time. The current document addresses nine substances that are considered not to require further assessment activities at this time for reasons that include:

- Regulatory or non-regulatory measures are already in place or proposed under CEPA or other acts which address exposures;
- The substance is being addressed in Canada in accordance to an international convention to which Canada is a signatory;
- Non-CEPA Canadian assessment activities found the substance to be of low potential concern to the environment and human health; and/or
- Indoor Air Quality Guidelines or Guidelines for Canadian Drinking Water Quality have been developed taking potential risks into consideration.

The Chemical Abstracts Service Registry Numbers (CAS RN[1]), DSL names and common names for the nine substances described herein are presented in Table 1-1.

Table 1-1. Substance identities

CAS RN	DSL name	Common name
630-08-0	Carbon monoxide	CO
79-43-6[a]	Acetic acid, dichloro-	Dichloroacetic acid; DCA
76-03-9[a]	Acetic acid, trichloro-	Trichloroacetic acid; TCA
68188-19-2[a,b]	Paraffin waxes and Hydrocarbon waxes, chloro, chlorosulfonated	NA
72854-22-9[a,b]	Paraffin waxes and Hydrocarbon waxes, chloro, sulfonated, ammonium salts	NA

[1] The Chemical Abstracts Service Registry Number (CAS RN) 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.

CAS RN	DSL name	Common name
121-82-4[a]	1,3,5-Triazine, hexahydro-1,3,5-trinitro-	RDX
67-97-0[a]	9,10-Secochloesta-5,7,10(19)-trien-3-ol, (3β,5Z,7E)-	Vitamin D_3
137-30-4	Zinc, bis(dimethylcarbamodithioato-S,S')-, (ß-4)-	Ziram
65996-77-2[a,b]	Coke (coal)	Coal coke

Abbreviation: NA, Not Available

[a] This substance was not identified under subsection 73(1) of CEPA but was included in this assessment as it was considered a priority on the basis of other human health concerns.

[b] This substance is of unknown or variable composition, complex reaction products, or biological materials (UVCB).

In addition to the activities summarized below, risk assessment or risk management activities under CEPA may be undertaken in the future if new information becomes available on these substances. This may include identification of new hazard or exposure information, which may impact previous risk analyses, international activities, or risk management activities (including performance evaluation and subsequent changes to risk management).

2. Substances

2.1. Carbon monoxide

2.1.1. Background

Carbon monoxide (CO), CAS RN 630-08-0, was identified as a priority for assessment as it met the categorization criteria under subsection 73(1) of CEPA (ECCC, HC [modified 2017a]).

CO in ambient air is formed primarily by the incomplete combustion of carbon-containing fuels as well as by photochemical reactions in the atmosphere (US EPA 2010). Data from the National Pollutant Release Inventory indicate that in 2017, releases to ambient air from all facilities in Canada totalled 928 819 tonnes (NPRI 2018). Sources of CO inside buildings include infiltration of ambient air indoors, and indoor sources such as gas stoves and tobacco smoke (US EPA 2010).

The exposure and potential impacts from CO are primarily related to human health, and the majority of the literature on CO focuses on the risks to human health. However, several jurisdictions in Canada have examined the potential ecological effects of CO exposure to the environment (MOEO 2001; QMDDEP 2010; BC MOE 2018). Air quality guidelines have been established for the protection of human health and/or the environment (BC MOE 2018, MOEO 2001, QMDDEP 2010).

In Canada, CO has one recognized use as a food processing aid. Exposure to CO, if any, from such use would be negligible. It has also been identified as an impurity in components used in the manufacture of some food packaging materials. It is not directly or intentionally added to these materials. Potential exposure to CO from its presence as

a residual impurity in components used in the manufacture of certain food packaging materials is expected to be negligible.

2.1.2. Existing risk assessments and risk management measures

In 2010, Health Canada published the *Residential Indoor Air Quality Guideline (RIAQG) for Carbon Monoxide* (Health Canada [modified 2016b]). The RIAQG for CO, which consists of a full science assessment document as well as the guideline itself, contains a summary of the adverse health effects of CO, provides information on exposure and sources in Canadian homes and recommendations on ways to reduce exposure, and recommends short-term and long-term health-based exposure limits. These health-based exposure limits, which are issued as voluntary objectives under subsection 55(1) of CEPA, are derived with the intent to protect all Canadians, including vulnerable and susceptible populations, from the health effects of CO in indoor air.

Health Canada has engaged in numerous initiatives related to CO, including: strategies that communicate the health effects associated with CO exposure; strategies to reduce exposure; strategies that educate Canadians on the risk of low-level CO exposure; and strategies targeted toward protecting the health of vulnerable and susceptible populations (Health Canada 2015, 2017a, 2017b). Health Canada participated in updating the *Canadian Standards Association (CSA) standard 6.19 Residential CO Alarming Devices,* which now includes a requirement for standard residential CO detectors to display low (< 30 ppm) CO levels. These devices are sold with documentation on health risk information and recommended actions to reduce exposure.

In partnership with CO alarm manufacturers and retailers, Health Canada conducted a CO awareness retail campaign with the goal of educating the public on health risks associated with CO in the home and promoting the installation and proper maintenance of CO alarms (Scout Environmental 2018). The campaign was conducted in October and November 2018 with the participation of more than 30 retail stores in Ontario and British Columbia. This campaign allowed Health Canada to gain information (through engagement and surveys) on the public's understanding of the health risk of CO (particularly low levels) in indoor air, promote new aspects of the revised CSA CO residential alarming standard that provides greater protection for health-compromised individuals, and compare the public's knowledge of CO in a province where CO alarms are mandatory and in one province where they are not. Key partnerships included firefighting associations and provincial/municipal public health units.

Health Canada funded the British Columbia Centre for Disease Control to formalize a CO monitoring and response framework for long-term care facilities (LTCFs), and to assess the effectiveness of this framework through piloting in LTCFs in Saskatchewan and British Columbia. As a result, an implementation guide, evaluation guide, and an educational presentation were developed and continue to be promoted for facilities across Canada.

Existing guidelines in Canada and internationally provide air quality objectives that take into consideration the impact of anthropogenic activities on air quality, to inform regulatory development in order to protect human health and the environment. Effects to the ecosystem and to human health are expected to be minimal when CO emissions meet objective criteria (BC MOE 2018, MOEO 2001, QMDDEP 2010).

The use of chemicals as food processing aids must not result in a violation of the safety provisions set out in section 4 of the *Food and Drugs Act*. The safety of chemicals used in food packaging materials is subject to the provisions of section 4(1)(a) of the *Food and Drugs Act* and Division 23 of the *Food and Drug Regulations*.

Therefore, carbon monoxide will not undergo further risk assessment under CEPA at this time.

2.2. Dichloroacetic acid and trichloroacetic acid

2.2.1. Background

Dichloroacetic acid (DCA), and trichloroacetic acid (TCA), were identified as priorities for assessment on the basis of other human health concerns (ECCC, HC [modified 2017a]).

Both substances were included in a survey issued pursuant to section 71 of CEPA (Canada 2009). In the 2008 reporting year, DCA was manufactured in Canada at a quantity in the range reported by stakeholders of 200 to 2000 kg in pulp bleaching processes and for oil recovery. DCA was not reported to be imported into Canada above the reporting threshold of 100 kg. TCA was manufactured at a quantity in the range reported by stakeholders of 100 to 1000 kg in pulp bleaching processes. TCA was also imported into Canada for use in laboratory research and as part of finished automobiles at a quantity in the range reported by stakeholders of 400 to 4000 kg per year (Environment Canada 2009)[2].

DCA and TCA do not occur naturally in the environment; however, they may be present in drinking water as disinfection by-products, which result from chlorine or chloramine reacting with organic material in the source water. The majority of drinking water treatment plants in Canada use some form of chlorine as a disinfectant to treat drinking water and/or to maintain a chlorine residual in the distribution system to prevent bacterial regrowth (Health Canada 2008). Similarly, aqueous products available to consumers that contain free chlorine as ingredients may contain unintentional trace levels of DCA or TCA.

The Pest Management Regulatory Agency reports that DCA is a formulant in some acaracide/insecticide products (personal communication, email from the Pest

[2] Non-confidential uses reported in response to the surveys conducted under section 71 of CEPA (Canada 2009). See survey for specific inclusions and exclusions (schedules 2 and 3).

Management Regulatory Agency, Health Canada, to the Existing Substances Risk Assessment Bureau, Health Canada, dated April 8, 2016; unreferenced).

2.2.2. Risk assessments and risk management measures

DCA and TCA were characterized using the Ecological Risk Classification of Organic Substances (ERC) approach (ECCC 2016a). The ERC approach is summarized in Appendix A of this document.

On the basis of low hazard and low exposure classifications according to information considered under ERC (ECCC 2016b), DCA was classified as having a low potential for ecological risk. According to information considered under ERC (ECCC 2016b), TCA was classified as having a low exposure potential. TCA was classified as having a moderate hazard potential on the basis of a moderate potential to cause adverse effects in aquatic food webs given its bioaccumulation potential. Overall, TCA was classified as having a low potential for ecological risk. The potential effects and how they may manifest in the environment were not further investigated due to the low exposure potential of this substance.

On the basis of current use patterns, these substances are unlikely to be resulting in concerns for the environment in Canada.

Haloacetic acids, a group of substances that includes DCA and TCA, were previously assessed by Health Canada in the *Guidelines for Canadian Drinking Water Quality: Guideline Technical Document – Haloacetic Acids* (Health Canada 2008). This document outlines the health risks associated with haloacetic acids in drinking water and sets a maximum acceptable concentration. Potential health risks are assessed, taking into account new studies and approaches, as well as water treatment considerations. This guideline takes into consideration the availability of appropriate treatment technologies and the ability of treatment plants to meet the permissible disinfection by-product levels presented in the guidelines without compromising the effectiveness of disinfection. This information is made available to provide Canadian jurisdictions (provinces, territories and federal departments) with the scientific basis they need to establish or update their requirements for disinfection by-products, including DCA and TCA, in drinking water.

Therefore, dichloroacetic acid and trichloroacetic acid will not undergo further risk assessment under CEPA at this time.

2.3. Sulphonated chlorinated alkanes

2.3.1. Background

The Sulphonated Chlorinated Alkanes Group is comprised of two UVCB substances:

- Paraffin waxes and Hydrocarbon waxes, chloro, chlorosulfonated (CAS RN 68188-19-2); and,

- Paraffin waxes and Hydrocarbon waxes, chloro, sulfonated, ammonium salts (CAS RN 72854-22-9).

Both substances were identified as priorities for assessment as a result of information identified during the development of a follow-up report on the *Priority Substances List assessment for chlorinated paraffins* (Environment Canada, Health Canada 2008).

2.3.1.1 Representative structures and description of UVCBs

Substances in the Sulphonated Chlorinated Alkanes Group are produced by reacting alkane (paraffin) feedstocks with chlorine gas, sulphur dioxide, and/or other substances to yield compounds meeting desired parameters for each batch (Fiedler 2010; Makwell 2017; UNEP 2010). Alkane feedstocks, however, are generally not uniform, containing alkanes of various chain lengths and conformations, as well as various impurities. Similarly, the chemical reactions used to produce chlorinated alkane substances are variable, resulting in varying degrees of chlorination and saturation of other functional groups depending on reaction conditions (e.g., temperature, relative concentrations of substances in reaction vessels). As such, each batch of these substances is a potentially unique mixture encompassing a range of carbon chain lengths, degrees of chlorination and/or functionalization, and impurities, and these substances are thus classified as UVCBs. Due to the variability of the reactions used to produce these substances, it is expected that that these substances will contain unknown proportions of short-chain chlorinated alkanes (SCCAs), medium-chain chlorinated alkanes (MCCAs), and/or long-chain chlorinated alkanes (LCCAs).

2.3.1.2 Degradation potential

Biodegradation information available for sulphonated chlorinated alkanes suggests that these substances undergo primary and ready biodegradation within the environment. A modified MITI (Ministry of International Trade and Industry, Japan) test for CAS RN 68188-19-2 estimated a 28-day degradation level of 68% (ECB [date unknown]). Similarly, an OECD 301B ready biodegradability test for CAS RN 68188-19-2, submitted as part of a REACH registration dossier, reported a 28-day degradation level of 89% (ECHA [modified 2018]).

In addition, modelling of representative structures for both CAS RNs was conducted using CATABOL to identify degradation products (CATALOGIC 2017; see Appendix B for lists of modelled structures). CATABOL is a QSAR model that predicts stable degradation products and biological oxygen demand (BOD) based on simulation of the OECD 301C test guideline. Model results typically predicted initial degradation products to be chlorinated alkane sulphonic acids, with subsequent degradation steps often yielding chlorinated alkane chemical structures. While predicted degradation products were dependent upon the initial structure(s) entered into the model, their stability was generally observed to increase with initial carbon chain length and degree of chlorination. These observations were also supported by BIOWIN modelling results (BIOWIN 2008). BIOWIN estimates aerobic and anaerobic biodegradability of organic

chemicals using a variety of models. Based on empirical and modelled degradation results, it is expected that these UVCB substances could be precursors to chlorinated alkanes, including SCCAs.

As described in the 2008 follow-up assessment for chlorinated alkanes (Environment Canada, Health Canada 2008), analysis of sediment cores collected from Canadian lakes found chlorinated alkane residues as far back as the 1940s, and half-lives back-calculated from both fresh and marine sediment cores exceeded one year. Chlorinated alkane degradation products are thus expected to persist within the sediment compartment.

While concentrations would necessarily be lower than those in equivalent (i.e., non-sulphonated) chlorinated alkanes, sulphonated chlorinated alkane substances are expected to form stable chlorinated alkane degradation products, and have also been identified as likely containing SCCAs, MCCAs, and/or LCCAs as part of their respective UVCB compositions (UNEP 2010, 2014). As these substances are expected to persist in the environment, the risk assessment and associated regulatory actions previously developed for SCCAs, MCCAs, and LCCAs (discussed below in section 2.3.2) should be interpreted as also applying to these substances (Environment Canada, Health Canada 2008; Canada 2011a, 2012a).

2.3.2. Risk assessments and risk management measures

While relatively limited hazard and exposure data are available for CAS RN 68188-19-2 and CAS RN 72854-22-9, it has been determined that these UVCBs could reasonably be expected to both contain, and be precursors for, the chlorinated alkanes that were previously determined as meeting the definition of toxic under section 64 of CEPA (Environment Canada, Health Canada 1993, 2008).

Chlorinated alkanes (referred to in earlier assessments and communications as “chlorinated paraffins”) are chlorinated derivatives of alkanes with carbon chain lengths from 10 to 38 carbon atoms, and with varying chlorine contents. These substances were assessed as part of the Priority Substances List under the *Canadian Environmental Protection Act, 1988* (Canada 1988). At that time, the assessment found insufficient data to conclude whether these substances were harmful to the environment and/or human health (Environment Canada, Health Canada 1993). A 2008 follow-up assessment (Environment Canada, Health Canada 2008) determined that chlorinated alkanes with 20 or fewer carbon atoms meet the criteria for toxic to the environment under paragraph 64(*a*) of CEPA, and that all chlorinated alkanes met the criteria for toxic to human health under paragraph 64(*c*). In addition, chlorinated alkanes with 10 to 20 carbon atoms were found to meet the persistence and bioaccumulation criteria set out in the *Persistence and Bioaccumulation Regulations* of CEPA (Canada 2000). As such, chlorinated alkanes composed of 10 to 20 carbon atoms were added to Schedule 1 of CEPA (Canada 2011a). SCCAs, composed of 10 to 13 carbon atoms, were prohibited under the *Prohibition of Certain Toxic Substances Regulations* in 2012 (Canada 2012a). A subsequent update to the human health assessment (Health

Canada 2012) concluded that LCCAs (i.e., containing 18 or more carbon atoms) did not pose a risk to human health due to low exposure levels.

Internationally, SCCAs with chlorine content greater than 48% were added to both Annex III (Chemicals subject to the prior informed consent procedure) of the *Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade* (Rotterdam Convention) (UNEP 2017a) and Annex A (Elimination) of the *Stockholm Convention on Persistent Organic Pollutants (POPs)* (Stockholm Convention) (UNEP 2017b). The documents referenced in the decisions to add SCCAs to both of these Conventions contain non-exhaustive lists of CAS RNs representing compounds either containing or synonymous with SCCAs (Rotterdam Convention; UNEP 2014), or that could contain SCCAs (Stockholm Convention; UNEP 2010); CAS RNs 68188-19-2 and 72854-22-9 were included on both lists.

According to information reported in response to a survey issued pursuant to section 71 of CEPA for the reporting years 2014 and 2015 (Canada 2017)[3], and subsequent follow-up with industry stakeholders in 2018, no consumer or commercial uses for CAS RNs 68188-19-2 or 72854-22-9 were identified in Canada. As such, these substances are considered to be not in commerce in Canada.

2.3.2.1 Regulatory actions

As the UVCBs in this group are expected to both contain and act as precursors to SCCAs and other chlorinated alkanes, regulatory actions taken regarding chlorinated alkanes will apply to these UVCBs. In Canada, regulatory actions taken to date include adding chlorinated alkanes with the molecular formula $C_nH_xCl_{(2n+2-x)}$, in which $10 \leq n \leq 20$, to Schedule 1 of CEPA, with a recommendation for virtual elimination[4] (Canada 2011a). SCCAs, and products containing these substances, are prohibited under the *Prohibition of Certain Toxic Substances Regulations, 2012* (Canada 2012a). Additionally, MCCAs and LCCAs with fewer than 20 carbons are included as Group B substances (subject to alternate [lower] reporting thresholds) in the National Pollutant Release Inventory for 2018 and 2019 (Canada 2018a).

Therefore, these two UVCBs (CAS RN 68188-19-2 and CAS RN 72854-22-9) will not undergo further risk assessment under CEPA at this time.

[3] Non-confidential uses reported in response to the surveys conducted under section 71 of CEPA (Canada 2017). See survey for specific inclusions and exclusions (schedules 2 and 3).

[4] A persistent and bioaccumulative substance to be added to Schedule 1 of CEPA that is present in the environment primarily from human activity and that is not a naturally-occurring radionuclide or naturally-occurring inorganic substance, would be subject to the virtual elimination provisions of the Act. According to the Toxic Substances Management Policy 1995, virtual elimination means, in respect of a toxic substance released into the environment as a result of human activity, that the substance will not be released into the environment in measurable concentrations at any point in its life cycle (Canada 1995).

2.4. RDX

2.4.1. Background

RDX, CAS RN 121-82-4, was identified as a priority for assessment on the basis of other human health concerns (ECCC, HC [modified 2017a]).

RDX was included in a survey issued pursuant to section 71 of CEPA (Canada 2012b). For the 2008 reporting year, less than 200 kg of RDX was reported to be manufactured in Canada and between 75 000 and 152 000 kg were imported into Canada. RDX is used in munitions and explosive materials for industrial activities (Environment Canada 2013)[5].

2.4.2. Risk assessments and risk management measures

The ecological risk of RDX was characterized using the ERC approach (ECCC 2016a), which is summarized in Appendix A of this document. According to information considered under ERC (ECCC 2016b), RDX was classified as having a low exposure potential. RDX was classified as having a high hazard potential on the basis of agreement between reactive mode of action and elevated toxicity ratio, both of which suggest that this chemical is likely of high potency. RDX was initially classified as having a moderate potential for ecological risk; however, the risk classification was decreased to low following the adjustment of risk classification based on current use quantities (see section 7.1.1. of the ERC approach document [ECCC 2016a]). The potential effects and how they may manifest in the environment were not further investigated due to the low exposure potential of this substance. On the basis of current use patterns, this substance is unlikely to be resulting in concerns for the environment in Canada.

RDX is currently being assessed by Health Canada through the development of a screening value for drinking water. Screening values are used to identify limits for contaminants in water that may be used as a source of drinking water. These screening values are intended to protect human health if such source water is consumed prior to treatment and if there are no existing drinking water guidelines for these contaminants. A lifetime of exposure to these contaminants up to the screening value through drinking or showering/bathing, is not expected to result in increased health risk for any Canadian. The screening value for RDX is 0.1 mg/L (Health Canada 2020a).

The screening value may be used as guidance to help jurisdictions and drinking water consumers understand the potential health effects of RDX. A short-term exceedance above the screening value is not expected to cause harm; although it signals the need to consider a broader monitoring effort. Health Canada recommends that for more

[5] Non-confidential uses reported in response to the surveys conducted under section 71 of CEPA (Canada 2012b). See surveys for specific inclusions and exclusions (schedules 2 and 3).

significant, longer-term exceedances, jurisdictions should develop and implement a plan to address these situations. This may include treatment of the source water.

Therefore, RDX will not undergo further risk assessment under CEPA at this time.

2.5 Vitamin D_3

2.5.1 Background

Vitamin D_3, CAS RN 67-97-0, was identified as a priority for assessment on the basis of other human health concerns (ECCC, HC [modified 2017a]).

Vitamin D comes in two main forms, D_2 (ergocalciferol) and D_3 (cholecalciferol); vitamin D_2 comes mainly from plant sources, whereas vitamin D_3 comes mainly from animal sources. Vitamin D_3 is a fat-soluble vitamin that acts as a pro-hormone in the body. It is obtained from foods, drugs and natural health products, and can also be synthesized in the skin under the influence of UV-B radiation from the sun. The main role of vitamin D in the body is to elevate plasma calcium and phosphate concentrations, which are required for bone mineralization. Plasma calcium concentrations, in turn, also help control neuromuscular junctions, vasodilation, nerve transmission and hormonal secretion (IOM 2011).

Vitamin D_3 was included in a survey issued pursuant to section 71 of CEPA (Canada 2012b). In the 2011 reporting year, vitamin D_3 was not reported to be manufactured or imported in quantities above the 100 kg reporting threshold (Environment Canada 2013)[6].The dietary sources of vitamin D include natural occurrence and fortification of certain foods. According to the *Canadian Nutrient File* (Canada 2018b), there are a few naturally occurring food sources of vitamin D_3, including fatty fish such as Greenland halibut (turbot), sockeye salmon and tuna, and egg yolk. Additionally, vitamin D_2 may be obtained from mushrooms; however, the major sources of vitamin D in the Canadian diet are fortified foods, predominantly milks and margarines (email communication from the Food Directorate to Existing Substances Risk Assessment Bureau, Health Canada, dated 21 February 2019; unreferenced).

As prescription drugs in Canada, oral vitamin D in the form of capsules of high-dose cholecalciferol (vitamin D_3 up to 50 000 International Units [IU]) is indicated for the treatment of refractory (Vitamin D-resistant) rickets, familial hypophosphatemia, familial hypoparathyroidism, and in the management of hypocalcemia and renal osteodystrophy in patients with chronic renal failure undergoing dialysis. Vitamin D is also used in conjunction with calcium in the management and prevention of primary or corticosteroid-induced osteoporosis. Vitamin D supplementation is indicated when dietary intake is insufficient, e.g., in breast-fed infants (Orimed Pharma Corporation 2013, 2017;

[6] Non-confidential uses reported in response to the surveys conducted under section 71 of CEPA (Canada 2012b). See surveys for specific inclusions and exclusions (schedules 2 and 3).

Pharmascience Inc. 2011). There are 21 marketed prescription oral vitamin D products listed in Health Canada's *Drug Product Database* (DPD modified 2018b).

Vitamin D is listed as a medicinal ingredient in the *Licensed Natural Health Products Database* (LNHPD 2018) with doses up to 2500 IU/day (i.e., 62.5 µg/day).

2.5.2 Risk assessments and risk management measures

The ecological risk of Vitamin D_3 was characterized using the ERC approach (ECCC 2016a), which is summarized in Appendix A of this document. According to information considered under ERC (ECCC 2016b), vitamin D_3 was classified as having a low exposure potential. Vitamin D_3 was classified as having a high hazard potential on the basis of agreement between reactive mode of action and elevated toxicity ratio, both of which suggest that this chemical is likely of high potency. Vitamin D_3 was also profiled to have a high potential to cause adverse effects in aquatic and terrestrial food webs given its high bioaccumulation potential. Vitamin D_3 was classified as having a moderate potential for ecological risk; however, the risk classification was decreased to low following the adjustment of risk classification based on current use quantities (see section 7.1.1. of the ERC approach document [ECCC 2016a]). The potential effects and how they may manifest in the environment were not further investigated due to the low exposure potential of this substance. On the basis of current use patterns, this substance is unlikely to be resulting in concerns for the environment in Canada.

It can be challenging for Canadians to meet vitamin D intake recommendations through the current food supply. The prevalence of the risk of vitamin D deficiency is higher in certain Canadian subpopulations, including those with dark skin and those who are overweight or obese (Greene-Finestone et al. 2017). Vitamin D dietary intake data are available from the *Canadian Community Health Survey* [CCHS] *Cycle 2.2, Nutrition (2004)* (Health Canada 2007) and the subsequent *2015 Canadian Community Health Survey – Nutrition* (Statistics Canada 2017). Using the most recent Dietary Reference Intakes (DRIs) for vitamin D, established in 2011, by the National Academy of Medicine (NAM) (formerly the Institute of Medicine [IOM]) and dietary intake data from the CCHS 2015 survey, the proportion of Canadians with vitamin D intakes (food only) below the Estimated Average Requirement (EAR) ranged from 86 to 99%, depending on age-sex group. The CCHS 2015 findings also indicate that there were no age-sex groups whose intake exceeded the IOM's tolerable upper intake level (UL) (Statistics Canada 2017).

Estimates of inadequate intakes of vitamin D must be interpreted with caution because the reference values to assess adequacy assume no vitamin D is contributed to the body by sun exposure. For this reason, data on vitamin D intakes from food and supplement sources cannot stand alone and consideration must be given to serum 25-hydroxy-vitamin-D levels, a well-established biomarker for vitamin D status.

The Canadian Health Measure Survey Cycle 1 (2007-2009) and Cycle 2 (2009-2011) collected blood samples, from which vitamin D status can be assessed. Using this data,

about 19% of Canadians are at risk of vitamin D inadequacy while about 7% are at risk of deficiency (Sarafin et al. 2015).

The *Food and Drug Regulations* (FDR) set the framework for the addition of vitamin D to foods in Canada. The fortification of certain foods, such as milk, with vitamin D is long-established since it was recognized early on as important for the prevention of rickets (IOM 2011). A summary of the ranges of vitamin D levels used for food fortification, based on the appropriate sections of the FDR, Interim Marketing Authorizations (Health Canada 2017c), and as per amendments to the FDR proposed in *Canada Gazette Part 1* on February 10, 2018 (Canada 2018d) are presented in Appendix C. In February 2018, Health Canada proposed to amend the FDR to increase the level of vitamin D in cow's milk, goat's milk and margarine. The purpose of these amendments is to help improve the vitamin D status of Canadians by bringing their dietary intakes closer to the 2011 recommendations of the IOM. Vitamin D may also be added to foods outside of the provisions of the FDR if a Temporary Marketing Authorization Letter (TMAL) has been issued. TMALs related to vitamin D addition have been issued for a number of breakfast cereals, meal replacements, nutritional supplements, formulated liquid diets and supplemented foods. As of November 2020, there are 52 authorized supplemented foods containing added vitamin D (email communication from the Food Directorate to Existing Substances Risk Assessment Bureau, Health Canada, dated November 20, 2020; unreferenced).

Health Canada has authorized the use of vitamin D for treatment of vitamin D deficiency. As per the Prescription Drug List, the dose of vitamin D in oral natural health products must not exceed 2500 IU/day (62.5 µg/day), above which vitamin D is classified as a non-natural health product (NNHPD 2019).

These data indicate that, in general, the dietary intakes of vitamin D for the Canadian population are below intake recommendations. As described above, the Government of Canada has set requirements under the *Food and Drug Regulations* minimize the risk of vitamin D deficiency and excess within the Canadian population.

Vitamin D_3 is described as a restriction on the Cosmetic Ingredient Hotlist (Health Canada [modified 2018]). The Hotlist restriction limits the average daily absorption to equal to or less than 25 µg/day. There were no cosmetic notifications reported for vitamin D_3 in Canada (email communication from Consumer and Hazardous Products Safety Directorate, Health Canada to Existing Substances Risk Assessment Bureau, Health Canada, dated May 30, 2017; unreferenced).

Therefore, vitamin D_3 will not undergo further risk assessment under CEPA at this time.

2.6 Ziram

2.6.1 Background

Ziram, CAS RN 137-30-4, was identified as a priority for assessment as it met the categorization criteria under subsection 73(1) of CEPA (ECCC, HC [modified 2017a]).

The substance was included in a survey issued pursuant to section 71 of CEPA (Canada 2009). For the 2008 reporting year, ziram was not reported to be manufactured in Canada above the reporting threshold of 100 kg. For the same reporting period, ziram was reported to be imported into Canada at quantities ranging from 6400 to 64 000 kg, as part of finished automobiles, or unidentified plastic and rubber materials (Environment Canada 2009)[7].

Ziram does not occur naturally in the environment. When used for commercial purposes, the substance functions as a vulcanization accelerator in the manufacture of rubber or plastic materials, as a component of adhesives and sealants (Environment Canada 2009) or as an active ingredient in pest control products (PMRA 2018a).

In the United States, ziram is a permitted indirect additive to food when used in food packaging as a component of adhesives, rubber articles intended for repeat use (e.g., hoses), or in animal glue (US FDA 2018a, 2018b). In Canada, ziram is used as a component in the manufacture of rubber articles (hoses) intended for repeat use. Exposure to the general population from this use is considered negligible (email communication from the Food Directorate to Existing Substances Risk Assessment Bureau, Health Canada, dated June 19, 2019; unreferenced).

2.6.2 Risk assessments and risk management measures

Ziram is a zinc-containing substance and is within the scope of the *Draft Screening Assessment for Zinc and Its Compounds* conducted under the Chemicals Management Plan (ECCC, HC 2019). The draft screening assessment proposed to conclude that there is risk of harm to organisms, but not to the broader integrity of the environment from zinc and soluble zinc compounds (ECCC, HC 2019a).

A risk management scope has been published for zinc and soluble zinc compounds to address the risks identified in the draft screening assessment (ECCC, HC 2019b), namely the release of zinc from metal mining and some base metals smelting and refining facilities. Risk management options have been proposed in the Risk Management Scope and will be finalized, if needed, in the Risk Management Approach document. Zinc was also previously assessed by Health Canada (Health Canada 1987) to develop a guideline technical document for elemental zinc in drinking water sources.

[7] Non-confidential uses reported in response to the surveys conducted under section 71 of CEPA (Canada 2009). See survey for specific inclusions and exclusions (schedules 2 and 3).

The pest control uses of this substance are registered and managed under the *Pest Control Products Act* (Canada 2002). In 2018, the Pest Management Regulatory Agency (PMRA) published a re-evaluation decision for ziram and its associated end-use products for agricultural uses, announcing the cancellation and phase out of all currently registered agricultural uses of ziram in Canada (PMRA 2018a).The PMRA also published a note of intent to re-evaluate the use of ziram used as a preservative in paints, coatings and related uses (PMRA 2018b).

The safety of chemicals used in food packaging materials is subject to the provisions of section 4(1)(a) of the *Food and Drugs Act* and Division 23 of the *Food and Drug Regulations*.

Therefore, ziram will not undergo further risk assessment under CEPA at this time.

2.7 Coal coke

2.7.1 Background

Coal coke, CAS RN 65996-77-2, was identified as a priority for assessment on the basis of other human health concerns (ECCC, HC [modified 2017a]).

Coal coke consists of a cellular carbonaceous mass resulting from the destructive distillation of coal at temperatures greater than 700°C. Coal coke is composed mainly of carbon, but may also contain sulphur and ash (NCI 2015) and is characterized based on grain size. The typical composition of coal coke is given in Table 2-1 (MSDS 2017). Coal coke has a specific gravity of approximately 0.77 g/cm^3.

Table 2-1 Typical ranges for elemental composition of coal coke (MSDS 2017)

Component	Range (wt%)
Carbon	85 – 95
Hydrogen	0.5 – 1.0
Oxygen	0.2 – 1.5
Nitrogen	0.3 – 1.3
Sulphur	0.5 – 2.0
Ash	8 – 15

According to information submitted in response to a CEPA section 71 survey, between 1 000 000 and approximately 25 000 000 tonnes of coal coke were manufactured in Canada and approximately 500 000 to 750 000 tonnes of coal coke were imported into Canada in 2008 (Environment Canada 2011). From October 2018 to February 2019, between 182 000 and 226 000 tonnes of coal coke were produced each month in Ontario (Statistics Canada 2019). Coal coke is only produced at integrated steel mills in the province of Ontario (Statistics Canada 2019). Coal coke is produced from coal at these facilities and is used as a smokeless fuel and a reducing agent in iron-making

furnaces. In addition to its fuel use, coal coke is used in the metallurgical industry as a carbon-based additive (MSDS 2016), in monolithic refractory products (MSDS 2006), and in disc brake pads (MSDS 2015).

In Canada, coal coke has been identified as an impurity in a component used in the manufacture of glass bottles. It is not directly or intentionally added to food packaging materials. Potential exposure to coal coke from its presence as a residual impurity in components used in the manufacture of certain food packaging materials is expected to be negligible (personal communication, email from the Food Directorate, Health Canada (HC) to the Existing Substances Risk Assessment Bureau, HC, dated March 25, 2019; unreferenced). No uses of coal coke in natural health products, cosmetics, veterinary medicines, or formulants in pest control products have been reported (personal communication, email from the Natural and Non-prescriptive Health Products Directorate, Health Canada, to the Existing Substances Risk Assessment Bureau, Health Canada, dated March 29 2019; unreferenced; personal communication, email from the Consumer and Hazardous Products Safety Directorate, Health Canada, to the Existing Substances Risk Assessment Bureau, Health Canada, dated March 14, 2014; unreferenced; personal communication, email from the Pest Management Regulatory Agency, Health Canada, to the Existing Substances Risk Assessment Bureau, Health Canada, dated March 29, 2019; unreferenced).

2.7.2 Risk assessments and risk management measures

Polycyclic aromatic hydrocarbons (PAHs), benzene and particulate matter may be released during the coking process in integrated steel mills, where coal is converted to coal coke. Additionally, the International Agency for Research on Cancer (IARC) classified coke production and the associated emissions as category 1A carcinogens [IARC 2012].

In 2005, the Ontario Ministry of the Environment, Conservation and Parks (MECP) introduced *Regulation 419/05: Air Pollution – Local Air Quality* (MECP 2005). This Regulation aims to limit exposure to substances released from industrial and commercial facilities into air that can affect human health and/or the environment.

Under this Regulation, industry can implement one of three compliance approaches, each designed to manage the risks associated with a facility's air emissions:

- Meet the general air standard by the phase-in period;
- Request and meet a site-specific standard (SSS); or
- Register and meet the requirements under a technical standard, if available.

In 2011, the Regulation was amended to include new annual average air standards of 0.45 µg/m^3 for benzene (CAS RN 71-43-2) and 0.00001 µg/m^3 for benzo(a)pyrene (CAS RN 50-32-8) as a surrogate for total PAHs. These standards took effect on July 1, 2016. Further details on this Regulation can be found on Ontario's *Rules on air quality and pollution* website (MECP 2014).

Individual facilities may also have an *Environmental Compliance Approval* for discharge into air, subject to conditions, in accordance with section 9 of the *Ontario Environmental Protection Act* (MECP 1990).

Between 2016 and 2017, all four integrated steel mills in Ontario obtained approvals for SSS for benzo(a)pyrene and benzene. The approval of a site-specific air emissions standard requires each facility to develop an action plan that consists of, among other things, restoration projects, improvements in emissions control efficiency, refurbishment of specific equipment, improvement in the quality of feedstock, and implementation of United States Environmental Protection Agency rules for coke plants. The implementation of SSS is expected to result in a 30-40% reduction in coke oven battery air emissions (*e.g.*, benzo(a)pyrene, benzene, total particulate matter). The SSS for benzo(a)pyrene and benzene have an initial 2019 target and a more stringent target for 2021. In addition, there are requirements for a benzene measurement program that is intended to confirm that all necessary actions to reduce benzene air emissions have been taken at each subject facility [Ontario 419/05, s33(7)(ii), s35(7)(a), s35(7)(b)].

Ontario Regulation 419/05 and the SSS for benzo(a)pyrene and benzene for integrated mills are considered as relevant and enforceable risk management measures for integrated steel mills. These measures are also expected to cover emissions originating from the production of coal coke at these facilities. The Government of Canada intends to work with the Government of Ontario and industry to review progress in reducing benzene and PAHs emissions and to evaluate the degree to which the risk management objectives for these substances have been met. If new information is received indicating that coal coke production is occurring under conditions that would not fall under the above regulations, additional risk assessment or risk management activities may be undertaken.

The safety of chemicals used in food packaging materials is subject to the provisions of section 4(1)(a) of the *Food and Drugs Act* and Division 23 of the *Food and Drug Regulations*.

Therefore, coal coke will not undergo further risk assessment under CEPA at this time.

3. Overall determination

The nine substances described herein, carbon monoxide, dichloroacetic acid, trichloroacetic acid, sulphonated chlorinated alkanes (two substances), RDX, vitamin D_3, ziram, and coal coke will not be subject to further assessment under CEPA at this time. These substances are considered to be addressed by existing and ongoing risk assessment activities, existing regulations, or current risk management actions taking place under CEPA, other acts, guidelines or international conventions.

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Appendix A – Ecological risk classification of organic substances (ERC) approach

The ecological risks of DCA, TCA, RDX and vitamin D_3 were characterized using the ERC approach (ECCC 2016a). The ERC is a risk-based approach that considers multiple metrics for both hazard and exposure, with weighted consideration of multiple lines of evidence for determining risk classification. The various lines of evidence are combined to discriminate between substances of lower or higher potency and lower or higher potential for exposure in various media. This approach reduces the overall uncertainty with risk characterization compared to an approach that relies on a single metric in a single medium (e.g., median lethal concentration) for characterization. The following summarizes the approach, which is described in detail in ECCC (2016a).

Data on physical-chemical properties, fate (chemical half-lives in various media and biota, partition coefficients, and fish bioconcentration), acute fish ecotoxicity, and chemical import or manufacture volume in Canada were collected from the scientific literature, from available empirical databases (e.g., OECD QSAR Toolbox 2014), from responses to surveys issued pursuant to section 71 of CEPA, or they were generated using selected (quantitative) structure-activity relationship ([Q]SAR) or mass-balance fate and bioaccumulation models. These data were used as inputs to other mass-balance models or to complete the substance hazard and exposure profiles.

Hazard profiles were based principally on metrics regarding mode of toxic action, chemical reactivity, food web-derived internal toxicity thresholds, bioavailability, and chemical and biological activity. Exposure profiles were also based on multiple metrics, including potential emission rate, overall persistence, and long-range transport potential. Hazard and exposure profiles were compared to decision criteria in order to classify the hazard and exposure potentials for each organic substance as low, moderate, or high. Additional rules were applied (e.g., classification consistency, margin of exposure) to refine the preliminary classifications of hazard or exposure.

A risk matrix was used to assign a low, moderate or high classification of potential risk for each substance on the basis of its hazard and exposure classifications. ERC classifications of potential risk were verified using a two-step approach. The first step adjusted the risk classification outcomes from moderate or high to low for substances that had a low estimated rate of emission to water after wastewater treatment, representing a low potential for exposure. The second step reviewed low risk potential classification outcomes using relatively conservative, local-scale (i.e., in the area immediately surrounding a point source of discharge) risk scenarios, designed to be protective of the environment, to determine whether the classification of potential risk should be increased.

ERC uses a weighted approach to minimize the potential for both over- and under-classification of hazard and exposure, and of subsequent risk. The balanced approaches for dealing with uncertainties are described in greater detail in (ECCC 2016a). The following describes two of the more substantial areas of uncertainty. Error with empirical or modelled acute toxicity values could result in changes in classification of hazard, particularly metrics relying on tissue residue values (i.e., mode of toxic action), many of which are predicted values from (Q)SAR models (OECD QSAR Toolbox 2014). However, the impact of this error is mitigated by the fact that overestimation of median lethality will result in a conservative (protective) tissue residue value used for critical body residue analysis. Error with underestimation of acute toxicity will be mitigated through the use of other hazard metrics such as structural profiling of mode of action, reactivity and/or estrogen binding affinity. Changes or errors in chemical quantity could result in differences in classification of exposure as the exposure and risk classifications are highly sensitive to emission rate and use quantity. The ERC classifications thus reflect exposure and risk in Canada on the basis of what is estimated to be the current use quantity, and may not reflect future trends.

Appendix B – Simplified molecular-input line-entry system (SMILES) notations of representative sulphonated chlorinated alkane structures

Table B-1. SMILES notations of representative sulphonated chlorinated alkane structures for the UVCB CAS RN 68188-19-2 modelled using CATABOL (CATALOGIC 2017)

SMILES
ClS(=O)(=O)CCCCC(Cl)CCCCCC
ClS(=O)(=O)CCC(Cl)CC(Cl)CC(Cl)CC(Cl)CC
ClS(=O)(=O)C(Cl)C(Cl)C(Cl)C(Cl)CC(Cl)CC(Cl)C(Cl)CC
ClS(=O)(=O)CCCCCCCC(Cl)CCCCCCCC
ClS(=O)(=O)CCCC(Cl)CCCC(Cl)CCC(Cl)CCC(Cl)CC
ClS(=O)(=O)CC(Cl)C(Cl)CC(Cl)CCC(Cl)CC(Cl)CC(Cl)CC(Cl)CC
ClS(=O)(=O)CCCCCCCCCCCC(Cl)CCCCCCCCCC
ClS(=O)(=O)CCCCCC(Cl)CCCCC(Cl)CCCCC(Cl)CCCC(Cl)CC
ClS(=O)(=O)CCC(Cl)CC(Cl)CCC(Cl)CCC(Cl)CCC(Cl)CCC(Cl)CCC(Cl)CC
ClS(=O)(=O)CCCCCCCCCCCCCCCC(Cl)CCCCCCCCCCCCCCCC
ClS(=O)(=O)CCCCCCCC(Cl)CCCCCC(Cl)CCCCCCC(Cl)CCCCCC(Cl)CCC
ClS(=O)(=O)CCCC(Cl)CCCC(Cl)CCCCC(Cl)CCC(Cl)CCCC(Cl)CCC(Cl)CCCC(Cl)CCC

Table B-2. SMILES notations of representative sulphonated chlorinated alkane structures for the UVCB CAS RN 72854-22-9 modelled using CATABOL (CATALOGIC 2017)

SMILES
CCC(Cl)CC(Cl)CC(Cl)CC(Cl)CCS(ON([H])([H])[H])(=O)(=O)
CCC(Cl)CCC(Cl)CCC(Cl)CCCC(Cl)CCCS(ON([H])([H])[H])(=O)(=O)
CCC(Cl)CC(Cl)CC(Cl)CC(Cl)CCC(Cl)CC(Cl)C(Cl)CS(ON([H])([H])[H])(=O)(=O)
CCC(Cl)CC(Cl)CCC(Cl)CCC(Cl)CCC(Cl)CCC(Cl)CCC(Cl)CCS(ON([H])([H])[H])(=O)(=O)
CCCCCCCC(Cl)CCCCCC(Cl)CCCCCCC(Cl)CCCCCC(Cl)CCCS(ON([H])([H])[H])(=O)(=O)
CCCC(Cl)CCCC(Cl)CCCCC(Cl)CCC(Cl)CCCC(Cl)CCC(Cl)CCCC(Cl)CCCS(ON([H])([H])[H])(=O)(=O)

Appendix C – Vitamin D levels used for food fortification

A summary of the ranges of vitamin D levels used for food fortification purposes, based on the appropriate sections of the *Food and Drug Regulations*, Interim Marketing Authorizations (Health Canada 2017c), and as per amendments to the *Food and Drug Regulations* proposed in Canada Gazette Part 1 on February 10, 2018 (Canada 2018d).

- Cow's milk (B.08.003-005, B.08.007, B.08.010-014, B.08.16-020, B.08.023, B.08.026, B.08.029): **mandatory** (except **voluntary** for goat's milk) – as proposed in Canada Gazette Part 1, the standards would be replaced with a single level of 2 µg/100 mL which is 5 µg per Reference Amount of 250 mL (the current range is equivalent to 0.9 to 1.2 µg/100 mL);
- Plant-Based beverages: mandatory in fortified plant-based beverages at 0.85 µg/100 mL; Health Canada plans to increase the required level to 2 µg/100 mL which is 5 µg per Reference Amount of 250 mL (Canada 2018d)
- Margarine (B.09.016): **mandatory –** as proposed in Canada Gazette Part 1, the FDR would be amended to increase the level of vitamin D to 26 µg/100 g which is 2.6 µg per Reference Amount of 10 g (the FDR currently prescribe an amount equivalent to no less than 13.3 µg/100 g and no more than 17.5 µg/100 g)
- Infant formulas (B.25.054; Canada 2004, Health Canada 2017c): **mandatory** Vitamin D NLT 40 IU/100 kcal, NMT 100 IU/100 kcal
- Formulated liquid diets (B.24.102; Canada 2006; Health Canada 2017c): **mandatory** Vitamin D NLT 100 IU/1000 kcal or 100 IU/1500 kcal, NMT 800 IU/1000 kcal or NMT 400 IU/1500 kcal;
- Food represented for use in very low energy diets (B.24.303, D.01.011): **mandatory** Vitamin D NLT 0.005 mg/day; NMT 400 IU/day
- Meal replacements (B.24.200): **mandatory** Vitamin D NLT 1.25 µg/serving, NMT 2.50 µg/serving
- Nutritional supplements (B.24.201): **mandatory** Vitamin D NLT 0.25 µg/100 kcal, NMT 1 µg/100 kcal
- Liquid whole egg, dried whole egg, frozen whole egg, liquid yolk, dried yolk, frozen yolk, liquid egg white (liquid albumen), dried egg white (dried albumen), liquid whole egg mix, dried whole egg mix, frozen whole egg mix, liquid yolk mix, dried yolk mix, frozen yolk mix (B.22.038, D.03.002): **mandatory if necessary to restore the vitamin content that was present before processing**
- **Voluntary:**
    - Other similar substitutes for butter (D.01.009 to D.01.011): **voluntary** Vitamin D Not Less Than (NLT) 300 IU per reasonable daily intake, Not More Than (NMT) 400 IU per reasonable daily intake
    - Vitamin D (2.5 µg/250 mL) may also be added to calcium-fortified orange or orange and tangerine juice (Canada 2006, Health Canada 2017c)
    - Yeast-leavened bakery products (up to 2.25 µg vitamin D/100 g of product as consumed) (Canada 2011b, Health Canada 2017c)
    - Health Canada also intends to permit fortification of yogurt (5 µg/reference amount) (Canada 2018d).

- Vitamin D can be added to certain breakfast cereals that have been issued Temporary Marketing Authorization Letters (TMALs) (1 µg/reference amount) (Health Canada 2020b)
- Vitamin D can be added to supplemented foods (up to a maximum of 25 µg/day)(Health Canada 2016a)